

IRB Guidelines for Researchers

Institutional Review Board

ESP, Corning Tower, Rm. 942
Albany, NY 12237-0001

Dear Researcher:

This document is designed to serve as an introduction to the New York State Department of Health's Institutional Review Board (IRB) and how it functions to insure the protection of human subjects in research. It also outlines the procedures and requirements that investigators must follow when submitting proposals to the IRB and in the subsequent conduct of research.

Please note that these guidelines have been revised to conform to the new processes and forms instituted by the IRB Administrative Unit. The new application form and instructions are available on our website: <http://www.health.ny.gov/professionals/irb/index.htm>.

The Guidelines will assist you in understanding the need for IRB review as well as providing directions for applying to the IRB for research review and approval. If you have questions or concerns, please contact Robin Krause, MS, IRB Administrator I/Compliance Officer` at (518) 474-8539.

All comments and suggestions that you may have are welcome.

James Tesoriero, Ph.D.
IRB Chair

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INTRODUCTION

The New York State Department of Health's (NYSDOH) Institutional Review Board (IRB) is an administrative body composed of NYSDOH research and legal staff, as well as outside members drawn from other state agencies, institutions and community organizations. The primary goal of the IRB is to prevent abuses in research and ensure adherence to the legally recognized ethical principles governing the involvement of human subjects in research. These protections are detailed in federal law (Code of Federal Regulations 45 CFR 46 as well as 21 CFR 50), state laws, and departmental policy. **Research involving human subjects may not proceed without prior written IRB approval.**

The IRB has the authority to ensure that research is designed and conducted in such a manner that protects the rights and welfare of participating subjects. The authority of the IRB includes, but is not limited to:

- Review, approve, require modification, or disapprove, all research activities that fall within its jurisdiction based upon consideration of human subject protection;
- Conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the investigators, auditing the conduct of the study, and observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
- Conduct Limited IRB Review (for activities under 46.104 for which limited IRB review is a condition of exemption)
- The IRB may suspend or terminate approval of a study; and
- The IRB may place restrictions on a study. (45 CFR 46.109, 116, 117)

NYSDOH's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The IRB is a key component of NYSDOH's efforts to ensure human subject protections. It supports our researchers in assuring the ethical conduct of research and compliance with federal, state and institutional regulations and provides a professional office staff to assist both investigators, participants, and two on-site IRBs. In addition, the overall human research protection program at NYSDOH includes additional organizational, administrative, and investigator components, and is based on all individuals fulfilling their roles and responsibilities.

The IRB is funded using State and Federal funds. The IRB's Administrative Director will meet annually with Health Research Inc. and NYSDOH executive staff to evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed and recommend adjustments as needed in accordance with IRB policies and procedures.

Our Human Research Protection Plan describes NYSDOH's plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

IRB ADMINISTRATION

The NYSDOH IRB Administrative Office serves both Social & Behavioral Research and Biomedical Research IRBs. NYSDOH IRB Administrative Office staff facilitates the review process of human

subject studies and provides professional guidance and support to the research community and helps researchers navigate the submission process.

PURPOSE

The purpose of the IRB is to protect the rights and welfare of individuals who serve as subjects of research. Under the authority of the Commissioner of Health, IRB members review and monitor **all** research that is conducted by or under the direction of any employee or agent of the NYSDOH or HRI, or in connection with his or her institutional responsibilities. This includes all research, regardless of funding source or the location of the participating human subjects.

Article 41 of the NYS Public Health Law authorizes the Commissioner of Health to approve “scientific studies and research which have for their purpose the reduction of morbidity and mortality within NYS.” The IRB functions as the Commissioner's designee in reviewing and approving requests for confidential data contained within the Department of Health's vital records and disease registries. Researchers from NYSDOH/ HRI and researchers from outside organizations must submit the appropriate application. The application will undergo a formal review process.

IRB review is conducted to protect human subjects from unnecessary and improper risk of pain, suffering or injury resulting from research conducted without their full knowledge and voluntary consent. Additionally, federal regulations grant special protection to subjects who are minors, fetuses, abortuses, pregnant women, prisoners, developmentally disabled, mentally disabled and subjects with decision-making impairment or diminished capacity.

Specifically, under our current Federalwide Assurance (FWA), the NYSDOH IRB reviews research involving the Department in accordance with the provisions of the Code of Federal Regulations (CFR) Title 45 CFR Part 46.

In its review of the submitted research protocol, the IRB will consider:

- the risks to the subjects;
- the anticipated benefits to the subjects and others;
- the importance of the knowledge that may reasonably be expected to result;
- the informed consent process to be employed (including proper documentation);
- the provision for monitoring the data collected to ensure the privacy of subjects and confidentiality of data; and
- the equitable selection of subjects.

APPOINTMENT OF THE IRB CHAIR AND VICE CHAIR

Pursuant to Public Health Law §206(8), the Commissioner of Health is responsible for appointing the IRB Chair. The Chair is appointed to serve for a three-year term. The IRB Chair may be reappointed for one (1) additional three-year term. The IRB Chair has ultimate responsibility for assuring that the IRB operates in full accordance with federal regulations, NYS law, and institutional policy governing IRB functions. The IRB Chair works with the IRB members, institutional officials, and investigators to ensure that the rights and welfare of research participants are adequately protected, and that the benefits of the research justify the risks to the research participant.

The Commissioner of Health, upon the recommendation of the IRB Chair, shall appoint a Vice Chair. The Vice Chair will be appointed to a three-year term. The Vice Chair may be reappointed for one (1) additional three-year term. The Vice Chair shall preside over convened IRB meetings in the absence of the IRB Chair. The IRB Chair and Vice Chair are voting members of the Institutional Review Board.

APPOINTMENT OF IRB MEMBERS AND ALTERNATES

The IRB must have a minimum of five (5) members of varying backgrounds to promote full and adequate review of proposed and ongoing research activities under the IRB's jurisdiction as defined in the Code of Federal Regulations (45 CFR 46.107). The Commissioner of Health based upon the recommendation of the IRB Chair appoints IRB members. New IRB members are recruited based upon their area of expertise and experience. Division Directors, Executive level staff, and experienced board members are often used as a source for referrals. Self-nominations are also considered. The IRB Chair shall also recommend a reasonable number of alternates who may serve in the place of absent members to the Board as necessary. In making appointments to the Board, the IRB Chair shall take reasonable steps to achieve a membership with diversity in race, gender and professional qualifications. At a minimum, to assure diversity and compliance with federal regulation, the membership of the Board shall include at least one member who is:

- 1) a person whose primary concerns are scientific;
- 2) a person whose primary concerns are non-scientific;
- 3) a person who is not otherwise affiliated with the institution (community representative);
- 4) a person who represents the perspective of the research participants (the member representing the general perspective of subjects, and the non-scientific member may be the same person or may be represented by two or more different persons.)

Each IRB at NYSDOH has a minimum of 7 and a maximum of 13 Primary voting members sufficiently qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The membership includes regular members who have designated alternates with qualifications comparable to the regular member. While not listed on the roster of the Office for Human Research Protections (OHRP) / US Food and Drug Administration (FDA), consultants provide guidance and input regarding IRB operations and protocol review as needed.

IRB membership complies with federal requirements outlined in 45 CFR 46.107, 21 CFR 56.107, and 38 CFR 16.107 to ensure appropriate diversity of the members through consideration of multiple professions/disciplines, ethnicities and cultural backgrounds, gender, and sensitivity to such issues as community attitudes. In addition, the NYSDOH IRB includes members who can determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable Public Health Laws, and standards of professional conduct and practice. If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership includes individuals who are knowledgeable about and experienced in working with those subjects.

The IRB invites individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the NYSDOH IRB(s). IRB Administrative Staff recruit ad hoc and cultural consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the NYSDOH IRB(s). These ad hoc and cultural consultants do not vote with the IRB and do not count toward a quorum at a convened meeting. Ad hoc or cultural consultants may provide comments or recommendations in

writing to the IRB prior to the meeting or they may attend the convened meeting to participate in the discussion and review.

ROLES OF IRB MEMBERS

Scientific Members

Scientific members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members may advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.

Nonscientific Members

Nonscientific members are expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.

Non-Affiliated (Community) Members

Non-affiliated members are expected to provide input regarding his/her knowledge about the local community and be willing to discuss issues and research from that perspective. A non-affiliated member is also a scientific or nonscientific member and would be expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise.

Chair & Vice Chair

In addition to scientific member responsibilities listed above, the Chair and Vice Chair review all studies presented to the IRB committee and communicate with other reviewers as needed so that important IRB issues or concerns are resolved or identified prior to the convened IRB meeting, and are empowered to administer convened IRB decisions. Chair directs the proceedings and discussion of convened IRB meetings or may delegate to the Vice Chair to assist or act on behalf of the Chair in IRB matters and at IRB meetings.

QUALIFICATIONS AND RESPONSIBILITIES OF IRB MEMBERS

IRB Chair

The Chair must hold a terminal degree (M.D., D.O., D.D.S., D.V.M., or Ph.D.) and be an employee of Health Research Inc. and New York State Department of Health. The Chairperson must have previous service on the NYSDOH IRB as Vice Chair or an IRB Primary Member.

Responsibilities:

- Chair the meetings to which they are assigned;
- Serve as Designated Expedited Reviewer;
- Participate in the on-call schedule for emergency consultation with investigators;
- Advise investigators on and acknowledging the appropriateness of emergency use of investigational drugs and devices in accordance with federal regulations;
- Participate on IRB meetings;
- Facilitate and participate in IRB educational activities;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Evaluate IRB member's thoroughness of review;
- Adhere to and administer determinations by the IRB;

IRB Vice Chair

The Vice Chair must hold a terminal degree (M.D., D.O., D.D.S., D.V.M., or Ph.D.) and be an employee of Health Research Inc. or New York State Department of Health. The Vice Chair must have previous experience as an IRB Primary Member.

Responsibilities include:

- Serve as substitute chair of the IRB to which the individual is assigned and to other convened IRBs;
- Serve as an alternate IRB member as needed;
- Serve as Designated Expedited Reviewer;
- Participate in the on-call schedule for emergency consultation with investigators;
- Advise investigators on and acknowledging the appropriateness of emergency use of investigational drugs and devices in accordance with federal regulations;
- Participate in the IRB meetings;
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research;
- Adhere to and administer determinations by the IRB;
- Facilitate and participate in IRB educational activities.

Scientific IRB Committee Member

Scientific Members must hold a scientific degree (e.g., M.D., D.O., D.D.S., D.V.M., Ph.D., Pharm.D. M.P.H., M.P.A., M.S.W., M.S., B.S. or B.S. in Nursing) and be an employee Health Research Inc. and NYS Department of Health employee. Scientific members must have professional training and experience in an occupation that would incline them to view scientific activities from the standpoint of someone within a behavior or biomedical research discipline. Registered nurses, nurse practitioners, pharmacists, therapists, radiologists and other biomedical health professionals would be regarded to have primary concerns in the scientific area.

Responsibilities include:

- Participate as a reviewer on applications to which the individual is assigned;
- Review and participate in a discussion of all applications and agenda items for each convened IRB meeting;
- Serve as an alternate IRB member as needed;
- Inform IRB Administration, a minimum of fourteen days in advance of the meeting, barring emergencies, of unavailability to attend a scheduled meeting;
- Provide a written review summary to IRB Administration prior to the meeting, if assigned as a primary reviewer and unable to attend the meeting due to an emergency;
- Keep abreast of regulations and policies governing IRB review and the conduct of human subjects research;
- Participate in IRB educational activities.

The Chair, the Vice Chair, and Scientific Members employed by NYSDOH must have the approval of their Center Director to serve on the IRB.

Non-Scientific IRB Committee Member

Non-Scientific Member must have experience with complex information and interpersonal communication. In addition, the non-scientific member must be comfortable with the electronic environment and can navigate email and the internet. Examples of non-scientific or non-medical occupations may include, but not limited to, Lawyers, Clergy, Ethicists, Teachers, Engineers, Accountants, Musicians, or Business Majors.

Responsibilities:

- Participate as a reviewer on applications to which the individual is assigned;
- Review and participate in a discussion of all applications and agenda items for each meeting;
- Serve as an alternate IRB member as needed. Inform IRB Administration, a minimum of fourteen days in advance of the meeting and barring emergencies, of unavailability to attend a scheduled meeting;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Participate in IRB educational activities;
- Contribute expertise with regulations, policies and the conduct of human subjects research;
- Represent nonscientific interests such as: how well is the research explained in order to comprehend the risk, benefit, and distributable justice (Belmont Principles).

Non-Affiliated (Community) Committee Member

The Non-Affiliated Committee Members must be experienced with complex information, interpersonal communication, and is sensitive to unique community populations and cultures. In addition, the non-affiliated member must be comfortable with the electronic environment, able to navigate in email, and have access to high-speed internet. The Non-Affiliated Member is not a current or former employee of NYSDOH and does not have an immediate family member who is a current or former employee of NYSDOH.

Responsibilities:

- Participate as a reviewer on applications to which the individual is assigned;
- Review and participate in a discussion of all applications and agenda items for each meeting;
- Serve as an alternate IRB member as needed;
- Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research;
- Participate in IRB educational activities.

Attendance Expectations and Length of Service for All Members

- The anticipated length of service for members is three years.
- The minimum attendance requirement is for at least 70% of the meetings to which the member is scheduled.
- When acting as primary IRB reviewer, attempt to resolve questions or concerns prior to the meeting, which may necessitate contacting researchers.
- Members are required to pursue current knowledge of human subjects regulations.
- Members are required to provide written review in emergent situations in which attendance cannot be realized.

Recruitment of IRB Members (except non-affiliated community members)

In April/May of each calendar year, the IRB will contact Center Directors throughout NYSDOH to seek recommendations for convened IRB members to replace members whose term ends during the next calendar year. There is an attempt to approach Centers/Divisions to achieve broad participation throughout NYSDOH and to ensure representation from those specialties that have a high volume of human studies research. The IRB also welcomes requests to join the IRB from members of the NYSDOH/HRI staff, and these requests are submitted to the individuals' Center Director for consideration for recommendation to the IRB. Unscheduled vacancies on the IRB that occur during the year are filled in a similar fashion.

The final determination of whether nominated IRB members' primary concerns fall into scientific or non-scientific areas is made by the IRB Chair and IRB Administration.

Evaluation of IRB Members

The performance of IRB Chair and Vice Chair will be reviewed annually by IRB Administrative Director and the Institutional Official. Should the determination be made that the IRB Chair or Vice Chair (1) failed to act in accordance with the IRB's mission, (2) failed to follow the policies and procedures set forth herein and in the federal rules and regulations, (3) has an undue number of absences, and/ or (4) failed to fulfill the designated responsibilities of the IRB Chair or Vice Chair, he/ she will be removed by the Institutional Official. Feedback is given during a one on one performance evaluation meeting with the Institutional Official.

IRB Members' performance will be reviewed by the IRB Chair in consultation with the IRB Administrative Director. Performance is assessed per the IRB mission and policies and procedures. IRB members, who have an excessive number of absences, may be removed. IRB Members will be assessed on level of participation during and outside of meetings, thoroughness of reviews, maintenance of confidentiality and understanding of the regulations. When necessary, the IRB Chair and/or Institutional Official will meet privately with a member to discuss concerns about their performance.

The membership roster is reviewed at least annually by the IRB Administrative Director and the IRB Chair to assure appropriate membership and diversity as outlined in 21 CFR 50 and 45 CFR 46. Attendance is recorded and if a member misses a majority of meetings without substantive cause/explanation, the IRB Chair and IRB Administrative Director will discuss the advisability of resignation with the board member and report to the Institutional Official.

To fulfill his or her duties, IRB members are expected to be knowledgeable of the regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of the New York State Department of Health and the NYS Public Health Laws germane to human subject protection.

Feedback will be given to each member either by letter, e-mail, phone call, or in person.

- IRB member self-assessment is used to provide members the opportunity to reflect on the IRB experience and identify potential learning needs. An *IRB Member Self-Assessment Form* and an *IRB Chair/Vice Chair Self-Assessment Form* are used to facilitate the annual assessment process between the IRB Members and IRB Chairperson/ Vice Chair and between the Chairperson and the NYSDOH Institutional Official.
- Chairperson assessment of each member's review of research is combined with a record of attendance and evaluated by IRB Administration and the NYSDOH Institutional Official for consideration of coaching or assessment regarding the ability of the member to meet the expectation for on-going IRB membership. Areas for improvement that are identified for an IRB Member is forwarded to IRB Administration and the NYSDOH Institutional Official for review and follow-up.
- In addition, IRB staff who may also serve as convened IRB members, undergo periodic performance evaluations as a component of NYSDOH's Human Resource Performance Evaluation.
- On an annual basis, a survey is distributed to all members and results are used to improve processes surrounding orientation, training, and education.

Recruitment and Recognition of Non-Affiliated (Community) Members

- Individuals not affiliated with NYSDOH are recruited to serve as board members.
- Non-Affiliated members participate in the IRB orientation, education and training program.

Alternate Members

- Each IRB member serves as an alternate for others within the same IRB member role (scientific, non-scientific, or non-affiliated). Qualifications, responsibilities, and recruitment processes do not differ from the member's primary role.
- The IRB roster designates the member role for which each member may substitute.

Related Documents

IRB Chair/Vice Chair Self-Evaluation Form (Appendix 20)

IRB Member Self-Evaluation Form (Appendix 21)

IRB Administrative Office Staff

The IRB Administrative Director is appraised annually using Health Research, Inc.'s Annual Performance Evaluation Form based on core values and job-related performance factors (specific duties and responsibilities) for the position held. These are specified in the job description for that position. Feedback is given during a one on one performance evaluation meeting with the Institutional Official.

COMMUNITY-BASED PARTICIPATORY RESEARCH PROJECTS

The IRB has sought a more collaborative process of research involving researchers and community representatives. In this process the IRB Members have an opportunity to inquire of NYSDOH Researchers if they have sought to engage community members and employ local knowledge in the understanding of health disparities and problems and design protocols that address community needs with realistic interventions.

The IRB Membership understands that by engaging in community-based participatory research projects, the community participates fully in all aspects of the research process. The IRB recognizes that the research may start with the community in collaboration with NYSDOH Researchers to understand a common problem or issue, or a community of individuals with a common interest or goal. These partnerships require sharing results and knowledge, including identifying the problem/issue, research design, research conduct, analysis, and determining how the results should be used for action. This makes community-based participatory research projects an interactive process, involving research, community involvement/investment and it results in a more cyclical process. Community members are invested in the dissemination and use of research findings and ultimately in the reduction of health disparities and problems in their studied communities.

IRB TERMINOLOGY AND DEFINITIONS

Appendix I includes a more complete list of important IRB terminology and definitions. The glossary is not intended to be a complete research glossary but seeks to cover concepts that are important in the completion of IRB applications. The first thing you must determine is whether your project is research that involves human subjects.

Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. [45 CFR 46.102(d)]

Human Subject

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” [45 CFR 46.102(f)]

What is a systematic investigation?

Systematic Investigation is generally thought of as a predetermined method for studying a group, program or occurrences. Program Evaluations, Program Assessments, Interviews, Surveys and Focus Groups are examples.

What is generalizable knowledge?

An activity may be thought to contribute to generalizable knowledge if the information collected can be applied to more than that program or activity.

Examples of activities or programs that would contribute to generalizable knowledge:

If a program evaluation, program assessment, or activity is:

- conducted to examine whether the program had the desired effect on program participants, and that evaluation can inform other programs.
- conducted with the intent to replicate the program.
- designed to draw general conclusions.
- designed to inform policymakers.

Examples of activities or programs that would **NOT** contribute to generalizable knowledge:

If a program evaluation, program assessment, or activity is used only for:

- internal improvements to a program or service.
- quality assurance purposes.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

When following FDA regulations:

Research means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (j) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c), 21 CFR 56.102(c))

Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

FEDERALWIDE ASSURANCE

All institutions engaged in human subject research that is not exempt from the regulations and is conducted or supported by any federal department or agency that has adopted the Common Rule must be covered by an OHRP-approved assurance of compliance.

The Federalwide Assurance (FWA) is an agreement with the U.S. Department of Health and Human Services that formalizes the NYSDOH's commitment to human subjects protection requirements for NYSDOH research. (Additional requirements of the Federal Food and Drug Administration (FDA) are applied as appropriate.) These requirements include IRB review of all research that involves human subjects.

The assurance is a legally binding agreement committing an institution to specified activities regarding the protection of human subjects. This requirement is incumbent upon both awardee and collaborating institutions. Pursuant to 45 CFR 46.102 (d), (f), these institutions become engaged in research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release or access individually identifiable private information for research purposes.

It should be noted that the awardee institution is considered engaged in human subject research when a direct HHS award is made to support such research, even when all activities involving human subjects are carried out by a subcontractor or collaborator. Under these circumstances, the awardee institution remains ultimately responsible for protecting human subjects under the award. In addition, the awardee is responsible for ensuring that all collaborating institutions hold an approved Assurance prior to initiation of the research. Further information on the circumstances under which an institution does, or does not become "engaged" in research, and thus does, or does not need an Assurance, may be found in the OHRP guidance document entitled "*Engagement of Institution in Research*" dated January 26, 1999.

For the NYSDOH to receive federal money for research purposes, institutional officials must sign a Federalwide Assurance with the federal government.

FWAs only apply to federally conducted or supported research. This means that non-federal research will not be part of the FWA and not subject to federal oversight, whereas under the pre-2018 rule an institution could “check the box” to apply the federal regulations and federal oversight to all research, regardless of funding. This “checking the box” is no longer an option under the Common Rule. Institutions may still voluntarily apply the federal regulations to all research, but federal oversight would only apply to federally conducted or supported research. The NYSDOH has opted to apply the Common Rule and subparts B, C, and D of the DHHS regulations at 45 CFR 46 to all research, regardless of source of support.

The FWA Number for the New York State Department of Health Institutional Review Board is FWA00003700. NYSDOH IRB’s Federalwide Assurance is approved through January 30, 2023.

ETHICAL PRINCIPLES

The origins of the ethical principles which IRBs are responsible for applying may be traced to the Nuremberg Code, developed in response to Nazi atrocities committed in the name of research during World War II, and to the 1964 Declaration of Helsinki, adopted by the World Medical Assembly and revised in October 2000. These principles include:

- the voluntary consent of the human subject;
- the capacity to consent;
- freedom from coercion;
- comprehension of the risks and benefits involved;
- minimization of risk and harm;
- a favorable risk/benefit ratio;
- qualified investigators using appropriate research designs; and
- freedom for the subject to withdraw at any time without loss of benefits.

The Belmont Report

The National Health Research Act was passed in 1974. It established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1978, the Commission published the most thorough examination of the ethical underpinnings of these guiding principles, entitled "*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*" This report continues to be the single most basic, concise embodiment of the ethical principles governing human subject research. The principles are:

- respect for persons
- beneficence
- justice

Respect for persons underlies the need for informed consent. **Beneficence** (protection from harm) underlies risk/benefit analysis and minimization of risks. **Justice** requires that subjects be chosen fairly and without reference to any personal prejudices held by researchers.

Further, the Belmont Report distinguished between **practice** (interventions designed solely to enhance the well-being of a patient or client) and **research** (an activity designed to test a hypothesis and contribute to generalizable knowledge). While practice and research may sometimes overlap, as in the case of clinical trials of experimental medications, attention to the protection of subjects always requires that the IRB ensure that proper procedures are followed in accordance with ethical

principles.

The Belmont Report can be accessed at
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

HOW TO CONTACT THE IRB

Forward correspondence to:

Tony Watson, MBS, CIP, IRB Administrative Director
New York State Department of Health
Institutional Review Board
ESP, Corning Tower Building, Room 474
Albany, NY 12237-0001
(518) 474-8539 (Phone)
(518) 408-1423 (Fax)
irbbml@health.ny.gov

IRB MEETING SCHEDULE

Except when an expedited review process is used, proposed research must be reviewed at convened meetings at which a majority of the members of the IRB are present (45CFR46.108). The annual schedule of meetings is posted on **NYSDOH News** and on the IRB website. It is also made available to all Principal Investigators in the Wadsworth Center via electronic mail.

Meetings are scheduled the third Thursday of every month.

Emergency Meetings

The IRB Chair may call emergency meetings of the IRB, as needed to review research protocols, address issues of noncompliance, or address serious and/or unexpected injury to research subject(s).

COLLABORATIVE PROJECTS

If a NYSDOH researcher is working in collaboration with another institution or organization and the institution/organization is engaged in the research, federal regulations require the second institution/organization have an assurance of compliance filed with the federal government and have its own registered IRB. The word 'engaged' means that the collaboration site will be assisting in conducting the research, such as recruiting participants, obtaining consent, conducting interviews, or analyzing identifiable data. If you are using another site for your research and its participation is limited to the use of its location, this would be considered a performance site and not a collaboration site. A performance site does not need an assurance. However, permission from an appropriate agency official at that site to conduct the research must be obtained. In some instances, the performance site may require its own IRB approval. In this case, the NYSDOH IRB requires a copy of their IRB approval.

If the collaborating institution has not filed an assurance or does not have an internal IRB, a formal agreement must be documented. The agreement must be signed by an official who is legally

authorized to represent the institution. Investigators from each site are responsible for maintaining complete and up-to-date study files in accordance with their institution's policy. In the rather unlikely case that an institution has an assurance on file with OHRP but does not have an IRB, the other institution must file an authorization agreement specifying that the NYSDOH will provide IRB review and oversight for this project. Contact the IRB for copies of this application.

More commonly, institutions/organizations may lack both an assurance and an IRB. If the research is federally-funded, the other institution/organization must complete an application for Federalwide Assurance (<http://ohrp.osophs.dhhs.gov/irbasur.htm>) or complete an IRB authorization agreement authorizing the NYSDOH IRB to act as the IRB of record for this research project.

If the non-NYSDOH collaborator is an unaffiliated independent investigator, an individual investigator agreement can be used to document assurance that the private practitioner will adhere to NYSDOH human protection policies and requirements. Federal regulations require written agreement with independent investigators who are not otherwise affiliated with the institution.

When the researcher is the lead researcher of a multi-site study, the IRB Applications MUST include information about the management of information that is relevant to the protection of participants, and should include information on:

- How unanticipated problems involving risks to participants will be handled and reported.
- How Continuing Reviews will be reported.
- How Protocol Changes will be applied for and when.

If the NYSDOH is the Lead Researcher of a multi-site study, this IRB will evaluate the management information that is relevant to the protection of participants to determine that it is adequate.

Research Not Involving NYSDOH Investigators

Occasionally an institution lacking an IRB will request the NYSDOH IRB to review a research protocol. Under these circumstances, the outside institution must complete an IRB authorization agreement stipulating that the NYSDOH IRB will act as the IRB of record. The IRB Chair will determine whether to accept such requests based on the workload of the IRB and the interests of the NYSDOH.

SUBMISSION PROCEDURES

Applications for full board review should be submitted to the IRB, through IRBNet.org, no less than four weeks prior to published meeting date. A schedule of annual meeting dates and submission deadlines is posted on NYSDOH News and is also available on the IRB website. Four-six weeks prior to each meeting, a reminder notice is posted on NYSDOH News. Applications that require Convened Full Board Review, but are submitted after the deadline, may be held for review at the next Convened Full Board meeting.

For IRB review, the IRBNet submission must include:

- a Protocol Review Request Form (NYSDOH 1871 or NYSDOH 1871S) completely filled-out,
- a protocol that describes the hypothesis and research plan,
- supplemental forms for research involving vulnerable populations, (if applicable)
- all recruitment materials (e.g., letter of invitation, recruitment script, advertisements, flyer),
- consent/parental permission/assent form(s) (when appropriate),
- HIPAA authorization, waiver of authorization, or 206(1)(j) approval (when appropriate)

- all surveys, questionnaires, instruments, etc.,
- documentation of IRB approval from each collaborating institution,
- a copy of current CITI Research training certificates for all research staff, and
- Conflict of Interest Form 3995 for all research staff.

All documents should be submitted electronically through IRBNet.org. IRBNet is the electronic system for the administration and management of IRB protocol records. Each submission must be signed electronically by the Principal Investigator, Center/Division Director and other required staff if indicated.

Applicants may be invited by the Board to attend the convened bi-monthly meeting to answer questions or offer clarification regarding their application. Applicants may request to attend meetings, as well to present their project. Applicants will be notified prior to the relevant meeting if they need to attend the meeting. Applicants may not be present during board members' deliberation or vote.

Applicants will be notified in writing within ten business days of the decision of the IRB.

Applicants may not proceed with research without the written approval of IRB.

If additional information/documentation is required for applications designated as approved pending; contingent approval; or tabled; the principal investigator should respond to the IRB within 30 days from the date of notification. If there is no communication between the IRB and the principal investigator during this timeframe, the IRB WILL close the study file.

Approval time frames are generally for a 12-month period. For studies reviewed and approved during a Convened IRB meeting, the IRB assigns the start of the approval period as the date of the Convened IRB meeting. If a protocol has been reviewed by either the Convened Full Board or by Expedited Review, and receives a vote of contingent approval, (the IRB requests minor revisions) or there are serious concerns or a lack of significant information requiring the IRB to complete its review and issue approval of the study at a subsequent meeting/time, the effective date of the initial approval is the date on which the IRB Chair (or designee) has reviewed and accepted as satisfactory any revised protocol and/or supporting documents or any other responsive materials required by the IRB from the investigator. In these circumstances, no research study activities involving human subjects may be initiated until the conditions have been satisfied in the manner set forth by the IRB and the approval becomes effective.

ELEMENTS OF PROTOCOL REVIEW

A protocol is a detailed description of the research plan including study design and all actions, documents, forms, data collection instruments and all other relevant documents. Any protocol submitted to the IRB must include the elements specified below. Before a research study involving human participants is initiated, it must be reviewed and approved by the NYSDOH IRB. All research involving human participants must be reviewed by the IRB when the research:

- is sponsored by the Institution,
- is conducted by or under the direction of any employee or agent of this Institution (including students) about his or her Institutional responsibilities.
- is conducted by or under the direction of any employee or agent of this Institution using any property or facility of this Institution.

- Involves the use of this Institution's non-public information to identify or contact human participants.

IRB administrative staff conduct a preliminary review of each application to ensure all the necessary documents and required signatures have been submitted. An IRB protocol number is then assigned to the study, and the protocol is forwarded to the Chair or the appropriate review subcommittee. The NYSDOH IRB will review each proposed human research project to determine:

- that the rights and welfare of the human subjects involved are adequately protected;
- that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained;
- that the consent/assent process is adequately explained, and appropriate consent/assent procedures are in place to protect research participants (assent is required based upon age and level of risk);
- that the persons proposed to conduct the research are appropriately competent, qualified and have current human subject protection training.

For safety of participants to be appropriate, the IRB will determine that the research plan makes adequate provisions for data and safety monitoring. The IRB might consider provisions such as:

- What safety information will be collected, including adverse events.
- How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
- The frequency of data collection, including when safety data collection starts.
- The frequency or periodicity of review of cumulative safety data.
- The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor, including the frequency of reporting.
- For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB needs to carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.
- If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring;
- Provisions for the oversight of safety data (e.g., by a data monitoring committee).
- Conditions that trigger an immediate suspension of the research, if applicable.

The applicant must submit a research protocol which includes the following:

- the purpose and need for the study;
- background and previous research (literature review);
- the specific location(s) of the study;
- the duration of the study and specific phase(s);
- the research plan, including the enrollment criteria, and the expected number of subjects to be enrolled;
- human subject procedures, including how subjects will be selected, the sampling frame, use of inducements/incentives/compensation, contact letters, informed consent form(s), assent and permission forms (where subjects are children), and recruitment notices;
- approvals by IRB of other institutions, if any (Authorization Agreement or Individual Investigator Agreement as applicable);
- a description of confidentiality/data storage procedures;
- questionnaires/surveys, if any; and
- a list of study personnel and proof of human subjects protection training

CRITERIA FOR IRB APPROVAL OF RESEARCH §46.111

The IRB shall determine that all the following requirements are satisfied prior to approving research:

- (1) Risks to subjects are minimized.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
- (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of Subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

INFORMED CONSENT

Before involving a human subject in research, an investigator must obtain the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek informed consent only under circumstances that provide the prospective participant/subject or the legally authorized representative sufficient opportunity to discuss and consider whether to participate and that minimizes the possibility of coercion. The information that is provided to the subject or the legally authorized representative must be in language that is understandable to them. The prospective subject or legally authorized representative must be provided with information that reasonable person would want to have to make an informed decision about whether to participate and provided an opportunity to discuss that information.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative understanding the reasons why one might or might not want to participate in research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent must present information in sufficient detail relating to the research project and must be organized and presented in a way that does not merely provide lists of isolated facts, rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

Informed Consent must not include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Required Elements of Informed Consent:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subjects;
3. A description of any benefits to the subject or others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained (also note that the study sponsor, staff from DHHS or staff from the approving IRB and the Research Compliance Officer may inspect the records);
6. For research involving more than minimal risk: an explanation of whether compensation or medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative, if this might be a possibility; or
 - A statement that the subject's information or biospecimens collected as part of the research even if identifiers are removed, will not be used or distributed for future research studies.

One or more of the following elements of information will be provided when appropriate to the subject or the legally authorized representative:

1. A statement that the treatment or procedure may involve risks to the subject or to embryo or fetus if subject is pregnant or may become pregnant that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant findings developed during the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results will be disclosed to subjects, and if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Informed consent is a process, and the signed Informed consent form serves only as documentation of the dialogue that must occur between the investigator and the potential subject regarding the research project. The discussion which precedes the signing of the Informed consent form must provide the subject with a full understanding of the purpose, procedures, benefits, risks and alternatives, to enable him or her to make an informed decision about becoming a study participant. This process and its related procedures must be described in the protocol. See Appendix 4-5 for a sample adult consent form and sample assent forms appropriate for children.

It cannot be overemphasized that the foregoing list of Informed consent topics should be used only as a guide in writing a narrative description specifically for the project and its human subjects procedures that will comprise the actual consent form to be used.

The IRB requires that the current IRB-approved Informed consent form affixed with the IRB expiration date on NYSDOH letterhead be used when obtaining consent. Study participants must sign the Informed consent form with the affixed IRB expiration stamp.

DOCUMENTATION OF INFORMED CONSENT

Written Informed Consent

Informed Consent shall be documented by a written informed consent form approved by the IRB and signed (including electronic formats) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the consent form.

Oral Consent

Oral consent is permissible under certain circumstances for research that pose minimal risk to subjects, such as in situations in which written consent is deemed culturally disrespectful or inappropriate, when there is no face-to-face contact with the subject, where a written consent procedure is not normally required, or when the only risk to the participants is a breach of confidentiality resulting from the documentation of identity on the consent document. Researchers proposing to obtain informed consent orally must include a script of the oral consent language and content with their IRB application. Oral informed consent should include all the elements of informed consent including contact information and should be given to subjects in writing. Investigators should keep a log documenting the oral consent process throughout the duration of the study. The investigator should indicate in writing that the elements of consent were read, and consent was obtained orally rather than by obtaining the subject's written signature. Investigators should specifically request a waiver of documentation of consent and provide evidence that the request meets the requirements of federal regulation 45 CFR 46.117.

Electronic Informed Consent

Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web Sites, biological recognition devices and card readers to convey information related to the study and to obtain and document informed consent. Electronic informed consent must include all elements of written informed consent (listed above under Informed Consent) including providing sufficient opportunity for the subject to consider whether to participate in the study. Electronic informed consent may be used to either supplement or replace paper-based informed consent

processes to best address the subject's needs throughout the course of the study. The investigator is responsible for ensuring that legally effective informed consent is obtained before a subject participates in a study.

Electronic informed consent may take place at the study site when the both the investigator and subject are at the same location or it may take place remotely e.g. subject's home or other convenient location. If the consent process takes place at the study site, study personnel can personally verify the subject's identification, review the electronic informed consent content with subject, answer any questions, have a follow-up discussion and witness the signing of the electronic informed consent form. If any or all the electronic consent process takes place remotely and is not personally witnessed by the study personnel, the electronic consent process must include a method to ensure that the person that is electronically signing for consent is the subject that will be participating in the study or is the person's legally authorized representative. Examples of verification methods that can be used are: verification of state-issued identification or other identifying documents or use of personal questions, biometric methods or visual methods.

To assist the subject in understanding the material, the electronic informed consent may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narrations. It should be appropriate for the intended audience, taking into consideration the subject's age, language and comprehension level. The electronic informed consent may use various methods to help an investigator assess the subject's understanding of the information being presented due the electronic informed consent process. It may include optional questions at any time during the electronic informed consent process to help educate the subject about information presented and/or assess the subject's understanding of the electronic informed consent materials. The questions can also be used to gauge comprehension of key study elements and highlight areas where the subject might need more information or explanation.

When appropriate, the electronic informed consent must include a statement that significant new findings developed during the research that may affect the subject's willingness to continue participation will be provided to the subject or legally authorized representative. Electronic informed consent may include an electronic method for signature of the subject or legally authorized representative. Electronic signatures based on biometrics must be designed to ensure that they cannot be used by anyone other their genuine owners. Electronic signatures based on biometrics are accepted provided they meet the requirements found in 21 CFR part 11: (a) they must contain pertinent information associated with the signing;(b) they are subject to the same controls as electronic records and must be included as part of any human readable form of the electronic record and (c) they must be linked to their respective electronic record.

The electronic informed consent process may be used to obtain assent from pediatric subjects and parental permission from their parent(s) or guardian. HIPAA authorizations may be obtained electronically, provided that the signature of the subject or the legally authorized representative is a valid electronic signature under applicable laws and regulations (HIPAA Security Rule).

***Broad Consent**

Broad Consent is an alternative consent process for use only for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research or nonresearch purposes or future, yet-to-be-specified research. If the subject or legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

1. A description of any reasonably foreseeable risks or discomforts to the subjects;

2. A description of any benefits to the subject or others which may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained (also note that the study sponsor, staff from DHHS or staff from the approving IRB and the Research Compliance Officer may inspect the records);
4. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
5. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This information must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
6. A description of the identifiable private information or identifiable biospecimens that might be used in research whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
7. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained and description of time that the identifiable private information or identifiable biospecimens may be used for research purposes;
8. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research and that they might have chosen not to consent to some of those specific research studies;
9. Unless that it is known clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
10. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related injury to the subject; and if appropriate:
11. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
12. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

***Please Note: NYSDOH will not implement the new regulatory Broad Consent option as an Informed consent process now. Exemptions 7 and 8, which rely on Broad Consent also will not be implemented.**

Waiver or Alteration of Informed Consent

A departure from the traditional consent process: DHHS regulation 45 CFR 46.116(d) specifies that an IRB may waive the requirement to obtain informed consent or alter the document of Informed Consent if it finds and documents that the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver and alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Additionally, the IRB can waive or alter the consent process by determining that the regulatory criteria

for waivers or alterations of the consent process are met and that the research is not regulated by the FDA. The IRB can waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met.

- When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants.
- When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research.

Waiver of Parental Permission – Public Demonstration Project

This applies when the research is conducted by or subject to the approval of state or local government officials. It also applies when the research or demonstration protocol is designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs.

Waiver of Documentation of the Informed Consent Process - Permission is not a reasonable requirement when:

- The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants.
- An appropriate mechanism for protecting the children who will participate as participants in the research is substituted.
- The research is not FDA-regulated.

Waiver of Documentation of the Informed Consent Process – Based on Harm is permissible when:

- The only record linking the participant and the research is the consent document.
- The principal risk is potential harm resulting from a breach of confidentiality.
- Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant's wishes will govern.
- The research is not FDA-regulated.

Waiver of Documentation of the Consent Process – Minimal Risk

- The research presents no more than minimal risk of harm to participants.
- The research involves no procedures for which written document of the consent process is normally required outside of the research context.

When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants. When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers having the investigator provide participants with a written statement regarding the research.

REVIEW CONSIDERATIONS

The Belmont Report identified information, comprehension and voluntariness as the basic elements of informed consent. Accordingly, the following are key considerations in the IRB's review of applications:

Language Level

To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). In general, the NYSDOH IRB expects adult consent forms to be written at the 8th grade reading level and use as few technical terms and as little jargon as possible. When the use of technical terms cannot be avoided, they should be explained in simple language. Abbreviations and acronyms should also be both spelled out and explained using simple language. The format should be narrative rather than bulleted. Microsoft Word can display the Flesch-Kincaid reading level as part of the spell-checking feature (for instructions, refer to the Readability Score procedure). Do not list the reading level on the consent form.

Oral Consent

As a rule, IRB requires all literate participants to receive a written copy of informed consent. However, if oral consent is used for participation in research then the following must be true: the research poses minimal risk to subjects, such as in situations in which written consent is deemed culturally disrespectful or inappropriate, when there is no face-to-face contact with the subject, where a written consent procedure is not normally required, or when the only risk to the participants is a breach of confidentiality resulting from the documentation of identity on the consent document. To approve oral consent, the IRB must find the criteria for a waiver of documentation are met. In all cases, the IRB must review in advance the language that will be used in obtaining oral informed consent. Researchers proposing to obtain informed consent orally must include a script of the oral consent language and content with their IRB application. Oral informed consent should include all the elements of informed consent including contact information and should be given to subjects in writing. Investigators should keep a log documenting the oral consent process throughout the duration of the study. The investigator should indicate in writing that the elements of consent were read and consent was obtained orally rather than by obtaining the subject's written signature. Investigators should specifically request a waiver of documentation of consent and provide evidence that the request meets the requirements of federal regulation 45 CFR 46.117.

Electronic Informed Consent

IRB must ensure that the electronic informed consent includes all elements of written informed consent (listed above under Informed Consent) including providing sufficient opportunity for the subject to consider whether to participate in the study. Electronic Informed Consent must be appropriate for the intended audience, taking into consideration the subject's age, language and comprehension level. It can be located at the study site or off-site at the subject's home or another convenient location. IRB should consider how the electronic signature is created and whether the informed consent or permission document can be produced in hard copy for review by the subject. IRB should also consider how a subject's or legally authorized representative's identity is being verified. When approving an electronic informed consent assent process, an IRB must consider whether the capability of the child assent may be affected by the method used to obtain and/or document child assent. Electronic informed consent should not impede a child's capability to provide assent.

Legally Authorized Representative

Under DHHS and FDA regulations a "legally authorized representative" means an individual or

judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.

When research is conducted in New York State, the following individuals meet this definition:

- A court appointed guardian who is specifically given authorization to consent to participation in research.

- In the absence of a court appointed guardian who is specifically given authorization to consent to participation in research, any of the following individuals, as defined in the New York Family Health Care Decisions Act, Mental Hygiene Law, and applicable NYS Public Health Laws:
 - A court appointed guardian who is specifically given authorization to consent to health care.
 - A previously designated health care proxy
 - Spouse (if not legally separated) or domestic partner
 - Children > 18 years of age
 - Parents
 - Siblings > 18 years of age

For research outside New York, a determination of who meets the DHHS and FDA definitions of "legally authorized representative" is to be made with consultation from the NYSDOH Division of Legal Affairs. This consultation will be facilitated by the IRB staff.

NYS Public Health Laws should be followed concerning determination of capacity to consent. Attention should be paid regarding who can make these determinations when incapacity may be due to mental illness or intellectual disabilities.

Children

Under DHHS and FDA regulations "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Subpart D of the DHHS must be applied if and only if an individual involved in the research meets this definition.

When research is conducted in New York, all individuals under the age of 18 years meet this definition with the following exceptions:

- Minors, defined as individuals who meet one of the following criteria, do not meet the DHHS and FDA definition of "children": (Article 24-A §2504)
 - Married/widowed/divorced;
 - A parent;
 - In the case of medical, dental, health and hospital services relating to prenatal care a female who is pregnant.
- Individuals under the age of 18 when the research procedures are limited to:
 - Diseases dangerous to the public health;
 - Chemical dependency (Mental Hygiene Law §22.11) if, in the judgment of a physician, parental or guardian involvement and consent would have a detrimental effect on the course of treatment of a minor who is voluntarily seeking treatment for chemical dependence or if a parent or guardian refuses to consent to such treatment and the physician believes that such treatment is necessary for the best interests of the child.
 - Prenatal care in the case of pregnant children.

- Certain outpatient mental health services as described in Mental Hygiene Law §32.21(c) through §32.21(e).

For research outside New York State, a determination of who meets the DHHS and FDA definitions of “children” is to be made with consultation from the NYSDOH Division of Legal Affairs. This consultation will be facilitated by the IRB staff.

Guardian

Under DHHS and FDA regulations a “guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. When research involves children and parental permission is required, consent may only be obtained from parents (biologic or adoptive) or a guardian as defined by DHHS and FDA regulations. When research is conducted in any jurisdiction and permission for a child to participate in research is to be obtained from an individual other than biological or adoptive parents, the Principal Investigator should verify the legal ability of this individual to consent to the child’s participation in research. When documentation from this individual is provided, a copy of this documentation is to be kept with the consent document in the investigator’s files.

Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

IRB staff will facilitate consultations with the NYSDOH Division of Legal Affairs regarding research outside of New York State. [45 CFR 46.102, 45 CFR 46.402]

Language Translation

When studies include non-English speaking subjects, all written and oral materials must be provided in the language of the participant and must be comparable to the English language documents they will replace. A written attestation certifying the accuracy of the translation must be provided. In addition, the study staff must include personnel who are able to facilitate conversation with a non-English speaking subject.

Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject’s consent will not truly be informed and may not be legally effective. Alternatively, a “short form” may be used when the majority of subjects in a study are English speakers, but there is a portion of the subjects who will not be able to understand the consent form written in English. In these instances, a short form may be used in conjunction with an oral presentation of the consent information (45 CFR 46.117). A summary of what will be said to the subject or representative must be approved by the IRB and then presented orally to the subject or representative in front of a witness. Only the short form is signed by the subject or representative. The person obtaining consent shall sign a copy of the summary. A copy of the short form and a copy of the summary must be given to the subject or representative.

Contact Letters

Sometimes it is necessary to send an introductory letter to potential subjects prior to approaching them. When such a letter is used, the IRB will review it along with the consent form. Expectations concerning discussion of the elements of consent, the description of the project, and the language level used is the same as applied in the review of consent forms.

Advertisements & Advertising Brochures Seeking Research Participants

The IRB reviews advertising to ensure that advertisements do not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

Advertisements should be limited to the information prospective participants need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.
- Describe acceptable and unacceptable payment arrangements for the sponsor, organization, researcher, and those referring research participants.
 - Address the acceptability of payments in exchange for referrals of prospective participants (“finder’s fees” or “referral fees”).
 - Address payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”).

Risk-Benefit Analysis

Most research conducted by NYSDOH involves minimal risk or less than minimal risk. When a project entails greater than minimal risk of physical or psychological harm, it is the duty of the IRB to determine whether, on balance, the likely benefits of the research, either for society or the subjects themselves (as in clinical trials), exceed those risks. Projects that expose subjects to considerable risk but offer remote and minimal potential benefits are unlikely to be approved. In other cases, the IRB may ask the investigator to minimize known and unnecessary risks. In all cases, risks and benefits must be accurately and thoroughly explained to subjects in the Informed Consent form. Subjects must also be afforded opportunities to have their questions answered and to report injury. In certain circumstances, the IRB may require ongoing monitoring of the project and its informed consent records.

Privacy and Confidentiality

The IRB is responsible for systematically evaluating proposed research for adequate provisions which protect the privacy interests of participants and to maintain the confidentiality of identifiable data. The federal regulations differentiate between privacy and confidentiality, and it is important to understand the difference to determine whether these regulatory criteria for approval of human subject research are appropriately met. Privacy concerns people, whereas confidentiality concerns data. The research proposal should outline strategies to protect privacy, including how the investigator will access information from or about participants.

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, sharing, and discarding of data. When appropriate, certificates of confidentiality can be

used to protect identifiable data from subpoena (see below). NYS Public Health Law contains strict confidentiality mandates regarding protection of medical records.

Anonymous and De-Identified Data

A study is anonymous if identifying information is NOT recorded (e.g. names, address, date of birth) or detailed demographic information (e.g. race, age, income, educational degree, job title) about study participants. Personal identifiers are replaced by assigning codes to study participants. If the code is random (cannot be linked back to the subject), the data are anonymous. If the code can be linked back to the subject, the data are confidential. Generally, data are considered anonymous when there is no possible way to identify the participants from the data collected. Data are not anonymous if anyone or any procedure (such as accessing a computer database) will allow a subject to be identified. In most instances, the omission of specific identifiers, such as name, social security number, address, or patient number, is sufficient to qualify a study as anonymous.

Archived pathology or diagnostic specimens that are considered residual biological material and destined to be destroyed can be used in research. They are considered anonymous if there are no patient identifiers linked to the specimen and if the data are not intended to be used in the diagnosis or treatment of a patient. There are additional ethical concerns for genetic research (e.g., the potential for discrimination with regards to employment or insurability) that may not apply to other types of research with biological specimens. Please contact the IRB Office for additional information.

Health information is considered de-identified when it does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual. Information is considered de-identified if all of the identifiers listed below are removed from the health information and if the remaining health information could not be used alone, or in combination, to identify a subject of the information. De-identified data cannot contain the following identifiers:

- Names
- Dates (except year) including birth/death, and hospital admission
- Street address (city, state and 5-digit zip codes may be acceptable)
- Telephone numbers (including mobile phone)
- Fax numbers
- Email address
- Social Security number
- Medical record number
- Health plan number
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers (including license plate numbers)
- Device identifiers and serial numbers
- Web universal resource locators (URL)
- Internet protocol (IP) address numbers
- Biometric identifiers, including fingerprints and voiceprints
- Photographic images
- Any other unique identifying number characteristic or code

The omission of these specific identifiers may be sufficient to qualify a study as anonymous. Indirect identifiers, such as year of birth, race, gender, height or weight, usually do not allow for identification under reasonable circumstances.

If research involves anonymous or de-identified data, the investigator may not attempt to discern the

identity of individuals without the express approval of the IRB. To attempt to identify individuals from an anonymous or de-identified database without IRB approval will be considered investigator non-compliance.

Public Health Law Section 206(1)(j)

This section of the New York State Public Health Law (PHL) empowers the Commissioner of Health with the discretion to designate individual projects as scientific studies and research which have for their purpose the reduction of morbidity and mortality and the improvement of the quality of medical care within the state. The disclosure of information under Section 206(1)(j) is voluntary for whomever provides the information. When so designated, the identities of participants and data about them are classified as confidential and protected from public disclosure and most forms of legal discovery. Such a designation also places constraints on the ways in which researchers can utilize the data they obtain.

There are three distinct steps involved in completing the paperwork required for the 206(1)(j) designation. First, a transmittal memo describing the research and the need for outside designees is sent to the Commissioner of Health. Because information from a 206(1)(j) study can only be used for certain specific purposes, there is a risk that other information deemed appropriate for disclosure may come to light. However, the 206(1)(j) designation prevents such disclosure. To ensure that the Commissioner is fully informed, any such risks or potential embarrassments to the Department must be detailed. The second step involves a memo from the Commissioner to the Principal Investigator designating the study as a 206(1)(j) and also designating her/his representatives. Finally, there is a letter to each of the representatives from the Commissioner. The letter or a copy should be signed and returned to the Department of Health to ensure that she/he is aware of the scope of their responsibilities and authority.

Consent forms and contact letters may only make mention of authorization under Section 206(1)(j) when prior written designation of the study as a 206(1)(j) has been granted by the Commissioner of Health.

The IRB must receive a copy of the 206(1)(j) designation signed by the Commissioner prior to the implementation of any research being conducted under the mantle of Section 206(1)(j) of the PHL.

Certificates of Confidentiality

Certificates of Confidentiality (COC) are issued by the National Institutes of Health (NIH) agencies pursuant to Section 301(d) of the Public Health Services Act (42 U.S.C. Section 241(d)) as a means of providing special privacy protection to research subjects. A COC helps the researcher avoid compelled involuntary disclosure (e.g., subpoenas), to obtain identifying information about a research subject. However, it does not prevent voluntary disclosures such as those to protect the subject or others from serious harm, as in cases of child abuse. In the event a research subject consents to disclosure, the researcher may not rely on the COC to withhold data.

When a researcher obtains a COC, subjects must be informed about the protections provided by the certificate, and any exceptions to those protections. This information is usually included in the informed consent document. For more information, see <http://grants.nih.gov/grants/policy/coc/index.htm>

Effective October 1, 2017, NIH will provide Certificates of Confidentiality automatically to any NIH funded recipients that are covered by this policy. This automatic certification applies to research in which identifiable, sensitive information or biospecimens are collected or used. The policy defines identifiable information as any research that the individual's identity is known or could reasonably

discovered based on current science and statistical methods. The policy also defines the generation of individual level, human genomic data or the use of such data as being covered regardless of identifiability. For more information on this policy visit the NIH website:
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

Use of Inducements, Incentives and Coercion

Laws which apply to research do not sanction the use of coercion. Under certain circumstances, the use of valuable incentives relative to the living situation of the subject can be considered coercive. Therefore, the IRB will carefully review for appropriateness all inducements and incentives designed to improve participation. Incentives, especially those of the monetary type, should be reasonable in relation to the type and extent of participation being sought from the study subject. Principal Investigators should be able to justify the incentive based on the out-of-pocket expenses borne by the subject, the degree of anticipated discomfort or inconvenience, and related to the duration of time required of the subject or work-related loss of income. Modification of incentives may be sought when the voluntary nature of participation is potentially threatened.

The NYSDOH IRB has adopted the standard set by the FDA that clearly requires a system of prorating payments based on the duration of participation by the subject in the research. The FDA information sheets state, "Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study." Prorated payment should be made regardless of whether withdrawal was voluntary or involuntary. This is the recommended payment method for all NYSDOH studies since it allows the subject to withdraw from the study at any time and still be compensated for the time spent before the withdrawal. It is very important that the type and the amount of the incentive plus the payment schedule be clearly stated in the consent form.

Selection of Subjects

The selection of subjects must be equitable so that the benefits and burdens of research are distributed fairly. This means that children (i.e., individuals under the age of 18 in New York State and under the age of 21 in NIH Policy Guidelines), minorities and women should be included whenever appropriate. (*NIH Policy Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects and the NIH Policy Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* are available at <http://grants.nih.gov/grants/funding/children/children.htm>). Further, the IRB requires that potential subjects be told how and why they were included in the study sample. The inclusion of protected classes of subjects in research involves additional scrutiny by the IRB which is discussed in the Protected Classes section of the Guidelines.

Data and Safety Monitoring (DSM) in Sponsor Agreements

When the Sponsor has the responsibility to conduct data and safety monitoring, NYSDOH/HRI has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to NYSDOH

For sponsored research, NYSDOH/HRI agreements will specify that

- Provisions are made for monitoring study data which could affect participants' safety;
- The results of this monitoring are reported to the Principal Investigator so that:
 - Routine monitoring reports will be submitted as part of Continuing Review applications to the IRB, and
 - Urgent reports (Adverse Events/Unanticipated Problems which require Prompt Reporting to the IRB) are submitted per the guidelines previously mentioned.

PUBLICATION OF RESEARCH RESULTS

For sponsored research, NYSDOH/HRI understands the importance of disseminating research findings as one of its most important policies.

NYSDOH/HRI requires that provisions for fair and reasonable ownership of data and research results be included in its Standard NYS Contract Boilerplates and sponsored research agreements. NYSDOH has a process that allows investigators to place their surveillance and research data in the public domain if that would be in the best interest of technology transfer and if doing so is not in violation of the terms of any agreements that supported or governed the work.

In all sponsored research, NYSDOH/HRI requires the dissemination of research results in a manner consistent with the Health Data NY (<https://health.data.ny.gov/>). “The NYSDOH launched the Maximizing Essential Tools for Research Innovation and eXcellence Project, or the METRIX Project, in August 2011. The METRIX Project is a multi-year open government initiative designed to improve access to NYSDOH data assets and expand creative use of this data beyond government by encouraging innovation and collaboration among stakeholders. The vision for METRIX is to strategically utilize existing data and engage external partners and stakeholders to develop targeted health care policies and projects that focus on improving the quality of health care for all New Yorkers.”¹

Summary of Review Considerations

Approval of research requires that all the following conditions of 45CFR46.111 are satisfied:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB will consider the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by §46.116.
- Informed consent will be appropriately documented, in accordance with and to the extent required by §46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically

or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- Research studies have the resources necessary to protect participants:
 - Adequate time for the researchers to conduct and complete the research.
 - Adequate number of qualified staff
 - Adequate facilities
 - Access to a population that will allow recruitment of the necessary number of participants.
 - Availability of medical or psychosocial resources that participants may need as a consequence of the research

The IRB is required to review:

- The information contained in the advertisement.
- The mode of its communication.
- The final copy of printed advertisements.
- The final audio or video taped advertisements.

The IRB reviews advertising to ensure that advertisements do not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants
- The location of the research and the person or office to contact for further information.

When following FDA regulations, the IRB MUST review advertising to ensure that advertisements do not:

- Make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
- Use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational.
- Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

NOTE: When following Department of Defense regulations, the definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall **NOT** be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. As an example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against

the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

ELECTRONIC SUBMISSIONS VIA IRBNET

The NYSDOH Institutional Review Board has partnered with IRBNet to bring to the NYSDOH research community a suite of tools, accessible via the internet. IRBNet allows electronic protocol management, on-line submissions and many other important research oversight features. IRBNet can be accessed from virtually any computer using a web browser by visiting www.irbnet.org.

Effective January 2015, all submissions to the IRB (including revisions, annual renewals and amendments) must be submitted electronically via IRBNet, and all review decision letters will be issued electronically via IRBNet.

All IRB forms are available in IRBnet. Note that written signatures are no longer required on the forms. They have been replaced by digital signatures done through IRBnet.

How to Register in IRBNet and Upload CITI Training Certificates

Go to <https://www.irbnet.org> and click on “New User Registration” tab located in the upper right-hand corner. You will be prompted to select a user name and password and enter your contact information. Select “New York State Department of Health, Albany” as your local institution. Follow the prompts to complete the new user registration process.

After successfully registering for your IRBNet account, login to irbnet.org to update your user profile to include your current CITI or other, human subject protection training certificates. Please note you MUST upload current certificates to your “USER PROFILE.” They should not be attached in any other area within IRBNet.

How to Create a New Study/Project and Submit in IRBNet

We highly recommend reviewing IRBNet’s two brief and very helpful tutorial videos before using the submission system. Both tutorials offer extensive information about navigating the IRBNet submission system. The first video walks the user through the five steps of submitting a protocol. The second video demonstrates the IRBNet messaging structure, how to update project documents, and how to submit an amendment or continuation.

The IRBNet [training](http://www.irbnetresources.org/tresources/training.html) website: <http://www.irbnetresources.org/tresources/training.html> “New Project Submission” (use the username and password below to access the training video). When you are ready to submit your new protocol, make sure you are logged into IRBNet.org – Not the training site.

***Username:** nyhealth ***Password:** training

Once you have created an account in IRBNet (use the menu items in the left-hand menu to guide you for most of the steps below):

1. Select "Create New Project" from the upper left-hand portion of the IRBNet screen. Follow the prompts to properly set up your brand-new application.
2. Download blank forms as needed from “Forms and Templates”. At minimum, this includes the Initial Application, Protocol, and conflict of interest forms.
3. Upload completed forms via the Designer Page, including the above forms, any other relevant documents.
4. Share the Project with colleagues and with the Center Director (for signature).

5. Sign the Project (PI signature is required).
6. Submit the Project.

*If you don't click on Submit, we'll never know there is a protocol waiting to be processed. If you click on Submit too soon, you will be locked out of your project and unable to upload any subsequent documents. Follow the steps outlined in the instructional video, which is available on the IRBNet training website: <http://www.irbnetresources.org/tresources/training.html> "New Project Submission" (use the username and password below to access the training video). When you are ready to submit your new protocol, make sure you are logged into IRBNet.org.

Please NOTE: All NEW studies/projects, being submitted in IRBNet for the first time, must include the NYSDOH-1871 Protocol Review Request Form and Form 3995-NYSDOH and HRI Disclosure of Reportable Interest in Research Project. All new studies/projects must include all pertinent documents, including, but not limited to (as applicable): study protocol, consent forms, consent/recruitment/phone scripts, recruitment material, questionnaire(s), data collection tool(s), appropriate clearance/approval from another institute(s), etc.

For additional information or instructions on using IRBNet, please contact IRB Administrative Staff at irbbml@health.ny.gov or 518-474-8539.

APPLICATION PROCEDURES

The following section describes the actual IRB application process, i.e., those steps that need to be taken to submit a protocol to the IRB for review and approval.

The initial step involves completion of an application, the Protocol Review Request Form (Form 1871), a document with very specific requirements that must be adhered to in order to ensure the most expeditious review. This form must be submitted regardless of the level of review being requested by the investigator. It is mandatory that the criteria be reviewed and checked to indicate the type of research activities that are being proposed for implementation. In the event questions arise concerning the appropriate level of review, or criteria to use, please call the IRB office for assistance. This will help clarify the issues as well as save time in processing your application.

Incomplete Applications

Incomplete applications delay the review process. An incomplete application will not be placed on the agenda for consideration by the full board until all required information has been received. When an incomplete application is submitted for expedited review, conditional approval may be granted. However, the research may only proceed after all study documents are reviewed. Upon satisfactory completion of this review, full approval to proceed will be granted.

Exempt Review

It is incumbent upon the researcher to apply to the IRB for exemption prior to the conduct of the study. Final decisions regarding the exemption of research studies involving human subjects are not within the purview of the principal investigator. Exempt status is granted only after review by the Chair or Vice Chair of the IRB. Applications for exemption are usually reviewed within five to ten business days of their receipt.

The decision to exempt studies from IRB review and approval is made on a case-by-case basis. Thus, a survey which is both anonymous and poses no threat of liability or damage to respondents may still be denied exemption because it deals with sensitive behaviors that are not usual and

customary for the target population, such as questions concerning subjects' illegal conduct, drug use, sexual behavior or use of alcohol, or because it will involve follow-back to the index subjects' relatives, friends or co-workers.

- the information will not be recorded by the investigators in such a manner that subjects can be identified directly or through identifiers linked to the subjects; and,
- any disclosure of subjects' responses could not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation.

Exempt status does not apply to the following categories: children and minors, pregnant women, fetuses, human in-vitro fertilization, adults with decisional and/or cognitive impairments, and prisoners.

Studies designated as exempt will not be assigned an expiration date, do not have to undergo continuing review, and can initiate minor protocol changes without IRB approval (changes that do not affect the level of risk or change the category designation).

Even when continuing review is not required, investigators remain responsible for:

- conducting the study as approved,
- updating the IRB about adverse events or unanticipated problems,
- seeking IRB approval for major changes that affect the risk/benefit ratio or change the exempt classification, and
- completing a final progress report to inform the IRB when the research is complete.

The IRB Chair can require expedited or full review of any research at his/her discretion, even if the research would otherwise qualify for exempt review status.

NOTE: The criteria allowing exemption are not applicable to FDA-regulated research

Limited IRB review

The revised common rule allows more research to qualify for exempt review where the primary risk is breach of privacy and confidentiality. To maintain protections for subjects, certain exempt categories now require limited IRB review which includes an IRB determination that, when appropriate, adequate provisions are in place to protect the privacy of subjects and the confidentiality of data. This is the same IRB approval criteria related to privacy and confidentiality that is required for nonexempt human subjects research. This review must be done by the IRB Chair or an experienced IRB Committee member (although it can be conducted by the full IRB). Continuing review is not required; however, Investigators will have to notify the IRB of any changes to the original approved study e.g. change of personnel and protocol, consents and any other documents that were originally approved, as well as if the study closes.

Expedited Review

Federal rules permit expedited review for certain kinds of research. New projects that involve no more than minimal risk to human subjects and involve only procedures listed in one or more of the seven expedited review categories are eligible for consideration. Please note that those activities listed should not be of minimal risk simply by being included on the list. Inclusion on the list signifies that the activity is eligible for expedited review when the proposed research involves no more than minimal risk. In addition, minor changes in protocol or consent forms for research that has already been approved are eligible for consideration under expedited review.

The determination as to whether to grant the application an expedited status is usually made by a subcommittee of the IRB designated by the IRB Chair or IRB Vice Chair. Federal regulations prohibit

disapproval of any research reviewed using the expedited method. If the application is recommended for disapproval, the applicant will be notified that full board review is required. If the application for expedited review is received close to the date of a regularly scheduled meeting of the IRB, generally the application may be provided to the convened IRB for review.

Applicants should be aware that there is a difference between the expedited review procedure and designation as an expedited research project. Under expedited review procedures, the IRB chair, Vice Chair or one or more experienced IRB members review the proposed activity instead of the full IRB at a convened meeting. Research activity that conforms to the categories established by the Department of Health and Human Services and the Food and Drug Administration are eligible for the expedited designation.

Research activities involving no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories **MAY** be eligible for the Expedited Review procedure. The Expedited Review procedure **MAY NOT** be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Research categories ineligible for expedited review include those involving:

- more than minimal risk and greater than minor changes in already approved protocols or consent forms;
- research involving vulnerable populations, (e.g., minors, the mentally incapacitated, pregnant women/fetuses and prisoners) unless using blood spots or blinded phone surveys;
- drawing of blood from other than healthy individuals, and;
- requests for emergency approval of investigational drugs. (for more information see, www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency)

In addition to the IRB application (for NYSDOH 1871), the request should include: the protocol, informed consent form(s), a description of how consent will be obtained, copies of other IRB approval(s) (if applicable), recruitment flyers, training certificates, and any other necessary documents.

Full Board Review

A full board review is required for research that is not eligible for exempt or expedited review. In short, research that involves more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

The following categories of research require full IRB approval:

- Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
- Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
- Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
- Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

In addition to the IRB application (for NYSDOH 1871), the request should include: the protocol, informed consent form(s), a description of how consent will be obtained, copies of other IRB approval(s) (if applicable), recruitment flyers, training certificates, and any other necessary documents.

The essential elements of a protocol are:

Project overview -- including a protocol summary, and a list of Investigators and their qualifications, collaborating institutions, and funding sources.

Introduction -- justification for the study, use of study findings, study design and locations and hypotheses.

List the Procedures and Methods to be used with the subjects including the study timeline and risk-to-benefit analysis. It is also particularly important to describe the **consent process** by describing such procedures as who will obtain consent, when consent will be obtained and where consent will be obtained.

A description of the study population -- the variables and interventions, data handling and analysis, handling of unexpected or adverse events and dissemination, reporting and notification of results under the Procedures/Methods section. Survey instruments, including questionnaires, and data collection forms must also be submitted with the application.

Exactly what potential subjects will be told about what will happen to them if they consent to participate in this study, including the consequences of providing information about illegal or private activities.

In addition, please refer to the Checklist of Materials found in Appendix 6 for helpful information regarding the development of an IRB application. Not every item will apply to every project. If the protocol is more than five pages in length, please include parenthetical references to relevant protocol page numbers.

For full board review studies, all Board Members will be given access to the package via irbnet.org. For initial review of research by the convened IRB, a Primary Reviewer System is used, however all attending members are expected to have read and reviewed the protocols and participate in the discussion. If the study is approved, the PI and all study staff with "Full Access" will receive an automatically-generated email from irbnet.org. In addition, IRB staff will post an approval letter in irbnet.org. The IRB will no longer stamp each page of the application and study documents. If there is an informed consent form, an expiration date stamp will be affixed on every page along with the date of approval unless it has been stamped with an expiration date by another IRB.

STUDENT RESEARCH

The following section describes steps that need to be taken by a SUNY Albany School of Public Health (SPH) students to submit a protocol to the IRB for review and approval. This is required of any SPH student whose research includes the use of NYSDOH data for an internship, thesis and subsequent publication of research-related procedures or results.

The initial step involves completion of an application: [Student Protocol Application Form](#) 1871S). The specific requirements of this document must be followed to ensure the most expeditious review. The form must be signed by the student and their mentor/SPH professor. It must be submitted regardless of the level of review being requested by the student/investigator. It is mandatory that the criteria be reviewed and checked to indicate the type of research activities that are being proposed. In the event questions arise concerning the appropriate level of review, or criteria to use, please call the IRB office for assistance. This will help clarify the issues as well as save time in processing your

application.

Student Exempt Review

It is incumbent upon the student to apply to the IRB for exemption prior to the conduct of the study. Final decisions regarding the exemption of research studies involving human subjects are not within the purview of the student or their faculty advisor. Exempt status is granted only after review by the IRB Chair or Vice Chair of the IRB. Applications for exemption are usually reviewed within five to ten business days of their receipt.

The decision to exempt studies from IRB review and approval is, however, made on a case-by-case basis. A data or record review using NYSDOH data which is both anonymous and poses no threat of liability or damage to respondents may still be denied exemption because it deals with sensitive behaviors that are not usual and customary for the target population, such as questions concerning subjects' illegal conduct, drug use, sexual behavior or use of alcohol, or because it will involve follow-back to the index subjects' relatives, friends or co-workers.

Exempt status does not apply to the following categories: pregnant women, fetuses, human in-vitro fertilization, and prisoners.

Effective July 1, 2018: Research studies designated as exempt will be reviewed every 3 years. Student studies designated as exempt must be reviewed annually and can initiate minor protocol changes without IRB approval.

Student Expedited Review

Refer to the Expedited Review Section.

Student Applicants should be aware that there is a difference between the expedited review procedure and designation as an expedited research project. Under expedited review procedures, the Subcommittee reviews the proposed activity instead of the full IRB at a convened meeting. Research activity that conforms to the categories established by the Department of Health and Human Services and the Food and Drug Administration (45 CFR 46.110 and 21 CFR 56.110) are eligible for the expedited designation.

The Student Application (Form NYSDOH 1871S) should include: the protocol, informed consent form(s), a description of how consent will be obtained, copies of other IRB approval(s) (if applicable), recruitment flyers, training certificates, and any other necessary documents.

Student Full Review (Refer to Full Review Section)

Any student research involving greater than minimal risk must receive Full Review by a quorum of all IRB members in attendance at a full Board meeting. Studies involving one or more of the protected classes will automatically qualify for a Full Board review. Attach the IRB application, protocol, informed consent form(s), child assent/parental permission form (if applicable), a brief description of how consent will be obtained, a copy of other IRB approval(s), recruitment flyers, training certificates, and any other necessary documents to the form. Refer to the IRB meeting schedule for dates and deadlines.

Review of applications by a majority of IRB members in attendance at a bi-monthly full Board meeting is called-Full Review. Human subject's research that is not classified as exempt or expedited requires review by the full IRB at a convened meeting. Any study involving greater than minimal risk must receive Full Board Review.

Examples of research activities that must be reviewed by the full IRB include, but are not limited to:

- Research involving deception
- Research involving psychological or physiological intervention
- Non-curricular, interactive research in schools
- Interviews or surveys on sensitive topics
- Research involving a protected class

In addition, please refer to the Application Checklist found in Appendix 6 for helpful information regarding the development of an IRB application. Not every item will apply to every project.

CONTINUING AND PERIODIC REVIEW

The goals of continuing review are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard subjects are adequate, that the approved protocol is followed, and that the project reflects any changes that have been made in the research since the last approval.

The Revised Common Rule removes the requirement for continuing review for minimal risk research and for full-board research that is in data analysis only unless the research is FDA-regulated. Continuing Reviews for long-term follow-up research is reviewed by the Chair. However, the NYSDOH IRB has elected to continue annual review of research for all non-exempt studies that remain open to enrollment.

In accordance with 45CFR46.109(f)(1), NYSDOH will no longer be conducting continuing reviews of research that are in the following statuses:

- A. Data analysis, including analysis of identifiable private information or identifiable biospecimens.
 - The research is permanently closed to enrollment at the institution.
 - All subjects enrolled at the institution have completed all-research related interventions and interactions, including interventions and interactions related to collection of long-term follow-up data.
 - No additional identifiable private information about the subjects is being obtained by investigators at the institution.
 - Study procedures involve only evaluation of the data collected and manuscript writing, with no continued subject intervention.

Please Note: Principal Investigators remain responsible for conducting the study as approved, reporting to IRB any adverse events or unanticipated problems, must receive IRB's approval for changes to study personnel, protocol amendments (including, but not limited to, additional subject enrollment and changes to study documents), ensuring research personnel's training stays current, and completing a Study Closure/Final Progress Report to inform IRB when research is complete.

Continuing review of research must be substantive and meaningful. In accordance with DHHS regulations at 45 CFR 46.108(b) and 46.115(a) (2), continuing review by the convened IRB, with a recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110. Furthermore, HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied for the IRB to approve research. These criteria include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review.

There is no limit on the number of renewals that may be approved for a project. However, the IRB reserves the right to request that a new protocol be prepared if changes are extensive.

Continuing review of research previously approved by the convened IRB may be performed in an Expedited manner under the following circumstances:

- the research is permanently closed to the enrollment of new subjects;
- all subjects have completed all research-related interventions; and
- the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified;
- the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Projects involving more than minimal risks (more than one year's duration or not) may be subjected to one or more of the following additional reviews as determined by the IRB:

- inspection of written informed consent documentation;
- observation of the consent process and the research;
- more frequent than annual IRB review.

All non-exempt multi-year projects with open enrollment **must** also undergo a Convened Full Board or Expedited Review every **FIVE** years.

It is the Investigator's responsibility to provide the paperwork to have the project reviewed before the annual expiration date. The IRBNet sends out reminders to Principal Investigators that annual review is approaching (at 60 days and 30 days prior to expiration date). It is the Principal Investigator's responsibility to submit the continuing review progress report 2-3 weeks prior to the study expiring. Principal Investigators may notify the IRB of any protocol and/or staff changes at this time as well.

Continuing Review of Active Study by a convened IRB

All IRB Members have access to the Continuing Review Form for the research protocol, which includes:

- The number of participants accrued.
- Participant withdrawals.
- The reasons for withdrawals.
- Any complaints about the research.
- Any relevant recent literature.
- Any interim findings.
- Any relevant multi-center trial reports

Lapse of Approval

A lapse in IRB approval of research occurs when an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research – with or without conditions – by the expiration date of IRB approval. When continuing review of a research project does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. In such circumstances, all research activities involving human subjects must stop after IRB approval expired, *unless* it is determined to be in the best interest of already enrolled subjects to continue participating in the research. Enrollment of new subjects cannot occur after the expiration of IRB approval.

When IRB approval of an ongoing research project lapses and the investigator wants to continue the project, the IRB will complete the continuing review for the project as soon as possible after it is submitted. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred. IRB must document why the lapse in IRB approval occurred, and, if appropriate, any corrective actions that the investigator, institution, or IRB is taking to prevent any such lapse of approval of the project from occurring again in the future.

Continuation of research after expiration of IRB approval is a violation of federal regulations [45 CFR 46.103(a)]. There are no provisions for any grace period beyond the expiration date. If IRB approval has expired, research activities must stop, and no new subjects may be enrolled in the study, until IRB review and approval has been obtained. However, if the IRB determines that an overriding safety concern and/or ethical issue is involved or that it is in the best interests of the individual subjects to continue participating in the research activities, the IRB may permit the subjects to continue in the study for the time required to complete the process. If a protocol is not reviewed for renewal prior to the expiration date, the protocol will expire and thus be terminated. Investigators are required to formally close their protocols when study activities are complete.

Furthermore, when IRB approval of an ongoing research project lapses and the IRB subsequently re-approves the project, the IRB will re-approve the project for a period of less than 1 year to retain the original anniversary date on which prior approval periods expired.

Re-Opening a Closed Study

If more than thirty days has passed since the IRB file was closed (either by returning the annual Progress Report form indicating that the study is closed, or IRB approval expired), a new application must be submitted to the IRB to re-open the file. The IRB no longer keeps paper copies of closed files beyond 30 days. If less than 30 days has passed since the protocol closed or expired, submit a written request to re-open the study along with a completed progress report form. Re-opening of a closed study will require the same level of review as the original study. The PI must include written certification that all research activities ceased during the period of lapse in approval, Assurances need to be made regarding the following:

- no patients have been enrolled during the time the study was not approved,
- data collection during this unapproved time was discontinued, and
- this is a continuation of the same study.

Determining When a Project May Be Closed

A study may be closed when the following apply:

- All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary.
- All collection of individually identifiable private information has been completed for all study participants. No further collection of data/information from or about the individuals will be obtained.
- All publications, presentations, additions to web sites derived from individually identifiable private information have been completed.
- If the study is funded, the sponsor agrees to or recommends closure.
- When the PI is no longer affiliated with NYSDOH/HRI and a change in PI is not requested.

A PI cannot close a study if he or she is making any use of individually identifiable private information collected as part of the protocol. If after a study is closed, the PI seeks to engage in an activity such that one of the criteria noted above would no longer be met, a new protocol must be submitted to the IRB for review and approval. It is the responsibility of the PI to inform the IRB when a study has closed.

FIVE-YEAR REVIEW

In addition to the annual continuation review, the NYSDOH IRB stipulates that all ongoing research classified as expedited or full-board, and open to enrollment must undergo full review every five years. The Principal Investigator is notified a five-year review is due 60 days prior to the expiration date. In addition to submitting the Progress Report, it is necessary to complete and submit the Protocol Review Request Form (Form 1871) as well. This material should be submitted prior to the board meeting that convenes before your five-year review due date to ensure that there is no lapse in your IRB approval. Federal guidelines require that continuing review takes place within 30 days of a study's expiration date.

The following must be included:

- Protocol Review Request Form NYSDOH 1871
- Continuing Review/Progress Report Form and Narrative
- Study Protocol
- Unstamped Consent Form
- Conflict of Interest Form 3995 for ALL study personnel listed
- Advertisements, surveys, letters, memos and any other related material used to complete this study
- Any changes to study protocol or personnel
- All research personnel must have completed and are current with their CITI Research Training.

PROTOCOL CHANGES

Changes in approved research not designated as exempt, during the period for which approval has already been given, may not be initiated without prior IRB review and approval. As a rule, if there are any changes or updates in any information previously provided to the IRB, this information would need approval by the IRB before implementation. The only exception to this rule is when a change is necessary to prevent immediate harm to research participants. When this occurs, the PI must submit a request for an amendment after the occurrence to make the protocol consistent with the changes. The PI must provide justification as to why it was necessary to make these changes prior to receiving IRB approval.

In order to request a protocol change, the PI must submit a completed [Protocol and/or Staff Change Application](#) form to the IRB and attach an updated version of the protocol. Examples of items that would be included as an amendment:

- Changes/additions of the PI, Co-Investigator and key personnel
- Changes/additions to advertisements/notice/fliers
- Changes/additions to the consent/assent form/information sheet
- Changes/additions to the Investigator's brochure/package insert
- Changes/additions to the protocol including administrative changes, study design, enrollment criteria, data collection methods, and risk/benefit ratio
- Submission of Data safety monitoring reports/minutes
- Submission of interim reports and/or analysis

When requesting changes of PI, Co-Investigators, and key personnel, it is a requirement that all persons have completed the NYSDOH IRB approved CITI training programs or equivalent and a Conflict of Interest Form 3995. The original PI should submit the amendment relinquishing responsibility for the study. If the original PI is not available, the new PI can submit the protocol change accepting responsibility for the study. Contact information for the new PI should be submitted with the amendment form.

Any changes to the informed consent must consider both prospective research participants and if applicable, research participants already enrolled in the study. All consent/assent form changes must be submitted with the changes highlighted. If there is an additional consent added to the protocol, justification for the addition should be clearly stated on the protocol change form. Consent forms must have a submission/revision date in the footer.

Requests for review of protocol changes must include the exact text of the amendment, administrative change, or other revision to the protocol; a summary of changes; rationale for the change; and a copy of the NYSDOH IRB-approved consent form with the proposed changes clearly marked (if applicable).

Modifications that constitute minimum risk (i.e. do not affect the assessment of the risk/benefit ratio or substantially change the specific aim/design of the study) can be reviewed under expedited process. Examples of changes that may qualify for expedited review include additions of activities that qualify for exempt or expedited review per the federal guidance, an increase/decrease in participant enrollment that is justified, narrowing of inclusion criteria, broadening exclusion criteria, increase in study visits for safety reasons, addition/deletion of qualified co-investigators or key personnel, or minor changes that were specifically requested by the IRB. Review of expedited amendments is normally completed within approximately 10 working days.

Changes determined by the IRB Chair or designee to constitute more than minimal risk will be sent for full board review. Any change that affects the assessment of the risk/benefit ratio or substantially changes the specific aims or design of the study is considered more than minimal risk. Examples of major changes that would require full board review include broadening inclusion criteria, narrowing exclusion criteria, deletion of visits that may affect safety evaluations, addition of risk to informed consent, alterations in dosage or route of test administration. All submissions for full board review must meet submission deadlines. Upon completion of the review, a disposition letter will be issued to the PI.

POST-APPROVAL MONITORING PROGRAM

The New York State Department of Health Institutional Review Board (NYSDOH IRB) is committed to the improvement of the quality, efficiency and integrity of our research environment and activities. In keeping with this commitment, the IRB has instituted a Post-Approval Monitoring Program (PAM) as a means of quality assessment of the research conducted under our Federalwide Assurance agreement (FWA) with the Office of Human Research Protections (OHRP).

Post-Approval Monitoring is a routine compliance review of study documents and/or the observation of the consent process. Post-Approval Monitoring Reviews are done by the Compliance Officer within the IRB Administrative Office. The objective of this review program is to ensure that proper, scientific, ethical and regulatory requirements are followed in IRB-approved protocols. The program is also designed to encourage compliance by detecting errors and/or omissions that might

inadvertently occur while implementing research activities. The program serves as a useful educational purpose and enhances research activities at NYSDOH.

The Post-Approval Monitoring Program also serves in an advisory capacity to the Institutional Review Board, providing the Board with routine summaries of its findings and addressing recurrent compliance issues relevant to human subjects protection.

Randomly Selected Reviews

Protocols are chosen at random. However, long-term projects and those involving vulnerable populations (for example: children or mentally impaired persons), and those with significant adverse events may be given higher priority. All active studies that receive NYSDOH IRB approval, regardless of review designation, are eligible for review.

Review for Cause Audits

Review for Cause Audits are not a routine compliance review and are usually triggered by the following events:

- Participant Complaint
- Employee Complaint
- Whistleblower
- IRB request due to new information that might affect the rights and welfare of research participants

RESEARCH vs. NON-RESEARCH

Certain activities have the characteristics of human subjects research but do not meet the definition of human subjects research for IRB review (see Appendix 1 for the definition of program, program evaluation and research). Example activities that do not require review by the IRB are:

- Data collection for internal departmental or other administrative purposes (e.g. teaching evaluations, student evaluations, and “customer service” surveys);
- Program evaluation carried out by an agency that is for their internal purposes only. Examples include personnel studies, human cost benefit analysis, treatment effectiveness studies, and customer satisfaction studies;
- Course related activities (e.g. research methods instruction) that involve the use of human participants but have no connection with research beyond the instructional function preclude the need for IRB review. However, efforts that lead to presentation outside of the classroom and/or the publicizing of the student-prepared documents in any manner are considered research. Instructors of research courses are encouraged to consult with IRB administrative staff to determine the appropriate procedures for assuring that student projects conform to ethical guidelines;
- Public health surveillance activities authorized by a public health authority to assess onsets of disease outbreaks or conditions;
- Public Health Policy or Program that identifies and controls a health problem or improves a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants’ community; data collected are needed to assess or improve the program or service, the health of the participants or the participants’ community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.
- Scholarly and journalistic activities (e.g. oral history, journalism, biography, legal research and historical scholarship).

For a project to be considered research it must include the following:

- A systematic approach involving a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.
- Activities designed to develop or contribute to generalizable knowledge are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).
- The activity involves obtaining information about living individuals through intervention or interaction with the individuals.
- The activity involves obtaining identifiable and private information about living individuals.
- The activity involves the use of coded private information and/or specimens.
- The activity involves individuals (healthy or patient) who will be a recipient of any test article (i.e., drug, biologic, or medical device).

If the intent of the project is to create generalizable knowledge with the expectation that it will be submitted for publication in a scientific journal or presented at a scientific meeting, IRB review and approval must be obtained prior to implementation of the study. If the project is done without IRB approval, then the NYSDOH IRB may prohibit dissemination of the results in the interest of the Department.

Federal, foundation, and corporate grants are generally given for research purposes. However, research may be funded through internal funding sources as well. The awarding entity should be able to advise the grantee if the expectation is that research or program evaluation will be conducted with the awarded funds.

If you need further clarification or consultation regarding research vs. non-research please contact the IRB Administrative office prior to embarking on research projects and before securing a grant, IRB staff are available to assist.

IRB SUBCOMMITTEES

The IRB has three subcommittees for the expedient review of protocols and study documentation. Each Subcommittee is charged with the review of a specific protocol type. They are:

Expedited Reviews for New Studies and Multiple-Site Studies: This is a three-member subcommittee that changes each month whose focus is 1) review research conducted by a consortium of investigators using the same overall research plan at several different local, regional, national, or international sites; and 2) review new protocols classified as expedited (45CFR46.110). The subcommittee is provided with a copy of the complete study file, along with the current submission. This subcommittee reviews each file and votes to approve, approve pending modification, or refer to the full board. A majority decision is required for subcommittee approval.

Expedited Continuing Review and Five-Year Study Reviews: This is a three-member subcommittee whose focus is review of expedited studies still open to enrollment- seeking continuing review or five-year review. The subcommittee is provided with a copy of the continuing review progress report, current submission and have access to the complete package via IRBNet for review. Five-Year Study Reviews require the investigator to resubmit the entire package for review. The

subcommittee reviews each submission and votes to approve, approve pending modification, or refer to the full board. A majority decision is required for subcommittee approval.

Registry Reviews for New Studies: This is a three-member subcommittee whose focus is to review NYSDOH Vital Records and Cancer Registry Research studies. The subcommittee is provided with copies of the applications seeking access to registry data. The subcommittee members review the study and vote for approval, approval pending modification, or submission for full board review. A majority decision is required for subcommittee approval. In addition, the Registry Director must recommend approval. Following conclusion of their deliberations, the disposition is communicated to the PI and the Registry Director.

Studies may not be disapproved through Expedited Review procedures. All Subcommittee activities (including study disposition) are regularly reported to the Convened Full Board, via Activity Reports, submitted by the IRB Administrative Office to the Convened Board.

SPECIAL CLASSES OF SUBJECTS

Federal regulations require IRBs to give special consideration to protecting the welfare of particularly vulnerable subjects -- that is, those who have no ability to consent or whose ability is compromised. These include: children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Research involving special classes of subjects cannot be exempt from the federal regulations because these classes of subjects are considered vulnerable populations. In general, the special federal regulations outlined below allow the IRB to approve research that is of minimal risk or that will benefit the subjects directly.

Though Pregnant Women, Human Fetuses and Neonates have been removed from the vulnerable population list with the Revised Common Rule, Subpart B continues to provide Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research §46.201-207.

Protections for Children

Subpart D: Additional Protections for Children Involved as Subjects in Research (45 CFR 46 Subpart D).

The legal and ethical mandate of IRBs is to protect the rights and welfare of human research subjects. The special vulnerability of children makes consideration of involving them as research subjects particularly important. The IRB must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification considering the expected benefits to the children or to society. In calculating the degree of risk and benefit, the IRB should weigh the circumstances of the subjects under study, the magnitude of risks that may accrue from the research procedures, and the potential benefits the research may provide to the subjects or class of subjects. Research that is contrary to the rights and welfare of children is prohibited.

The IRB can approve research involving children only if it falls into one of three categories, if the criteria found in 45 CFR 46.111 are also fulfilled. The three categories are as follows:

Research not involving greater than minimal risk (45 CFR 46.404)

- a. Research involving greater than minimal risk but presenting the possibility of direct benefit to the individual subjects (45 CFR 46.405)
- b. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406)

If the IRB finds and documents that the research does not meet the requirements set forth in categories 45 CFR 46.404-406 and 21 CFR 50.51-53, the IRB may only approve the research if it finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. Additionally, the research may only proceed if the Secretary of the Department of Health and Human Services (DHHS), after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law), and following opportunity for public review and comment, determines either: that the research in fact satisfies the conditions of 45 CFR 46.404, 45 CFR 46.405 or 45 CFR.406, or the following:

- a. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- b. the research will be conducted in accordance with sound ethical principles;
- c. adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

When children or minors are involved in research, federal regulations require the **assent** of the child or minor as well as the **permission** of the parent(s). The IRB will determine whether permission of both parents is required as when the research involves greater than minimal risk with no direct benefit to the subjects. In the case of older adolescents and in certain circumstances such as when the research is about child abuse or neglect, the IRB may determine that parental permission is inappropriate and will set other requirements.

Research involving children can be Exempt in accordance with the federal Exempt criteria. However, the Exempt status for research involving surveys, interviews, or observations of public behavior (45 CFR 46.101(b)(2)) is not available for research involving children except for the observation of public behavior where the investigator does not participate in the activities being observed (45 CFR 46.401(b)). Expedited review of research involving children can be conducted.

Assent is defined as a child's or cognitively impaired person's affirmative agreement to participate in research. A child gives assent instead of consent since a child is not able to give consent until reaching legal age, which is 18 in New York State. A child's passive resignation to submit to an intervention or procedure must not be considered assent. Assent should be confirmed using an assent document (see example in Appendix 5). Assent needs to be tailored to the level of comprehension of the prospective participants. It is a requirement that the assent of a child be witnessed by an impartial adult. This is to prevent coercion on an unwilling child. As a matter of both justice and respect for persons, efforts should be made to conduct research using children capable of assent before enrolling those less able to assent.

Research Involving Prisoners

Sub-Part C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (45 CFR 46 Subpart C).

Definition of Prisoner: "Prisoner" is defined by DHHS regulations at 45CFR 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

The regulations regarding prisoners in research pertain not only to those studies in which prisoners

are initially anticipated, but also include situations where a human subject becomes a prisoner after the research has commenced. In this case, the IRB needs to make provision for reviewing the study as a prisoner study. This may involve putting a hold on the study until it has been reviewed by a board with a prisoner/prisoner representative.

Because incarceration may make it difficult for prisoners to give voluntary informed consent, federal regulation requires additional protection be afforded to this class of research subjects. The consent form must clearly inform each prisoner in advance that participation in the research will have no effect on his or her parole. Other key issues for the IRB in research involving prisoners are:

- Whether the prisoners have a real choice regarding their participation;
- Whether confidentiality regarding their participation and the resulting data can be maintained in the prison; and,
- Whether coercion (as in the withholding of special treatment or rewards for nonparticipation) is involved.

To protect prisoners from exploitative conditions, research with prisoners is generally limited to studies with an independent and valid reason for involving this population (e.g., studies of the effects of incarceration) and involving no more than minimal risk or a therapeutic benefit to the subject. In this context, minimal risk means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. There are also special requirements for the IRB involved with review of projects that involve prisoners. The Board must have a member who is either a prisoner or a prisoner representative with an appropriate background and expertise. Records are kept in the IRB administrative office that can provide details on the appointment and background of the prisoner representative.

For research involving prisoners conducted or supported by the DHHS, two actions must occur for research to be carried out:

- the IRB must certify to the Secretary, OHRP, that it has reviewed and approved the research in accordance with regulations found at 45 CFR 46.305; and
- the Secretary (OHRP) must determine that the proposed research falls within one of the permissible categories specified in regulations found at 45 CFR 46.306(a)(2). No prisoner-subjects can be enrolled or involved in research until the IRB receives a determination letter from OHRP.

At convened meetings:

- When the convened IRB reviews research involving prisoners, the prisoner representative is present.
- At least one unaffiliated member is present at convened meetings.
 - This may be accomplished by:
 - Requiring an unaffiliated member as part of quorum.
 - Documenting the attendance of all unaffiliated members (e.g., minutes indicate attendance at meetings).
 - At least one member who represents the general perspective of participants is present at convened meetings. This may be accomplished by:
 - Requiring the members as part of quorum.
 - Documenting the general attendance of all members (e.g., minutes indicate attendance at meetings).

Individuals with Impaired Decision-Making Capacity

Individuals with psychiatric, cognitive, developmental disorders, may have reduced capacity to

understand information presented to them. This may limit their ability to give truly informed consent. In addition, such individuals may be institutionalized, which could affect their perceptions of voluntariness. Care needs to be taken to distinguish between persons who are impaired and persons who have a condition that may cause impairment. It would be incorrect to assume that all the subjects with impaired decision-making capacity will lack sufficient capacity to provide informed consent.

The legal standards for competence include the four related skills of communicating a choice, understanding relevant information, appreciating the current situation and its consequences, and manipulating information rationally. The capacity to provide informed consent is an essential component of valid consent. Assessment of the capacity to consent is part of the process of obtaining informed consent. The PI (or his/her designee) may only seek consent when he or she is satisfied that the person can make an informed decision.

Only after the potential subject is presented with the informed consent material and has had an opportunity to discuss and ask questions about the proposed study, can a potential subject's capacity to give consent on the standards listed below be determined.

- Does the subject understand the facts of the study and what is being requested of them?
- Does the subject understand that this is a research project and not just the usual standard of care?
- Is the subject able to assess the possible risks and benefits of participation?
- Does the subject understand they can refuse to participate without it affecting their access to the usual standard of treatment for their condition?
- Can the subject make a reasoned decision about participation that is free of psychosis, confusion, or denial of the facts?
- Can the subject express a free choice and clearly communicate that choice?

The permission of a court-appointed guardian is required for persons legally considered incompetent. Specific and not fully resolved legal issues exist regarding consent to more than minimal risk therapeutic and non-therapeutic research for this population. Any specific questions should be addressed to the IRB's representative from the Division of Legal Affairs via the IRB Administrative Director.

People with Economic or Educational Disadvantages

Economic vulnerability arises when prospective subjects are disadvantaged in the distribution of social goods and services (income, housing, or healthcare).

Participation in research offers the possibility of payment or attainment of healthcare or other services that are otherwise not available. Payments induce potential subjects to enroll in a research study when it might be against their better judgment and when otherwise they would not do so. These inducements to enroll threaten the voluntary nature of consent and raise the danger of exploitation. Investigators need to be aware of this when offering payments or medical care to potential research participants to ensure that recruitment is equitable and justified.

Educational vulnerability occurs when prospective subjects lack the opportunity to attend school or receive a quality education. Participation in research requires a level of comprehension and literacy. Lack of education could cause potential participants to enroll in a research study that they may not fully understand the study including benefits and risks to themselves leaving the participant vulnerable.

Pregnant Women, Human Fetuses and Neonates

Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in

Pregnant Women

Research involving women who are or may become pregnant receives special IRB attention because of health concerns during pregnancy, the need to avoid unnecessary risk to the fetus, and the need to determine when the informed consent of the father is required. In addition, protection is enhanced because of the inability of the fetus to give or withhold consent. Pregnancy is defined as the period of time from the implantation of a fertilized ovum until delivery. A pre-menopausal woman with an intact reproductive system shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative, or until delivery.

In general, in research involving pregnant women, the IRB will assess:

- Where scientifically appropriate, studies on pregnant animals and studies on nonpregnant women have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
- No pregnant woman may be involved as a research subject unless either: 1) the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or 2) the risk to the fetus is minimal.
- Any risk is the least possible for achieving the objectives of the research.
- The woman's consent or the consent of her legally authorized representative is obtained in accordance with the informed consent provisions of 45 CFR 46, subpart A, unless legally altered or waived.
- For children who are pregnant, assent and permission are obtained in accordance with the provisions of 45 CFR 46, subpart D.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- Individuals engaged in the research will have no part in determining the viability of a fetus.
- Individuals engaged in the research will have no part in any decisions as to the timing, methods, or procedures used to terminate a pregnancy.
- Both the mother's and the father's consent to research directed to the study of pregnancy, labor and delivery are required unless:
 - The purpose of the research is to meet the health needs of the mother;
 - The pregnancy is the result of rape or incest; or,
 - The father is not reasonably available, or his identity or whereabouts are unknown.

Fetuses and Abortuses

There are five federal requirements for research involving fetuses and abortuses.

- A federal amendment prohibits federal funding for any research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under existing federal regulations.
- There is the effort to separate embryo or fetal donors from directing that the embryos or tissues be given to specific recipients and from getting monetary or other inducements.
- Regulations specify that researchers will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy or in determining the viability of the fetus at the termination of the pregnancy.
- Prior research with animals, and if feasible, research with nonpregnant persons should form the basis of the risk/benefit assessment for fetal research.
- All research in which human fetuses are the subjects of research must have the consent of the mother and of the father, where he is known and reasonably available. Consent need not be obtained if the father is unable to consent because of unavailability, incompetence,

temporary incapacity, or the pregnancy resulted from rape or incest.

The IRB will approve research directed toward the fetus, in utero, if:

- The purpose of the research is to meet the health needs of the fetus and is conducted in a way that will minimize risk; or,
- The research poses no more than minimal risk to the fetus and the purpose of the activity is the development of important biomedical knowledge that is unobtainable by other means.

Research involving a non-viable fetus that would either artificially maintain vital functions or hasten their failure is forbidden.

OTHER CONSIDERATIONS

Human Biological Materials

In recent years, the IRB has seen an increase in the number of studies utilizing human biological and pathological materials. It is the policy of the NYSDOH that any Principal Investigator conducting research that involves human biological and pathological materials first must apply to the IRB for protocol review. As noted previously, the exemption may only be granted by the IRB and is not a determination to be made by the Principal Investigator. If the research is not exempt, it may qualify for expedited review with waiver of consent.

Human Biological Material means any material that comes from a person (e.g., blood, urine, cells, DNA, etc.). It may be material that is removed from patients during the process of clinical care and is available after all clinical procedures have been completed. It may also include use of material originally collected for research purposes.

These studies may be reviewed and granted an exemption under category four (4) found in 45 CFR 46.101(b)(4). Such studies may also include specimens obtained from tissue or cell banks/repositories created for research purposes (increasing the knowledge of human diseases and to improve the methods for the prevention, diagnosis and treatment of diseases). They may also include specimens that are identifiable through links maintained by the repository, or non-identifiable. To qualify for exempt status, the materials must have been submitted to a repository with no identifiable private data or information and no codes. No links of any kind may be maintained by the submitting entity or the repository which would subsequently allow identification of the individual from whom the material was procured (OPRR, *Submission of Non-Identifiable Materials to the Repository*, May 22, 1997). Specimens for whom identifiers are maintained will be subject to full board review. All new protocols must justify the planned acquisition and use of tissues.

Licensure of Collectors and Users of Tissue for Research Part 52 of 10 New York Codes, Rules and Regulations (10 NYCRR), Tissue Banks and Non-Transplant Anatomic Banks, are regulations established under the authority of Article 43-B of the New York State Public Health Law. These regulations require anyone who operates a tissue bank or non-transplant anatomic bank or who distributes tissue or non-transplant anatomic parts in NYS to obtain a license from the Department of Health. These regulations also establish administrative and technical standards for tissue banks and non-transplant anatomic banks. The licensure and regulation is overseen by the Wadsworth Center's Blood and Tissue Resources Program.

A person or entity who recovers, processes, stores and/or distributes bodies, body segments, organs or tissues from living or cadaveric donors, for educational and research purposes must be licensed as a non-transplant anatomic bank. A person or entity that uses bodies, body segments, organs or tissues in education or research purposes must be licensed unless: (1) all tissue material is obtained

from a tissue bank or non-transplant anatomic bank that is licensed by the department, and (2) such person or entity is a physician, medical school or other legal donor entitled to receive anatomical parts pursuant to Public Health Law section 4302.

An entity that uses prepared slides and/or human-derived cell lines for purposes of research or education does not constitute a tissue bank and does not need to be licensed. A facility that is located out of NYS does not need to be licensed as long as it distributes to a licensed non-transplant anatomic bank.

Genetic Research

The State of New York has adopted additional protections for individuals participating in research regarding genetic testing, based on the following definitions:

Genetic test: any laboratory test of human DNA, chromosomes, genes or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual's offspring; such term shall also include DNA profile analysis. A genetic test does not include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation.

Genetic predisposition means the presence of a variation in the composition of the genes of an individual or an individual's family member that is scientifically or medically identifiable and that is determined to be associated with an increased statistical risk of being expressed as either a physical or mental disease or disability in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder.

Under this law, the IRB does not consider "genetic testing" to include studies of gene expression.

Specific provisions are required in consent forms used for studies involving genetic testing. See the sample genetic testing consent form language in Appendix 4. Any researcher contemplating submission of a research proposal involving genetic testing should refer to *New York State Civil Rights Law (CRL), Section 79-I*. Note that revisions to *CRL 79-I* became effective in January 2002.

Transferring Human Biological Material to Outside Collaborators

To transfer tissue to outside academic or industrial collaborators, there must be a *bona fide* intellectual collaboration between the two parties, or the transfer must otherwise further the mission of NYSDOH, as determined by the IRB and Office of General Counsel. Simple transfer of patient samples for profit ("tissue for dollars") is not permitted. Investigators are responsible for submitting to the IRB all the relevant and requested information for a Materials Transfer Agreement (MTA), including the following: IRB approved protocol, current IRB approval letter, and consent form, if relevant. The MTA fixes in writing the rights and obligations governing the "no-cost" distribution of biological or chemical substances owned or held by such parties to others. In exchange for granting the right to use the materials, the Providing Party places certain demands on the Receiving Party due to the proprietary nature of the material(s), the approved research plan, or the nature of the transfer itself.

The methods to be used by the investigator to protect the privacy of the subject and confidentiality of the data should be described within the IRB submission. No directly identifiable materials should be sent to outside collaborators -- no sample should contain a name, date-of-birth, medical record number or social security number, unless the subject has explicitly given consent and authorization for such disclosures. Whenever possible, specimens should be rendered totally anonymous -- there should be no link retained anywhere to the individual from whom the sample was derived. If it is necessary for scientific reasons to retain a link to the individual, this should be scientifically and

ethically justified in the IRB submission. Such samples should be coded with a random number, and the key to the code linking the sample to an individual kept in a separate secure location, available only to designated investigators. Keys to such codes and identities of subjects should never be provided to outside collaborators unless the subject has explicitly given consent and authorization for such disclosures.

INVESTIGATIONAL OR UNLICENSED TEST ARTICLES RESEARCH WITH DRUGS, DEVICES OR BIOLOGICS

When research involves investigational or unlicensed test articles, NYSDOH/HRI confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.

This policy relates to:

- research using investigational drugs, devices, or biologics (investigational means unapproved drugs, unapproved devices or devices not cleared to market, or unlicensed biologics)
- research with FDA-approved, commercially available drugs, approved/cleared devices, or licensed biologics
- sponsor-investigator research
- radiation devices and radioactive materials
- handling of investigational drugs, devices, or biologics
- emergency, humanitarian, or compassionate use of investigational drugs, devices, or biologics

FDA regulates clinical trials (investigations/research) “that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.” (See 21 CFR 56.101)

All such investigations must be conducted in accordance with FDA requirements for informed consent and IRB review, regardless of funding source or sponsor.

Required Study Registration

ClinicalTrials.gov: Applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), must be registered on ClinicalTrials.gov; clinical trial information must be submitted for inclusion in the clinical trial registry databank (Public Health Service Act, section 402(j) and a corresponding statement added to the Informed Consent Form.

Applicable clinical trials are:

- Drug or biologic studies, with or without IND (except Phase 1, expanded access/compassionate use, or drug being used as part of routine care and not under study)
- Device studies, with or without IDE (except small feasibility studies, expanded access/compassionate use, or device being used as part of routine care and not under study)

The FDA web page Comparison of FDA and DHHS Human Subject Protection Regulations outlines differences between FDA regulations and OHRP 45 CFR 46 regulations for the protection of human subjects. Where regulations differ, the IRB applies the stricter one.

Research with Test Articles

Research with FDA-regulated test articles may commence only after the IRB has approved the

protocol and:

- receives documentation that the research will be conducted under an applicable Investigational New Drug Application (IND) or Investigational Device Exemption (IDE); The IND goes into effect generally 30 days after the FDA assigns the IND, unless the sponsor receives earlier notice from the FDA; or
- formally determines and documents that the proposed use of any investigational device satisfies the FDA criteria for non-significant risk devices; or
- formally determines that satisfactory justification has been provided by the investigator as to why an IND or IDE is not required.

Definitions

Biologic: A biological or related product, regulated by the FDA, including blood, vaccines, allergenics, tissues, and cellular and gene therapies. Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources (such as humans, animals, and microorganisms). Studies of unlicensed biologics are regulated according to the IND regulations, except in some cases when the biologic is in a combination product with a medical device. FDA regulates biologics general use and licensing under 21 CFR 600 and 601. (42 U.S.C 262 of the Public Health Service Act.

Clinical Investigation: Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act (FD&C Act), or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part. (See 21 CFR 56.102)

Combination Product: A product containing a combination of a drug, a device, or a biological product. Studies of combination products are regulated according to the IND or IDE regulations, depending on the components of the product. The FDA determines which of its organizational components has primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug, device, and/or biological. (See 21 CFR 3.2(e))

Human Subject: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (See 21 CFR 56.102)

Off-Label: Use of an FDA-Approved drug, an approved or cleared device, or a licensed biologic for an indication not in the approved labeling. Most research involving off-label uses requires IND or IDE applications. See FDA "Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices.

Test Article: Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act. (See 21 CFR 56.102)

Research with Drugs

Clinical investigations of drugs are subject to the Investigational New Drug Application (IND) regulations, 21 CFR 312.

An investigational new drug application (IND) is synonymous with “Notice of Claimed Investigational Exemption for a New Drug.” An investigational drug must have an IND before it can be shipped, unless one of the exemptions outlined in 21 CFR 312.2 is met.

Applications for research on the use of a drug, unless that research is exempt from the IND regulations, must be accompanied by documentation from the FDA that includes a valid IND number. The IND number must either match the number on the sponsor protocol with the same title as the proposed research, or be listed on communication from the sponsor specific to the proposed research, or on communication with the FDA. IND numbers may not be validated with an Investigator Brochure (which may serve multiple INDs).

As stated in 21 CFR 312.2(b), clinical investigation of a drug is exempt from the IND regulations if the drug is lawfully marketed in the United States and all of the following are true:

- I. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- II. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- III. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- IV. The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
- V. The investigation is conducted in compliance with the requirements of 312.8 (Promotion and charging for investigational drugs).

A clinical investigation involving use of a placebo is exempt from the requirements of 21 CFR 312 if the investigation does not otherwise require submission of an IND. Clinical investigations that are exempt from IND regulations still require IRB review and approval.

When there is no immediate intent to change product labeling or advertising, investigators who are planning rigorous, carefully controlled clinical investigations of off-label uses of approved drugs or biologics should contact the FDA regarding obtaining an IND before submitting a protocol to the IRB.

If the investigator has not provided an IND or letter from the FDA granting an exemption from IND requirements, the IRB reviews and determines whether the research meets one of the FDA exemption requirements below. The IRB documents their determination in the meeting minutes or, when the review occurs by expedited procedures, the expedited reviewer’s Review Guide.

Exemption 1:

- a. The drug product is lawfully marketed in the United States.
- b. The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- d. If the drug that is undergoing investigation was lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in

- the advertising for the product.
- e. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
 - e. The investigation is conducted in compliance with 21 CFR 50 and 56.
 - f. The investigation is conducted in compliance with the requirements of 21 CFR 312.7 (Promotion and charging for investigational drugs).

A clinical investigation involving use of a placebo does not require an IND if the investigation does not otherwise require submission of an IND.

Exemption 2:

A clinical investigation involving an in vitro diagnostic biological product that meets the following:

- a. Product is blood grouping serum, reagent red blood cells, or anti-human globulin;
- b. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and
- c. The diagnostic test was shipped in compliance with 21 CFR 312.160.

Exemption 3:

A drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.

Exemption 4:

Clinical bioavailability or bioequivalence study are exempt from the requirement for an IND except when one or more of the criteria described below are met:

The drug product contains a new chemical entity (21 CFR 320.31(a)(1)), radioactively labeled drug product (21 CFR 320.31(a)(2)) or cytotoxic product (21 CFR 320.31(a)(3)).

The study involves a drug product containing an already approved, non-new chemical entity and is:

- A single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application,
- A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application, or
- A multiple-dose study on an extended release product on which no single-dose study has been completed.

Exemption 5:

A clinical bioavailability or bioequivalence study being conducted for approval of an abbreviated new drug application or supplemental new drug application, as long as samples of the reference standard and test article are retained as described in 21 CFR 320.38 and 320.63.

Studies involving potentially addicting drugs have additional informed consent requirements.

Research with Devices

Clinical investigations of devices are subject to the Investigational Device Exemptions (IDE) regulations, 21 CFR 812.

An approved investigational device exemption (IDE) permits a device that is not approved (via premarket authorization, PMA) or cleared to market (via 510(k)) by the FDA to be shipped to conduct

clinical investigations of that device. Significant risk investigational devices must have an IDE issued by FDA before they can be shipped. Non-Significant risk devices are considered to have an approved IDE when the IRB agrees with the sponsor that the device meets the criteria for a Non-Significant risk device.

Research with devices falls into three categories:

- Investigations of significant risk devices to determine safety and effectiveness of the device
- Investigations of Non-Significant risk devices to determine safety and effectiveness of the device
- Investigations exempted from the IDE regulations

See:

- Significant Risk (SR) and Non-Significant Risk (NSR) Medical Device Studies [FDA],
- Frequently Asked Questions Medical Devices [FDA],
- Significant Risk and Non-Significant Risk Medical Device Studies [FDA]

Studies that include medical device use in an incidental way, where the device or the use of the device is not the focus of the research, are generally not considered to be FDA-regulated research or subject to 21 CFR 812, and in some instances, are eligible for IRB review per the expedited procedure. IRB Administration will be responsible for validating that a test article has a valid IND or IDE number.

Significant Risk Device Research

Applications for research on the use of a significant risk device must be accompanied by documentation from the FDA that includes a valid IDE number. The IDE number must either match the number on the sponsor protocol with the same title as the proposed research or be listed on communication from the sponsor specific to the proposed research, or on communication with the FDA. IDE numbers may not be validated with a device manual (which may serve multiple IDEs). The IRB determines whether the device is a Significant Risk device.

Non-Significant Risk Device Research

When research is conducted to determine the safety or effectiveness of a device, the organization confirms that the device fulfills the requirements for an abbreviated IDE (21 CFR 812.2(b)(1)):

- The device is not a banned device;
- The sponsor labels the device in accordance with 21 CFR 812.5;
- The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, consent under 21 CFR 50 and documents it, unless documentation is waived;
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 21 CFR 812.150(a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

If the investigator applies to the IRB for a Non-Significant Risk (NSR) determination for a device study, but the IRB determines that the device is Significant Risk (SR), the IRB shall notify the investigator and the sponsor, as appropriate.

Exempt Device Research

Clinical investigations that are exempt from IDE regulations still require IRB review and approval. An investigation of a medical device in human subjects research that is exempt from the IDE regulations must fall into one of the following categories (Criteria in 21 CFR 812.2(c)):

- A device legally marketed in the US that is used or investigated in accordance with the indications in the FDA-approved labeling.
- A diagnostic device (that is, an in vitro diagnostic device) if the testing:
 - Is noninvasive
 - Does not require an invasive sampling procedure that presents significant risk,
 - Does not by design or intention introduce energy into a subject, and
 - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
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- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
- A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
- A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

In Vitro Diagnostic Device Research

In vitro diagnostic (IVD) device investigations may be exempt from the IDE requirements of 21 CFR 812 if the devices are properly labeled and meet the criteria set forth in 21 CFR 812.2(c)(3).

However, such studies are still subject to the FDA regulations and IRB review requirements if the research is to support an application for research or marketing of the device (see 21 CFR 50.1). This is true regardless of whether the samples to be used are individually identifiable or not. The FDA regulations define a subject to include a human on whose specimens an investigational device is used (21 CFR 812.3(p)). Thus, an IVD study to support a premarket submission to the FDA is considered a human subject investigation and is subject to IRB review under 21 CFR parts 50 and 56. IVD research may be eligible for expedited review and without informed consent if the study involves leftover human specimens and if subject privacy is protected by using only specimens that is not individually identifiable, when appropriate.

In addition to the above, FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable makes clear that IRB review is one of several criteria for IVD studies using leftover specimens that are not individually identifiable.

Radiology Devices and Radioactive Materials

The FDA regulates radiology devices and radioactive materials used in research. Most research

involving radiation is covered by an IND or an IDE, and must be reviewed and approved by the IRB.

As defined in 21 CFR 361.1 authority is retained by the FDA. If a radiopharmaceutical cannot be classified as “generally recognized as safe and effective,” the IRB may not review and approve the research, and an IND may be needed.

Research with Biologics

Clinical investigations of biologics will be regulated the same way as clinical investigations for drugs, and require an IND, unless the biologic is part of a combination product that the FDA has assigned for premarket approval. In this case the biologic/device combination product would require an IDE prior to research approval by the IRB.

Generally, protocols using biological agents or recombinant DNA vectors will be reviewed by the Biomedical IRB.

CONTROLLED SUBSTANCE RESEARCH

The purpose of this policy is to ensure that all investigational drugs, agents and/or biologics used in human participants’ research are stored, handled, and dispensed in compliance with regulations or requirements of the FDA, the New York State Board of Pharmacy, the New York State Department of Health Bureau of Narcotic Enforcement and in accordance with applicable policies and guidelines. The Bureau of Narcotic Enforcement (BNE) is responsible for protecting the public health by combating the illegal use and trafficking of prescription-controlled substances. The Bureau provides millions of secure Official New York State Prescriptions annually to over 95,000 prescribing practitioners across the State. BNE monitors and regulates controlled substances through its issuance of licenses to manufacturers, distributors, hospitals, nursing homes, and researchers. BNE Narcotic Investigators investigate suspected drug diversion or illegal sales involving theft, forgery, and fraudulent visits to practitioners’ offices, and work closely with local, state and federal law enforcement. The Bureau also prevents prescription drug abuse through educational materials and presentations for parents, educators, and healthcare professionals.

Policy

The Bureau of Narcotic Enforcement and IRB must approve the investigator’s written request to manage test article storage, integrity, and accountability. NYSDOH Form 4330 must be completed for use of Controlled Substance Research

The investigator’s responsibility is to work with the BNE to ensure that the planned receipt, storage, handling, dispensing and return or destruction of the Investigational Agent follows Institutional, State and Federal (FDA) requirements.

Storage of Investigational Drugs and Biologics:

Investigational agents should be stored under the direct supervision of the PI and in accordance with the sponsor, if applicable. The BNE should be aware of EVERY alternative storage site. BNE monitoring may be incorporated into the IRB auditing process to ensure compliance.

Controlled substances must be stored under lock and key preferably in the Institution’s Pharmacy.

Sponsor-investigator IND studies must use the BNE for initial review of the proposed project.

Dispensing of investigational drugs and biologics:

Investigational agents should be dispensed through the Institution's Pharmacy. Justification for requesting to deviate from this standard should be provided.

Institution's Pharmacy:

If the Institution's Pharmacy is not used to dispense investigational drugs and biologics, the Principal Investigator must ensure that dispensing is in accordance with the Institution's Investigational Drug Service Policy.

"Dispensing" may only be done by licensed pharmacists, dentists, podiatrists and physicians; all other activities carried out by other licensed professionals (e.g., RN) are considered "distribution."

An investigational agent is "distributed" when it is provided to a subject in a pre-labeled container with subject-specific identification and does not require any manipulation (i.e., counting, packaging, transfer to another container, mixing, preparing, compounding).

"Distribution" of investigational drugs and biologics must be carried out upon the order of an authorized prescriber.

The Institution's Pharmacy must prepare and dispense the following drugs and biologics:

- Controlled substances for all inpatients and outpatients.
- Drugs and biologics prescribed for inpatient use.
- Drugs and biologics prescribed for administration in the General Clinical Research Center.
- Hazardous drugs and biologics.
- Drugs and biologics requiring sterile admixture preparation.
- Drugs and biologics requiring compounding or repackaging.
- Drugs and biologics with specific sponsor requirements for control by a pharmacy.

If the Institution's Pharmacy is not used, the Principal Investigator must dispense the drug or biologic only to subjects under their personal supervision or under the supervision of a Co-Investigator responsible to the Investigator. The Principal Investigator may **NOT** supply the investigational drug or biologic to any person not authorized to receive it.

Records necessary to document test article accountability and integrity must be maintained, which include:

- Shipping invoices;
- Inventory and condition upon receipt;
- Storage conditions and temperature logs;
- Preparation/compounding logs;
- Packaging and labeling;
- Dispensing and return logs; and
- Final inventory and disposition.

As part of its role in ensuring proper labeling, storage, distribution, and control of all investigational drugs and biologics, the Institution's Pharmacy will be available to assist investigators.

The Institution's Pharmacy must review and approve all Investigational Drug Data Sheets for all investigational drugs and biologics intended for administration to research participants.

The Institution's Pharmacy signs-off on the application to ensure participation and agreement.

Except for single-patient treatment protocols approved by the IRB in urgent situations, the Institution's Pharmacy must prepare written dispensing instructions ("Preparation Guidelines") for each protocol to be followed by pharmacy staff when dispensing investigational drugs and biologics. These instructions explain subject enrollment, test article preparation, dispensing, accountability and disposition.

The Institution's Pharmacy must distinguish investigational drugs and biologics from other drugs or biologics by the additional legend, "Caution – New Drug, Limited by Federal Law to Investigational Use", or its equivalent.

The Institution's Pharmacy or the Principal Investigator must return all unused or expired investigational drugs and biologics in accordance with the sponsor's requirements.

The final disposition of used drugs and biologics, and subject drug and biologic, returns (outpatient studies) should be handled in accordance with the sponsor's policies and procedures. If the site is authorized by the sponsor for on-site destruction, such activities will be documented, when applicable.

Appropriate procedures also apply to those sites storing drugs and biologics outside the Institution's Pharmacy. Information about these procedures should be described in the protocol and are subject to audit by the Institution's Pharmacy, BNE and the IRB.

The Institution's Pharmacy must review Investigational Agent usage (i.e., inventory stock) on a routine basis and order new supplies from the sponsor, on behalf of the Principal Investigator.

The Institution's Pharmacy and BNE (where appropriate) along with an IRB liaison will review the use of all investigational drug and biologic uses prior to final approval by the IRB. The use of FDA approved, non-formulary medications require Pharmacy approval. Use of FDA approved, formulary medications with Pharmacy approved restrictions and/or guidelines, use of FDA approved, formulary medications for off-label indications, and use of non-FDA approved medications require approval by the Institution's Pharmacy and an IRB liaison. At any time, the Pharmacy and/or an IRB liaison may request the formal review of the Institution's Pharmacy.

Control and Distribution of Devices Used in Research

Receipt and inventory of study device: This section applies to those study devices the investigator dispenses/administers to the study subject. The investigator is responsible for ensuring the following:

- Upon receipt of the study device, the shipment is inventoried by reviewing and documenting the type and quantity of device, the dates of receipt, and the batch number or code mark, and ensuring that the information on the packing slip matches what has been sent to the site, including the quantity and lot numbers.
- All discrepancies are promptly brought to the attention of the sponsor and/or supplier of the device(s).

- A copy of the shipping inventory, packing slips, and documentation of inventory are retained in the study files.
- An accountability log containing the names of all persons who received, used, or disposed each device is maintained.

Study device labeling

The investigator is responsible for ensuring the following:

- Study devices from sponsor companies are pre-labeled. They should not be defaced, relabeled, or changed in any way without written permission of the sponsor. It is recommended that an additional label is included containing the study staff contact name and/or number, but only if the sponsor agrees.
- If the investigator is responsible for device labeling, the investigator should be aware of applicable FDA regulations. Examples of the information to appear on a label are: name of device, model number, serial number, and manufacturer.
- When a study device is designated as “Investigational” per FDA regulations, there should be a label with the following information:
 - Name and place of business of the manufacturer, packer, or distributor.
 - Quantity of contents if appropriate, and the following statement: “CAUTION- Investigational device. Limited by Federal (or United States) law to investigational use.”
 - The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances, or devices, warnings, and precautions.

Storage of the study device including devices that record data from automated instruments

The Principal Investigator must:

- Establish and maintain access controls for essential and appropriate research personnel;
- Develop procedures for verifying physical access;
- Store the study device in a secure environment to include locks on doors and controlled access;
- Establish equipment control both into and out of the research site;
- Develop Security Incident Procedures to report any privacy breaches;
- Assess any privacy risks anticipated and develop methods to avoid those risks;
- Develop data backup, storage, and emergency mode procedures, if applicable
- Store the study device at the appropriate temperature, and maintain a storage and temperature log, if appropriate.

Dispensing of study device

The Principal Investigator is responsible for

- creating an access log to document each time the study device is dispensed/used, where it is dispensed/used, to whom it is dispensed/used, and the date and signature or initials of the person dispensing/using.
- Return/destruction of study device (as applicable to the specific device): The Principal Investigator is responsible for ensuring the following occurs in a timely manner:

- All documentation regarding receipt, storage, dispensing, return of used containers, and accountability is complete and accurate at the conclusion or termination of the study.
- Devices obtained from a sponsor for the specific purpose of a research study must be returned to the sponsor, with the reason why and the number of devices indicated.
- The same information must be detailed for devices that are repaired or otherwise disposed.
- Only with the written authorization (i.e., in the protocol or other written correspondence) of the sponsor, and in compliance with Federal regulations and Institutional policies, may the investigator discard the device on site, or retain the device.
- Unused study devices that include individually identifiable health information must not be passed on to other investigators without IRB approval and an authorization from the study subject.
- Unused study devices without individually identifiable health information must not be passed on to other investigators, used for animal research, or dispensed to non-study patients unless written consent is obtained from the Sponsor/Provider of the device.
- Device study records must be kept for a period of three years after the latter of the two following dates:
 - The date on which the investigation is terminated or completed; or
 - The date that for the purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

Record Retention. A Principal Investigator or Sponsor may withdraw from the responsibility to maintain records for the period required above.

The investigator may transfer custody of the records to any other person who will accept responsibility for them under 21 CFR 812.140, including the requirements of 21 CFR 812.145. Notice of a transfer shall be given to the FDA not later than ten working days after the transfer occurs.

Research on FDA approved devices for FDA approved indications

The Principal Investigator is responsible for ensuring:

- Receipt, storage, dispensing, and return of the device is documented.
- The FDA approved label is adequate.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Research (164.512(i) and 164.514(e))

The regulation allows covered entities to disclose protected health information (PHI) to researchers without patient authorization if an Institutional Review Board (IRB) or privacy board approves a waiver or alteration of authorization. Generally, the regulation seeks to extend the waiver of informed consent provisions of existing regulations - known as the Common Rule - that apply to federally-funded research to cover all research, regardless of the source of funding. If the researcher provides

treatment as a part of the research study and submits insurance claims electronically for payment of the care provided, the researcher will be treated as a covered health care provider and must comply with all relevant sections of the regulation. Covered Entities are Health Plans, Health Care Clearinghouses and Health Care Providers. Under the HIPAA Privacy Rule, the Department is a type of Covered Entity known as a Hybrid Entity, which means that some components of the Department perform Covered Functions (act as Health Plans, Health Care Clearinghouses or Health Care Providers), and therefore must comply with the HIPAA Privacy Rule, and others do not.

The programs within the Department that are required to comply with the HIPAA Privacy Rule (Covered Programs) are listed in Appendix 12. Additional programs might become Covered Programs after issuance of this item because, for example, of a change in program functions. Non-Covered Programs means the remaining components of the Department of Health that do not perform Covered Functions, including, but not limited to, all the programs that function as a Health Oversight Agency or Public Health Authority.

NYSDOH policy allows information to be disclosed to researchers if the research has been approved by an IRB (see APPM 100.4 for additional information on HIPAA).

HIPAA Review Criteria

The regulation requires research to meet three criteria for the waiver or alteration of authorization:

- (1) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on the presence, at least, one of the following elements:
 - (a) An adequate plan to protect the identifiers from improper use and disclosure;
 - (b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - (c) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of protected health information would be permitted by the regulation.
- (2) The research could not practicably be conducted without the waiver or alternation; and
- (3) The research could not practicably be conducted without access to and use of the protected information.

The regulation allows the waiver or authorization to be approved by full board review or by expedited review if the research is of minimal risk to the subjects. Expedited review allows the IRB Chair or the IRB or Privacy Board or a designee to approve the waiver alone, rather than by a majority vote.

Additional Disclosures to Researchers

The regulation allows information to be disclosed to researchers without authorization in two additional circumstances: 1) the information is necessary to prepare a research protocol (that presumably would later be presented to an IRB), or 2) some other activity in preparation for research; or the research uses decedent information. In both cases, certain conditions must be met.

Covered entities may also use or disclose a limited data set to researchers without authorization or a waiver of authorization from an IRB or privacy board.

Additional information on HIPAA can be found on the state web site: <https://goer.ny.gov/>.

HUMAN SUBJECTS PROTECTION TRAINING FOR RESEARCH STAFF

As part of the Federalwide Assurance, NYSDOH agrees to provide and monitor appropriate training and education for all research staff. The Assurance states, "Additionally, I recognize that providing all research Investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied."

Therefore, it is the intention of NYSDOH's IRB that all board members, institutional officials, investigators, and research personnel who work on research with human subjects (or the collection of private and/or identifiable information) receive training and have continuing education. Key personnel include: the principal investigator, co-investigators, study coordinators, and individuals having direct access to subjects or identifiable subject data and research materials. IRB Administration will verify that all research training requirements are met before processing any New Protocol submissions, Continuing Reviews and Amendments/Modifications.

The IRB sponsors the following training options:

CITI* On-Line Training:

NYSDOH IRB has partnered with Collaborative IRB Training Initiative (CITI) to provide a training program that meets the federal requirements for training in human subjects protections research. The current CITI Program offers multiple courses including training for:

Researchers are required to take one of the following trainings based on the type of research involved in:

Social & Behavioral Science Research

Biomedical Research

Biomedical Data or Specimens Only Research

If research is an USDA project and/or involves an investigational drug or device than the following trainings are required as well:

- **Good Clinical Practice Course (GCP) USDA Focus**
- **GCP involving Clinical Trials involving Investigational Medical Devices**
- **GCP involving Clinical Trials involving Investigational Drugs**

IRB Members are required to take the **IRB Members**. If IRB Members are researchers as well, they are required to take the appropriate research course, as well as, the IRB course in CITI training.

Students are required to take the **Student – Class Projects** Training.

The IRB will accept human subject protection trainings from other institutions on a case-by-case basis. A copy of the certificate or a confirmation from the other institution **IS REQUIRED. ALL TRAINING MUST BE LINKED TO RESEARCHER'S PROFILE IN IRBNet.**

It is the responsibility of the PI to ensure that all key study personnel possess a current and valid training certificate. If an individual's training certificate expires before completion of the study, that individual must be removed from the study, or all study activities must cease until an updated training certificate can be obtained. The IRB requires that all investigators and key personnel receive training before the submission of grant proposals for approval. Proof of such training is required to be submitted with each grant proposal and protocol review request.

If you have questions about which learner group is appropriate for you, please contact the IRB Office. These trainings provide a five-year training certificate.

CITI* Instructions:

To register as a new user, go to <http://www.CITIprogram.org> and follow these steps:

Click on the **Register** button to create a new account.

Select Your Organization Affiliation by entering **NYSDOH/Health Research Inc.** or selecting NYSDOH/Health Research Inc. from the drop-down box.

Review the **Terms of Service** and click on the **I Agree** box to accept.

Click on **I affirm that I am an affiliate of NYSDOH/Health Research, Inc.**

Click on **Continue To Create Your CITI Program Username/Password.**

Click **Continue To Step 2.**

Enter your **first name, last name, and preferred email address.**

Click **Continue To Step 3.**

Provide a **user name, password, and security question and answer.**

Click **Continue To Step 4.**

Indicate **Country of Residence.**

Click **Continue To Step 5.** Check appropriate boxes.

Click **Continue To Step 6.** Complete Required Fields.

Click **Continue To Step 7.**

Under **Select Curriculum**, answer Questions 1 & 2 and 3 (optional).

- Behavioral Science Researchers should select **Social & Behavioral Research Investigators.**
- Biomedical Researchers should select either **Biomedical Research or Biomedical Data or Specimens ONLY Research.**
- Student Researchers should select **Students – Class Projects.**
- IRB Members **MUST** select **IRB Members**
- Click **Complete Registration** (answer required questions).
- Click **Finalize Registration.**

Provide your NYSDOH work address and e-mail **NOT** your home address or private e-mail.

WHAT TO SUBMIT

All submissions are done electronically via IRBnet.org. It is not necessary to sign each form. Instead, use the “sign this package” feature to provide an electronic acknowledgment and signature.

Forms without all required signatures may be returned before review commences. Under extenuating circumstances, the signature of the Center Director may be submitted after the initial application is submitted; however, the signature must be in process and the IRB must be so apprised. Final approval will not be granted until **all signatures** are on file in IRBNet.

Initial Review Procedures

When a submission is received by IRB administrative staff, the review procedures are as follows: IRB administrative staff conducts a preliminary review to ensure that: application is properly completed, all required signatures have been obtained, key research staff have submitted conflict of interest forms and proof of human subject's protection training has been completed. IRB staff will correspond with the PI and/or research staff to obtain any missing documentation or ask for revisions to submitted documents if necessary. IRB review is on hold pending receipt of requested documentation or revisions. Once all documents and revisions have been made, IRB staff send the package to the designated reviewer: Exempt - IRB Chair or Designee; Expedited – Appropriate Subcommittee; Full Board – IRB Board members with a designated Primary Reviewer matched by knowledge and experience with package subject matter.

Exempt Studies

Complete and Submit the NYSDOH-1871 - Protocol Review Request Form (all boxes must be checked relevant to the exempt status), the protocol, conflict of interest form/s and training certificate/s for all study personnel, and all relevant study materials including, but not limited to informed consent/assent form, contact/recruitment letter, survey/questionnaire, phone script, advertisements. The package must be signed by the Principal Investigator and the Center/Division Director in IRBNet before submitting to IRB. For the Center/Division Director to the package the package must be shared to that individual. The IRB Chair or designee will review the package and report an approval status.

Expedited Review Studies

Complete and Submit the NYSDOH-1871-Protocol Review Request Form (all boxes must be checked relevant to the exempt status), the protocol, conflict of interest form/s and training certificate/s for all study personnel, and all relevant study materials including, but not limited to informed consent/assent form, contact/recruitment letter, survey/questionnaire, phone script, advertisements and upload to IRBNet. The package must be signed by the Principal Investigator and the Center/Division Director in IRBNet before submitting to IRB. For the Center/Division Director to the package the package must be shared to that individual. Check all applicable expedited research criteria that apply to the submitted research proposal. IRB staff will assign an appropriate subcommittee to review package and report an approval status.

Full Review Board Studies

Three weeks prior to the date of the full board meeting, submit an original of the entire proposal, including form NYSDOH-1871 - Protocol Review Request Form with appropriate program endorsements. Refer to IRB meeting announcements on **NYSDOH News** or call the IRB office for specific submission deadlines for Full Review. The package should contain the study protocol, conflict of interest documents and valid training certificates for all study personnel, contact letters, all informed consent/assent forms, advertisements, recruitment material, surveys, questionnaires, phone script, informed consent script if oral, if electronic informed consent all links to electronic format for IRB members to view and assess. Please see Appendix 6: Protocol Submission checklist to assist with preparing the application. Please note: Not every item will apply to every project.

If the IRB requests changes or additional information, an email will be sent to the PI explaining what issues or questions the IRB may have with the package. If minor changes are requested, IRB

administration has the authority to issue the final approval after resolution of the issues. For more substantive issues, the revision will be sent to the Primary Reviewer and/or a designated sub-committee for review and approval. Upon final approval, a letter of approval will be sent to the PI via irbnet.org with proper stamping procedures in place as described above. The electronic file will be affixed with date of approval. In most cases, non-exempt studies are approved for a one-year period.

The month of approval will coincide with the date of the meeting in which the study was presented. For example, if the committee meeting date is 10/17/19, then the date of IRB expiration is 10/16/20 for an annual approval. Whenever the IRB approves a research study with one or more conditions at the time of initial review, the effective date of the initial approval is the date on which the IRB Chair or designee(s) has reviewed and accepted as satisfactory any revised protocol or informed consent documents, or any other responsive materials required by the IRB from the investigator.

Appropriate Signatures

In irbnet.org, the '**Sign Package**' screen allows IRBNet users with access to a Project to record that they have '**read this Project's documents and agree that they are ready for submission**' to the IRB for review. The NYSDOH IRB requires that the PI and Center Director sign all initial protocol review request. (NOTE: your department/agency may require additional signatures).

By signing the Package, the PI acknowledges and accepts responsibility for protecting the rights and welfare of human research participants and for complying with all applicable federal, state and local regulations, including but not limited to: 45CFR46, HIPAA, NYS Law, NYSDOH policies and procedures and IRB guidelines. When the PI assumes a sponsor function, the investigator acknowledges the additional regulatory requirements of the sponsor and agrees to comply with them.

The Center Director certifies that he/she has reviewed the research protocol and attests to the scientific validity and importance of the study; to the competency of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

In the event the Principal Investigator for a study is the Center Director, it will be necessary to obtain the signature of the appropriate manager at a level above that of the PI. The Center Director cannot sign for his/her own study.

When the Principal Investigator is not a NYSDOH employee, but the proposed study will be conducted in conjunction with NYSDOH staff, the PI's name should appear in the PI box and the PI should sign the form. The NYSDOH staff person responsible for the study signs as the Project Director. The Center or Division Director for the NYSDOH employee signs as Center Director indicating the study has been reviewed and approved by NYSDOH management.

No study will be accepted for review without the proper signatures as described above, except in emergency review circumstances which might involve grant application deadlines or public health emergencies. Signatures must be submitted before approval is granted. There are no exceptions.

Use of Consultants by IRB:

The IRB may seek an ad hoc consultant when expertise is needed to assist in reviews that require expertise beyond or in addition to that available on the IRB. Such expertise may include scientific and scholarly expertise and/or knowledge about and experience working with certain topics or populations. Consultants may be used for all aspects of IRB review, including, but not limited to, initial review, modifications, reportable events, and continuing review. The rationale explaining the need for a consultant is documented in the Board Meeting Minutes. The IRB Chair, IRB Vice Chair, IRB

Administrative Director (AD) and Board Members will work together to determine if a consultant is required and to make an appropriate recommendation.

A consultant may participate, either in person or using conferencing technologies, in the convened meeting at which the application is reviewed by presenting his/her review and answering the IRB's questions. Alternately, the consultant may provide a written review that will be made available to the IRB members participating in the specific meeting.

The consultant must certify in writing that (s)he has no conflicting interest. Consultants may be given access to all documents relevant to the specific project under review, may participate in the IRB's deliberations and make recommendations on the project. However, consultants may not vote with the members of the IRB and a consultant's presence or absence will not be used in establishing a quorum. The minutes of the Convened Meeting will reflect the attendance of the Consultant, their duration in the meeting and a concise record of the discussion involving their participation. All written reports or other documentation of consultant reviews will be maintained in the IRB electronic system.

If the need for a consultant is not identified or not brought to the Chair's or AD's attention until the IRB meeting, the protocol must be tabled until the appropriate expertise can be obtained.

Procedure for Obtaining Consultants:

- A. Consultants may be IRB Members from other Boards, NYSDOH/HRI Employees, or experts outside of NYSDOH/HRI.
- B. The IRB Administrative Director (AD) and IRB Chair evaluate the IRB rosters to identify if any members of the other boards have the needed expertise and contact them to determine their willingness and availability for review. The AD or Chair will also review their qualifications for consulting on the proposal. The Consultant will be required to provide their curriculum vitae for review by the IRB Chairs and IRB Members. A copy of the curriculum vitae will be added to the IRB file
- C. After the individual's expertise and acceptance are confirmed, the consult will be sent the NYS Policy on Managing Conflicts of Interest in Research and asked to sign conflict of interest statements (Form 3995).
- D. If a Consultant with appropriate expertise is not available for the next IRB meeting, the protocol is assigned to another meeting when the expert is available or to another Consultant if available to conduct the review.

Consultant Responsibilities:

The IRB Chair explains to the Consultant that the same Ethical, Confidentiality, and Conflict of Interest standards apply to them as to IRB Members. Before each review, Consultants are required to complete a Conflict of Interest (COI) declaration; stating that they do not have any real or perceived financial and non-financial COI with the research. The AD or IRB Chair initially asks Consultants about any COIs at the time the assignment is made and again out loud at the time of the IRB meeting.

- A. The Consultant is required to return any materials provided by IRB Administration relevant to the specific research protocol under review.
- B. Consultants submit their findings in a written report to the IRB and may also present their findings at the IRB meeting in person. Copies are provided to IRB members with the agenda.
- C. The protocol file includes both the Consultant's report and credentials regarding the area of expertise needed.
- D. The Consultant is NOT permitted to vote, and their presence does not count toward a quorum.

- E. If a Consultant has a COI, the Administrative Director and the IRB Chair will determine if the Consultant can be used. If possible, another Consultant should be identified.
- F. The following procedures must be taken when a consultant with a COI is utilized:
 - 1. The IRB Administrative Director or the IRB Chair will announce the Consultant's conflict to the IRB Members at the meeting;
 - 2. The conflict will be written into the record and Meeting Minutes specific to the protocol for which their consultancy was sought.
 - 3. The Consultant may be present at the meeting to present their report and to answer any questions from the IRB Members; and
 - 4. The Consultant is not permitted to be present for the discussion or IRB vote.

APPLICATIONS AND REVIEW DEADLINES

There are no submission deadlines for Exempt protocols. They are reviewed on a rolling basis and are usually completed within 10 business days. The IRB Chair, Vice Chair or Administrative Director, will review exempt studies.

Allow at least three-four weeks from time of submission to a final disposition for studies fall within the nine criteria that require review by the Expedited Review Subcommittee. Applicants should indicate any submission deadline or funding issues at the time of application.

Studies submitted for full review at a bi-monthly IRB meeting must be submitted at least three weeks in advance of the scheduled meeting date. A reminder of upcoming IRB meetings and protocol due dates are posted on **NYSDOH NEWS** as well as on the IRB website. The principal investigator will be notified in writing of the board's decision within 10 business days of the meeting date.

NOTIFICATION

Applicants will be notified in writing of the decision of the IRB, which may include request for revisions or additional information. Re-submissions are often reviewed in an expedited manner. The PI must respond to revision requests, or request an extension, within 30 days from the date of the letter or the study may be closed. **Applicants may not proceed with research until written approval by the IRB is received.** Enrollment of study subject is NOT permitted until the IRB has reviewed and approved all changes required by the IRB.

STATISTICAL REQUESTS VITAL RECORDS, SPARCS, AND REGISTRY DATA

Vital Records

Birth and death certificates are an important source of public health data needed by the Department of Health to fulfill a wide variety of statutory and health program related functions. Data collected on birth and death certificates are used for statistical reporting, epidemiological analyses, program evaluation, and surveillance and in support of health program activities. Since birth and death certificates contain confidential and identifying information, great care is necessary to protect the personal privacy of the persons named on them.

While Article 41 of the Public Health Law specifically authorizes the use of death certificate information for research purposes, no specific provision for research use exists for birth certificate information including identifying data. However, Article 41 does authorize the use of birth certificate information when required for official purposes. Access to de-identified birth and death certificate data is available to Department of Health's programs for "proper purpose" (PHL 4174 1(e)).

Access to identifying birth and death certificate information will be approved only for those projects where a well-defined public health need or benefit **directly** linked to the program's mandate, mission or goals is clearly demonstrated, and, where risk of an invasion of personal privacy is outweighed by the benefits of the proposed project.

The IRB will evaluate the application to determine the appropriateness and scientific merit of the project/ research.

Requests involving identifying birth certificate information (APPM item 500.0 Categories 3 or 5) - If the appropriateness and scientific merit of the project/ research are approved, the IRB will submit the application for Executive Deputy Commissioner consideration. If the appropriateness and scientific merit of the project/ research are not approved, the IRB may discuss the issues with the Project Director. If such issues are not satisfactorily resolved, the IRB will send a disapproval letter to the Project Director.

Requests involving identifying death certificate information (Category 4) - If the appropriateness and scientific merit of the project/research is approved, the IRB will send the Project Director an approval letter. If the appropriateness and scientific merit of the project/research is not approved, the IRB will present/provide a list of issues with the Project Director. If such issues are not satisfactorily resolved, the IRB will send a disapproval letter to the Project Director.

Data Protection Review Board (DPRB)

The New York State Health regulations, NYCRR Title 10 §400.18, define how requests for deniable (identifying) Statewide Planning and Research Cooperative System (SPARCS) and Patient Review Instrument (PRI) data will be released. Deniable data are those specific data elements that, by itself or in combination, might identify an individual. A seventeen member Data Protection Review Board (DPRB) reviews all requests for deniable data. This public review body is broadly representative of the community, industry and government and is appointed by the Commissioner of Health. As per regulation, (NYCRR Title 10 §400.18) the SPARCS Unit of the Department of Health processes and reviews each data access application and then, prior to each DPRB meeting, submits a written recommendation to the Board for its consideration.

The DPRB and the New York State Department of Health recognize the need for data to be accessible so that there is a more effective, efficient, and responsive health care system. The identifying data access application process balances the need to know with the need to protect the confidentiality of patient records.

The Board's approval of a deniable data request is for a specific timeframe not to exceed three years. All approved data requests must be sent to the Commissioner of Health for ratification. The Commissioner may ratify or reverse the decision of the Board. The Board can overturn the Commissioner's decision by a two-thirds vote. This system of checks and balances, applied to all identifying data requests, guards the rights of individuals while providing access to needed health care information.

The Identifying Data Access Application supplies the Board with the information necessary to determine whether: the purpose of the request is consistent with the uses of the data as defined by regulation, the applicant is qualified to undertake the study, the proposed study/research is technically feasible, the applicant needs all the data requested and is able to ensure that patient privacy is protected.

The IRB **CANNOT** override the decision of the DPRB with regard to the release of SPARCS data. The IRB recommendations regarding the scientific merits of use of this data are shared with the DPRB for the purposes of IRB application approval.

Article 41 of the NYS Public Health Law authorizes the NYS Commissioner of Health to approve "scientific studies and research which have for their purpose the reduction of morbidity and mortality within New York State." The IRB functions as the Commissioner's designee in reviewing and approving requests for confidential data contained within the Department's vital records and disease registries. Requests for birth or death certificate as well as requests for data from the Department's disease registries for research studies are considered statistical requests. Each registry has its own procedures for data requests. Check with the contact person listed to determine where to apply for data from a registry. Research proposals seeking access to birth, death, and registry data requires IRB approval. Statistical requests usually are not governed by federal regulation but are governed by NYS laws and institutional policies. Principal investigators must apply to the NYSDOH IRB to obtain official approval for their research. Examples of registries include, but are not limited to:

Registry Name	Phone #	Contact
AIDS Registry	518-474-4284	Patricia Nardini
Alzheimer Disease & other Dementia Registries	518-473-7817	Ian Brissette
Cancer Registry	518-474-2255	Dr. Maria Schymura
Census for Fatal Occupational Injuries	518-402-7943	Ann Marie Gibson
Congenital Malformations Registry	518-402-7990	Dr. Marilyn Browne
Heavy Metals Registry	518-402-7900	Dr. Kitty Gelberg
Occupational Fatality Assessment& Control Evaluation	518-402-7900	Dr. Kitty Gelberg
Occupational Lung Disease Registry	518-402-7900	Dr. Kitty Gelberg
Pesticide Poisoning Registry	518-402-7900	Dr. Kitty Gelberg
Vital Records	518-486-3535	Jake LoCicero

Review Considerations for Statistical Requests

Before the IRB reviews an application for birth/death certificate or disease registry data, the programmatic holders of registries/records must review the application and make a recommendation. The IRB will determine whether the confidentiality procedures of the proposed project are adequate. Scrutiny is heightened when:

- There is a request for data containing identifiers;
- Data containing identifiers would be retained beyond the duration of the current project; or
- Follow-back to next of kin, co-workers or employers are planned.

No subject identifiers may be used in study reports or publications. In instances where a disease registry is to be the source of a list of possible subjects, the IRB frequently requires that the potential subjects' physicians first be contacted to determine whether the potential subject is aware of their diagnosis and whether the subject is deemed psychologically able to respond to questions concerning their treatment and condition.

Applying for Access to Birth and Death Certificates

The release of birth and death certificates for research use is governed by NYS Administrative Policy and Procedures (APPM). Refer to APPM item 500.0 for complete information on this policy. Death certificate requests are reviewed by an IRB Subcommittee and Birth Certificate requests must be reviewed by the Full Board.

Applicants must submit a **NYSDOH-4269 Request for Access to New York State Vital Records Data** to the Bureau of Production Systems Management. Form NYSDOH-4269 is available on the BBHS Intranet site (<http://biometrics>). Programs requesting use of identifying birth and death certificate information must obtain the endorsement of a Division Director or higher-level manager. The maximum length of time that access to a vital records data file can be granted under a single application is five years. The Bureau of Vital Statistics and Bureau of Biometrics and Health Statistics (BBHS) will review each request.

The New York State Department of Health is not authorized to provide access to New York City birth and death data. Under no circumstances will New York City birth or death data be released without the express written permission of the New York City Department of Health and Mental Hygiene.

Access to identifying birth and death certificate information will be approved only for those projects where a well-defined public health need or benefit **directly** linked to the program's mandate, mission or goals is clearly demonstrated, and, where risk of an invasion of personal privacy is outweighed by the benefits of the proposed project. All data requests that fall into one of the following categories will be referred to the IRB.

- Non-research projects that involve identifying birth certificate information, with follow-back, and are directly related to NYSDOH program mandates, program evaluation or surveillance.
- Research projects that involve identifying death certificate information, with or without follow-back, related to NYSDOH program mandates, program evaluation or surveillance.
- Research projects that involve identifying birth certificate information, with or without follow-back, that are related to NYSDOH program mandates, program evaluation or surveillance.

The IRB will evaluate the application to determine the appropriateness and scientific merit of the project.

Requests for Vital Records are accepted on a continuous basis, and IRB members will review these requests as received. Continuing review of request for death certificate data is not required. Requests for access to death certificate data will not be assigned an expiration date, do not have to undergo continuing review, and can initiate minor protocol changes without IRB approval.

For an application or more information on access to vital records data for research purposes contact:
Bureau of Vital Statistics
800 North Pearl St., suite 200
Menands, NY 12204
(518) 486-3535

UNANTICIPATED PROBLEMS AND ADVERSE EVENTS

Federal regulations require IRBs to establish written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and applicable regulatory agencies, of any unanticipated problems or adverse event involving risk to human participants or others (45CFR45 106(b)). Please

note that NYSDOH IRB procedures may be different than those established by sponsors and/or other institutions.

The IRB considers **unanticipated problems**, in general, to include any incident, experience, or outcome that meets **all** the following criteria:

- unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol and the characteristics of the subject population being studied;
- related (or possibly related) to participation in the research; and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All serious and/or unanticipated events/problems must be reported within 10 business days of the investigator's receipt of the information.

When an incident, experience, or outcome that meets the three criteria noted above is reported, it generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

An *adverse event* is defined as any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

A serious adverse event is any adverse event that is fatal, or life threatening, is permanently disabling, requires inpatient hospitalization or prolongs hospitalization, or results in a congenital anomaly or birth defect. It is the responsibility of the Principal Investigator(s) to promptly report internal adverse events or serious adverse events to the IRB within 48 hours of its occurrence, followed by a written report within ten working days of the event ([Adverse Event Report Form](#)). In addition, any collaborating investigators/institutions must promptly be made aware of such problems. The IRB Chair will review the AE report to determine whether immediate action is required. Otherwise the IRB will meet with the Investigator(s) at a convened IRB meeting to review the details of the problem/event and to discuss whether project procedures require revision and whether approval to proceed with the project should be suspended.

Failure to report such an event to the IRB within the time frame noted above will result in notification of the Commissioner of Health and immediate suspension of approval to continue the project.

Guidelines for Reporting Adverse Events

- An adverse event is considered serious if it is fatal or life-threatening; requires or prolongs hospitalization; produces a disability; or results in a congenital anomaly/birth defect.
- An adverse event is of moderate or greater severity if it requires medical evaluation (such as additional laboratory testing) and/or medical treatment; or if it is a serious adverse

reaction.

- An adverse event is unexpected if it is not identified in nature, severity or frequency in the current IRB-approved research protocol or informed consent document.
- An adverse event is associated with the research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).

Notification of Findings by Sponsor

Stipulations are required in a standard sponsored research contract template to include that the sponsor will notify the Principal Investigator or the NYSDOH IRB within 72 hours of:

- A. Non-compliance with the protocol or applicable laws, particularly those laws related to participants, that could impact the safety or welfare of the participants;
- B. Serious adverse events that have been reported to the FDA or other governmental agency in relation to the protocol at NYSDOH or any other site participating in a multisite study;
- C. Unanticipated problems in the protocol at NYSDOH or any other site that could relate to risks to participating participants, and
- D. Circumstances that could affect participants' willingness to continue to participate in the protocol or the IRB's continuing approval of the protocol.

When non-standard contract templates are used, the sponsor is asked to include equivalent statements.

Communicating Study Results to Participants

When the IRB learns of events that could affect participant welfare after a study has closed (e.g., a drug or device studied at NYSDOH has been withdrawn by the FDA), the IRB seeks information, deliberates, and considers whether (and how) to contact participants who might be affected. Even when the study is not yet closed, and participants have completed participation, the IRB informs former participants when information is learned that could affect their welfare.

For sponsored research, NYSDOH/HRI will address communication with sponsors regarding the impact of research results on participant health and safety by:

- Including in the standard contract templates a stipulation that the sponsor will develop a plan of communication with the Principal Investigator that is acceptable to the IRB when new findings or results of the protocol might impact the willingness of subjects to continue to participate or directly affect their current or future safety or medical care, or by asking for the inclusion of such a provision in any proposed contract that does not use their standard template. This information is to be provided to the NYSDOH 2 years following the study closure, as well.

NON-COMPLIANCE BY INVESTIGATORS AND INSTITUTIONS

The NYSDOH IRB is responsible for reviewing applications for human subject research and approving those studies that both meet the criteria set forth in the federal regulations and satisfies institutional goals and standards. The approval is limited to the specific protocol procedures, materials, forms, and processes set forth in the application. IRB approval notices detail any special conditions that accompany approval and provide a time limit for conduct of the study before the next IRB review period. The NYSDOH IRB expects principal investigators and research staff to comply with all ethical standards, institutional policies, governmental regulations and IRB conditions placed on the conduct of the research.

The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution, investigators and their research staff, the subjects who enroll in research, IRB members, and IRB Administrative Staff. The primary responsibility of the IRB is to ensure protection of the rights and welfare of research subjects. In performing that responsibility, the IRB addresses allegations of non-compliance with IRB requirements and federal regulations governing the conduct of human research. IRB Administrative Staff, IRB members or IRB consultants do not participate in alleged non-compliance reviews if they have a conflict of interest.

The IRB considers non-compliance to be:

- failure to adhere to the terms of IRB approval by the PI or research personnel.
- failure to abide by applicable federal and state laws, regulations, IRB guidelines and Department policies, including failure to submit research for IRB review and approval prior to commencing research and continuing research.

Instances of non-compliance vary in nature, severity, and frequency. The review and resolution of issues of non-compliance depend upon the seriousness or repetitive nature of the noncompliance.

DEFINITIONS

Non-compliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects research. For this IRB Guidelines, noncompliance does not include minor or technical violations which result from inadvertent errors, inattention to detail, or failure to follow operational procedures which do not pose risk to participants and/or violate participant's rights and welfare.

Continuing non-compliance is a persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious non-compliance is a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

- Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research participants, research personnel, or others; or
- Substantively compromising the effectiveness of an institution's human research protection or human research oversight programs.

Minor non-compliance is non-compliance that is neither serious nor continuing non-compliance. Non-compliance that occurs in the context of IRB approved research requires corrective action. The IRB will determine the actions required and will take into consideration the nature, severity, and frequency of the non-compliance and the risk that non-compliance poses to human subjects. The NYSDOH IRB and/or Institutional officials may consider a range of options to address documented cases of noncompliance.

IRB Procedures Regarding Non-Compliance

Allegations of Non-Compliance

- A. Anyone may submit allegations of noncompliance or continuing non-compliance involving human subjects research to the IRB Administrative Office verbally or in writing. The IRB Administrative Office maintains confidentiality regarding the identity of the person submitting the allegation to the extent possible.
- B. The IRB Compliance Officer screens the allegation of non-compliance to determine whether the protocol(s) affected is supported by federal funds.
- C. The IRB Compliance Officer also determines whether the protocol has issues pertinent to other research review committees, i.e., Vital Records, the Cancer Registry, Newborn Screening, and the Office of Sponsored Programs.
- D. If the IRB Compliance Officer finds any issues pertinent to research review committees, he/she coordinates with these committees as appropriate.

Review of the Allegation

- 1. The IRB Compliance Officer reviews all allegations to determine whether the facts justify the allegation (i.e., there are supporting documents or statements).
- 2. If the IRB Compliance Officer deems an allegation unjustified (i.e., finds no supporting documents or statements), he/she forwards the allegation materials to the IRB Administrative Director and IRB Chair.
- 3. If the IRB Administrative Director and IRB Chair deem the allegation unjustified, the appropriate convened IRB reviews the allegation. The convened IRB may dismiss the allegation as unjustified after reviewing the material(s) and decide to take no action.
- 4. If the convened IRB finds the allegation is unjustified and takes no action, the IRB Administrative Director communicates (by phone, email, and letter) the IRB's decision to the complainant (if the identity of the person is known) and to the investigator against whom the allegation was raised (respondent).
- 5. If the IRB Administrative Director and IRB Chair determines that an allegation is justified and concerns administrative issues, the IRB Administrative Director manages the concern through communications with the Principal Investigator.
- 6. If the complaint/concern is minor or administrative, the IRB Chair and IRB Administrative Director may determine not to require a formal inquiry, interview, or summary with opportunity to comment.
- 7. Upon resolution of the issue, the IRB Administrative Director provides an oral and written summary of the resolution to the IRB Board at the next convened IRB meeting for review and approval.

Allegation Inquiry

- 1. If the allegation involves more serious issues than administrative or minor concerns, the convened IRB decides whether to initiate an inquiry. The convened IRB bases the decision on the seriousness and/or the frequency of violations and/or disregard for the federal regulations, NYS Public Health Law and/or the institutional guidelines applicable to human subjects research.
- 2. If the convened IRB determines that an allegation is justified and suggests that subjects are at immediate risk; the convened IRB considers whether to immediately suspend IRB approval and to sequester research records including raw data. However, in most cases, the convened IRB conducts an inquiry to collect additional information and concludes the review before making a determination.
- 3. If the convened IRB initiate an inquiry to determine the validity of the allegations, IRB Administrative Staff notify the Principal Investigator. If the allegation involves a co-investigator or a research assistant, IRB Administrative Staff also contact that individual. The IRB Administrative Director or the IRB Chair makes the initial notification via telephone

and/or e-mail. The IRB Chair sends written follow-up correspondence.

4. The convened IRB may appoint one or more voting member(s) (e.g., the IRB Chair or Vice Chair) to gather information pertaining to the nature of the allegation, the procedures in the approved IRB protocol, as well as the procedures followed in conducting the study. The IRB Administrative Director and Compliance Officer assist the IRB Chair in conducting the inquiry. Periodically, with allegations involving administrative or minor noncompliance, the IRB may request that the IRB Administrative Director and/or the Compliance Officer gather the facts without involving an IRB member. In more serious cases, the convened IRB gathers the information as a group rather than delegating the responsibility.
5. The IRB representative interviews the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation interviews the complainant. The interviewer prepares a summary of the interview and gives the complainant the opportunity to comment on the written summary. In some cases, the complainant may have already submitted a written complaint, which the IRB Representative then verifies. The IRB Representative may request additional information from the complainant.
6. The convened IRB and IRB Chair interviews the respondent and gives him/her the opportunity to comment on the allegation and provide information. The IRB Administrative Director prepares a summary of the interview and gives the respondent the opportunity to comment on the summary. The respondent may submit a written rebuttal to the complaint, which the IRB Administrative Director verifies. The IRB Administrative Director may request additional information from the respondent.
7. Depending on the nature of the allegation and the information collected during the interviews, the convened IRB may interview other individuals. In addition, in conducting the review, the convened IRB may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; the applicable approved IRB protocol; and any other pertinent information.
8. When appropriate, the IRB member(s) conducting the inquiry prepares, with the assistance of the IRB Administrative Director, a summary report for the convened IRB. The report may consist of a summary of the allegations, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action. (In some cases, this simply provides the IRB with a summary of the allegations, the interview summaries, and copies of pertinent information without an accompanying written report from the review team.)

Administrative Review Procedures

1. The IRB Administrative Director advises the IRB regarding the applicable NYS Public Health Laws and federal regulations assists the IRB in documenting the review, answers questions about the review process, maintains records as required by state and federal laws, and serves as a liaison with the Office of Sponsored Programs.
2. The IRB reviews the material presented by the review team at a convened meeting at which a quorum is present. The materials provided include the summary report of the noncompliance, the protocol if applicable and the informed consent document if applicable. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the respondent the opportunity to meet with the convened IRB before it takes final action.

IRB Actions for Administrative Reviews

1. The convened IRB makes the determination whether the allegation is substantiated, and if so, whether the non-compliance is serious or continuing based on the materials compiled during the inquiry. If the non-compliance is serious or continuing and the research is

federally funded, the IRB, with the assistance of the IRB Administrative Director and/or Compliance Officer reports the incident(s) to the applicable federal agency. **The maximum time allowed between the recognition of a reportable event and fulfilling reporting requirements are no more than 30 days.**

2. The convened IRB may take a variety of actions, depending on the outcome of the review, including, but not limited to, the following:
 - Approve continuation of research without changes;
 - Request formal educational intervention;
 - Request minor or major changes in the research procedures and/or consent documents;
 - Modify the continuing review schedule;
 - Require monitoring of the research;
 - Require monitoring of the consent process;
 - Suspend or terminate IRB approval/disapprove continuation of the study;
 - Require audits of other active protocols of the investigator;
 - Disqualify the investigator from conducting research involving human;
 - Determine that the investigator may not use the data collected for publication;
 - Require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or re-consent them;
 - Request that the investigator inform publishers and editors if he/she has submitted or published manuscripts emanating from the research; and/or
 - The IRB Administrative Director communicates (phone call, email, and letter) the IRB decision to the person raising the allegation (if the identity of the person is known) and to the respondent.
3. The IRB informs the following individuals of the allegation, the review process, and the findings of the review, if appropriate:
 - Investigator;
 - Complainant;
 - The Division Director;
 - Center Director;
 - Executive Deputy Commissioner
 - Office for Human Research Protections (OHRP) and/or Food and Drug Administration;
 - Sponsor, if appropriate
 - When following Department of Defense regulations; Determinations of serious or continuing non-compliance of DoD supported research MUST be promptly (within 30 days) reported to the DoD Human Research Protection Officer;
 - Other administrative personnel, as appropriate.
4. The IRB resolves questions or concerns raised by a Principal Investigator regarding the outcome of a specific IRB noncompliance review through direct communication with the Principal Investigator.
5. The Principal Investigator submits concerns in writing to the IRB within thirty days of the date the IRB issues the final decision. The IRB limits concerns to a review of the procedures employed to reach the decision e.g., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect or grievances against sanctions imposed as a result of a finding of noncompliance. The Principal Investigator specifies the nature of any claimed procedural error or the perceived unfairness of sanctions issued.
6. The record for the concern raised shall be the record established during the protocol Review by the research compliance officer.

The Final Report will remain in the Protocol Study File until the file is purged and destroyed.
21 CFR 56.123 and 45 CFR 46.112

TIPS AND SUGGESTIONS

The following suggestions are offered for the benefit of research personnel.

ATTENDANCE AT MEETINGS

The Principal Investigator is not required to attend full board meetings. However, the Board recommends that the PI or a knowledgeable representative should be available by phone to answer any questions which the Board may have concerning the project. Occasionally, the IRB will ask a PI to attend the full board meeting in person to discuss their protocol if there are difficult issues or unique research methodology. An investigator may also request to attend the IRB meeting that will address their protocol, but this is not usually necessary. Principal Investigators should contact the IRB's Administrative Director about the advisability of attending the meeting to answer questions.

Application Number

The IRB receives numerous applications on a continuous basis. In addition, some Investigators file more than one application. The IRB administrative unit assigns a number to each application as it is entered into the database. Each PI is subsequently notified in writing of their IRB Reference Number. The use of that number in all communication or written correspondence with the IRB greatly facilitates the location of the correct file and is highly recommended. Please note: IRBNet automatically assigns a unique identifying number (IRBNET ID) when a package is submitted.

Readability Scores

Researchers should ensure that the informed consent document properly translates complex scientific concepts into simple language that the average person can read and comprehend. The IRB recommends adult informed consent documents be written at no higher than 8th grade reading level. However, there may be instances where the reading level would be more appropriate at the 3rd –6th grade levels.

Microsoft Word has a feature that will calculate readability scores based on the Flesch-Kincaid Grade Level Scores. When Microsoft Word finishes checking spelling and grammar, it can display information about the reading level of the document, including the following readability scores. Each readability score bases its rating on the average number of syllables per word and words per sentence.

- On the Tools menu, click Options, and then click the Spelling & Grammar tab.
- Select the Check grammar with spelling check box.
- Select the Show readability statistics check box, and then click OK.
- Click Spelling and Grammar on the Standard Toolbar.

When Word finishes checking spelling and grammar, it displays information about the reading level of the document.

Additional Assistance

In addition to reviewing this document, applicants who are unsure about how to apply or what to

include are encouraged to contact the IRB Administrative Director, IRB Administration or an IRB member to seek advice.

APPENDIX 1: IRB COMMONLY USED TERMS AND DEFINITIONS

Adverse Event

An unintended, but not necessarily unexpected, result of therapy or other intervention that is unpleasant or dangerous.

Approval/ Approved

The determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements; the study is approved as submitted (no stipulations required by the board)

Approved Pending/ Contingent Approval

The IRB requires minor changes to the protocol and accompanying document(s). The changes may be reviewed under expedited review by a designated reviewer. The study cannot begin until final approval is granted.

Anonymized

Refers to information/data where identifiers (and codes that are linked to identifiers) have been removed, as well as other values that would enable individuals to be identified by inference. For all practical purposes, anonymized data cannot be linked to the individual.

Article 24-A

Public Health Law Article 24-A, Sections 2440 through 2446, refer to the use of human subjects in medical research projects throughout NYS. The sections speak to safeguarding the rights and welfare of individual human subjects in the conduct of these human research projects. It is the policy of this state to protect its people against the unnecessary and improper risk of pain, suffering or injury resulting from human research conducted without their knowledge or consent.

Assent

An affirmative agreement by a child or cognitively impaired person to participate in research. Assent requires a full explanation as in the informed consent process and appropriate language level.

Assurance

An agreement or contract between an institution and the Office of Human Research Protections

(OHRP), on behalf of the Secretary of Health and Human Services; the Assurance stipulates the methods by which the institution will protect the rights and welfare of research subjects in accordance with the regulations.

Autonomy

The personal capacity subjects should possess in research conditions to consider alternatives, make choices, and act without undue influence or interference of others.

Belmont Report

A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

Certification

The official notification to the supporting department or agency that a research project or activity involving human subjects has been reviewed and approved by an IRB.

Child/Minor

A person who has not attained the legal age for consent to treatments or procedures involved in the research.

Clinical Investigation

A systematic study designed to evaluate a product (drug, device, or biologic) to treat, prevent, or diagnosis a disease or condition in humans, which can be conducted only after approval by the US FDA.

Common Rule

Refers to regulations that govern human subjects of research and have been adopted "in common" by seventeen federal agencies. The Common Rule is delineated in Title 45 of the Code of Federal Regulations Part 46 Subpart A.

Compensation

Payment or medical care provided to subjects injured in research; or payment (remuneration) for participation in research.

Confidentiality

Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. "Confidentiality" and "anonymity" do not have the same meaning and are not interchangeable.

Continual Review

Research that has been approved will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually.

Collaborative Research Projects

Those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor).

Covered Entity

Under HIPAA, this is a health plan, a health care clearinghouse, or a health care provider who

transmits any health information in electronic form in connection with a HIPAA transaction.

Data

Refers to information that is collected for analysis or used to reason or make a decision.

Data Privacy

Informational privacy especially when the information in question is stored in a database.

De-Identified

Health information is considered de-identified when it does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual. Information is considered de-identified if 18 identifiers are removed from the health information and if the remaining health information could not be used alone, or in combination, to identify a subject of the information (refer to the section on De-identified data for the list of identifiers).

Department or Agency Head

The head of any federal department or employee of any department or agency to whom authority has been delegated.

Device (medical)

Therapeutic, diagnostic or prosthetic articles, which do not interact chemically with the body (e.g., pacemakers, intrauterine contraceptive devices, diagnostic test kits, crutches, and artificial joints).

Disapproved

Questions regarding the rights and welfare of the subjects are of such significance that the Institutional Review Board determines approval of the study to be unwarranted.

Emergency Use

The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

Engaged in Research

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

Exempt

The Common Rule codified in 45 CFR 46.101(b) specifies that research activities may be exempt from the policy if human subjects involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable. As noted, NYSDOH IRB requires exempt studies to undergo initial review, and maintains open files on them for continuing review.

Expedited

The Common Rule codified in 45 CFR 46.110 specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk or a previously reviewed protocol is receiving modifications that are only minor. Expedited review is carried out by the IRB Chair or by one or more experienced reviewers designated by the chair.

Federal Regulations

Regulations are the rules that departments or agencies issue to provide specific guidance to themselves and others about how they will implement pertinent laws. In this particular report, "regulations" refers to federal regulations on human subjects protection to the Department of Health and Human Services' regulations.

Guardian

An individual who is authorized under applicable state or local law to consent on behalf of another person (e.g., children) to general medical care.

Human Subjects

Individuals about whom an investigator is conducting research: (1) that obtains information or biospecimens through the intervention or interaction with the individual, and uses, studies or analyzes the information; or (2) that obtains, uses, studies, analyzes or generates identifiable private information or biospecimens; (3) where there's an interaction including communication or interpersonal contact between investigator and subject; (4) with identifiable private information or biospecimens for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Hypothesis

A proposition (or set of propositions) proposed as an explanation for the occurrence of some specified group of phenomena to be tested by research.

Informed Consent

The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

Institution

Any public or private entity or agency (including federal, state, and other agencies).

Institutional Review Board (IRB)

A committee formed to ensure the protection of human subjects in research.

Interaction

Includes communication or interpersonal contact between investigator and subject.

Intervention

Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

Legally Authorized Representative

An individual or judicial or other body authorized under law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in research.

Minimal Risk

That the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Newborn Screening Specimens

Public Health Law sections 2500-a, 2500-e and Article 25 Title II-A; Section 4210 established infant testing for diseases and conditions. Blood is collected from the infant's heel and submitted as a dried blood spot specimen (DBS) for testing by the Newborn Screening Laboratory.

Non-Significant Risk Device Study

A Non-Significant Risk Device Study is one that does not meet the definition for a Significant Risk Device Study. It **IS NOT an investigational device that:**

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life; or
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Parent A child's biological or adoptive parent.

Permission

The agreement of parent(s) or guardian to the participation of their child or ward in research.

Personal Identifiable Health Information

Health or medical data or information that can be linked manifestly or inferentially to an individual.

Principal Investigator (PI)

The individual with primary responsibility for the design and conduct of a research project.

Program

Any action with the goal of improving outcomes for whole communities, for more specific sectors such as schools, workplaces, etc. or for sub-groups such as youth, people experiencing violence, HIV/AIDS, etc.

Program Evaluation

The primary purpose of program evaluation is to examine a program and to determine whether the program is effective in meeting its goals/criteria. Program evaluation does not require IRB review.

Protected Health Information (PHI)

PHI is individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.

Protocol

The formal design or plan of an experiment or research activity.

Remuneration

Payment for participation in research.

Research

A systemic investigation designed to develop or contribute to generalizable knowledge.

Significant Risk Device Study

Under 21 CFR 812.3(m), a Significant Risk device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Tabled

The protocol is judged to have serious problems or to lack sufficient information for the committee to appropriately assess the risks to subjects. Subsequent full board review of the investigator's response is required prior to approval.

Test Article

Any drug/biological product/medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

Voluntary

Free of coercion, duress, or undue inducement referring to a subjects' decision to participate or continue to participate in a research activity.

Waiver of Informed Consent

A departure from the traditional consent process. DHHS regulation 45 CFR 46.116(d) specifies that an IRB can alter or waive the requirement to obtain informed consent if it finds and documents that the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

APPENDIX 3: APPLICATION & INSTRUCTIONS

For the most up-to-date IRB Application and Instructions, go to irbnet.org and click on Forms and Templates.

APPENDIX 4: SAMPLE ADULT CONSENT FORM



**Department
of Health**

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

TEMPLATE: Consent to Participate in Human Research Study (Consent documents must be on NYSDOH letterhead)

Title of Project:	<i>Title of Project should reflect nature of research being conducted.</i>
Principal Investigator:	<i>Name(s) of Principal Investigator(s)</i>
Address:	<i>Principal Investigator's address</i>
Phone Number:	<i>Principal Investigator's phone number</i>

Overview of the Research Study

Provide a clear and concise statement/explanation informing participants that the study involves research, the purpose of the research, the expected duration of the research. The informed consent must be written in simple language. The IRB requires informed consent forms to be written at or below the 8th grade reading level and to explain the research using as few technical terms and jargon as possible.

(Insert Text):

Description of the Research

In clear, concise and simple language provide a detailed description of the procedures to be followed and identification of any procedures that are experimental. Include the approximate number of participants and what they are expected to do. Include a description of procedures that are required as part of the research and those that are optional (future testing of specimens, for example).

(Insert Text):

Potential Risks and Discomforts

Describe in clear and concise simple language any reasonably foreseeable risks or discomforts to the subjects include both the probability and magnitude of harms/risks; as well as, any physical, psychological, social and economic risks.

If applicable, a statement that the treatment or procedure may involve risks to the subject or to embryo or fetus if subject is pregnant or may become pregnant that are currently unforeseeable.

(Insert Text):

Potential Benefits

Describe in clear concise and simple language any benefits the participant or others may receive from participating in this research. Describe if there is no direct benefit, but the study will provide a future benefit to others.

(Insert Text):

Alternatives to Participation

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant, if applicable.

(Insert Text):

Confidentiality

*Provide a full explanation of confidentiality protections the investigator plans to use, including: a) where the data will be stored; b) who will have access to the stored data; c) how long the data will be kept; d) how the data will be reported. Describe any foreseeable risks to maintaining confidentiality and how these will be minimized. Explain certificate of confidentiality (if applicable). Include the following statement, **“The NYSDOH IRB has the authority to inspect consent records and data files to assure compliance with approved procedures”**.*

A statement regarding whether clinically relevant research results, including individual research results will be disclosed to subjects, and if so, under what conditions.

(Insert Text):

***If applicable the following must be included in the informed consent form as well:**

***Collection of Identifiable Data or Biospecimens**

A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative, if this might be a possibility; or

A statement that the subject’s information or biospecimens collected as part of the research even if identifiers are removed, will not be used or distributed for future research studies.

If applicable, A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

If applicable, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(Insert Text):

Research Involving More than Minimal Risk Disclosure

Provide an explanation of whether compensation or medical treatment is available if injury occurs and if so, what the compensation and medical treatment consists of and where further information may be obtained.

(Insert Text):

Costs

Describe any costs to be incurred by the participant such as lost time from work, mileage, etc. Indicate again length of time of participation. If applicable, any additional costs to the subject that may result from participation in research.

(Insert Text):

Compensation/Reimbursements

Describe any payment to be offered for participation, when it will be given, and any conditions of full or partial payment.

(Insert Text):

Voluntary Participation

Include a statement emphasizing that participation is voluntary and that participants can discontinue the research activity at any time (or decline to answer specific questions) without reprisal or penalty. Participants must receive a copy of the signed informed consent form for their records.

If applicable, a statement that significant findings developed during the research that may relate to the participant's willingness to continue participation will be provided to the subject.

(Insert Text):

Termination of Participation

Describe how to withdraw from the study and what will happen to documents/specimens already collected.

If applicable, a description of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent. Provide any consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the subject

(Insert Text):

Contact Person(s)

*1) Give the name and phone number of a study contact person for any questions regarding the study 2) **The following Statement MUST appear in its entirety:** Please contact Mr. Tony Watson, IRB Administrative Director, at (518) 474-8539, should you have questions about the research (e.g., investigator and other research team members), questions about your rights as a human subject in research, comments, suggestions, or input, and in the event of a research-related injury (depending on the nature of the research).*

(Insert Text):

Disclosure of Financial Interests

Disclose any financial interests of the PI(s).

(Insert Text):

Additional Consent Requirements (as applicable)

HIPAA-compliant consent language

Genetic testing (79-I) requirements

Reasons for dismissal from study

Compensation for injury

Signature of Research Subject and Date

The signature of the subject and/or subject's authorized representative must be obtained indicating an agreement to participate. The date (which should be in the subject's writing) is meant to indicate that consent was obtained prior to the subject's involvement in any research procedures.

(Insert Signature and date line here):

Signature of Witness/ Person Obtaining Consent

The signature of an auditor/witness attests to the fact that the form was read by or read to the subject, that an explanation of the research was given, that questions from the subject were solicited and answered to the subject's satisfaction, and that, in this person's judgment, the subject voluntarily agreed to participate. This signature is not required by the federal regulations; however, the IRB may require this signature for some research that presents greater than minimal risk to subjects.

(Insert Signature and date line here):

APPENDIX 5: ASSENT DOCUMENTS



Department
of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

SAMPLE: CHILD ASSENT FORM

Age Range of Study Subjects: 13-17

Study Title: _____

Age Range of Study Subjects: 13-17

1. My name is: _____

2. **Purpose/ Introduction:** This form describes a research study that we are asking you to be in. We are studying how < INSERT SIMPLIFIED PURPOSE OF STUDY HERE.> We are asking you to help us find out about this by being part of this study. Please read this form carefully and ask me any questions you may have before you decide whether or not to be in the study.

3. **Description of Study Procedures:** In this study, we will ask you to <INSERT SIMPLIFIED PROCEDURES HERE (focus on the child's perception of the study procedures, not the technical details).> If you are in the study for the whole time, from beginning to end, it will take about <X minutes/days/weeks/months> to finish.

(Depending on the ages of the children being enrolled, it may be appropriate to insert simplified information about risks, benefits, alternatives and/or payments here.)

4. Risks: There are no major risks or discomfort. You will not feel anything strange.

5. Benefits (to subject): This is an experiment. There are no direct benefits to you.

6. Benefits (to society or science): This work may lead to a new way for people who have trouble talking or moving to communicate.

7. We have already received permission from your parent(s) for you to take part in this research. Even though your parent(s) have given permission, you still can decide for yourself if you want to take part.

8. If you don't want to be in this study, you don't have to be. Remember, being in this study is up to you and no one will be upset if you don't want to take part or even if you change your mind later and want to stop.

9. You can ask any questions you have about this study. If you have a question later that you didn't think of now, you can ask it later.

10. Contact Information: If you have any questions about the study, please call: [PI] at (telephone number). **The following Statement MUST appear in its entirety:** Please contact Mr. Tony Watson, IRB Administrative Director, at (518) 474-8539, if you have questions about the research (e.g., investigator and other research team members), questions about your rights as a human subject in research, comments, suggestions, or input, and in the event of a research-related injury (depending on the nature of the research).

Name of Subject

Age of Subject

Signature of Subject

Date

Signature of Researcher

Date

Signature of Witness

Date



SAMPLE: CHILD ASSENT FORM

Age Range of Study Subjects: 7-12

(To be read aloud to the child)

My name is [*identify yourself to the child by name*]. I work with the New York State Department of Health. Right now, I am trying to learn more about [*provide a simple explanation of what the study is about in language that is appropriate to both the child's maturity and age*].

If you agree, you will be asked to [*describe what will take place using appropriate language from the child's point of view, including the time involved*].

You may be helping us understand [*describe topic*] or [*say what direct benefits are to child*].

[*If the study involves specific questions:*] There is no right or wrong answers.

Please talk this over with your parents before you decide if you want to be in my study or not. I will also ask your parents to give their permission for you to be in this study, but even if your parents say "yes," you can still say "no" and decide not to be in the study.

If you don't want to be in my study, you don't have to be in it. Remember, being in the study is up to you and no one will be upset if you don't want to be in the study or if you decide to stop after we begin, that's okay, too. Also, remember that no one else, not even your parents, will know what you've [*e.g., said, drawn, chosen, written; whatever the child is being asked to do.*]

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me or ask [*your parents, teacher, whoever the child may choose*] to call me at: [*insert telephone number*].

Would you like to [*e.g., play a game, talk to me, draw a picture; whatever the activity is*]?

[Child answers yes or no; only a definite yes may be taken as consent to participate.]

APPENDIX 6: CHECKLIST OF RESEARCH MATERIALS

- Curriculum Vitae/Professional qualifications to do research** (including a description of necessary support services and facilities)
- Training** (include a current certificate of completion from a workshop on Research Training based on the type of research performing e.g. Social/Behavioral, Biomedical, Specimens, etc.)
- Title of the study**
- Purpose of the study** (including the benefit obtained by doing the study)
- Sponsor of the study**
- Sponsor FWA number** (include a copy of the OHRP-approval)
- Collaborating Institutions FWA number** (include a copy of the OHRP-approval)
- Results of previously related research**
- Subject selection criteria**
- Subject exclusion criteria**
- Justification for use of special subject populations** (e.g. the intellectually and/or developmentally disabled, pregnant women, children, or prisoners etc.)
- Study design** (including as needed a discussion of the appropriateness of research methods)
- Description of procedures to be performed**
- Provisions for managing adverse reactions**
- Description of how confidentiality will be protected**
- The Circumstances Surrounding a Consent Procedure:**
 - Location
 - Time
 - Condition of subject
 - Subject's autonomy
 - Study personnel that will obtain consent

Elements of Informed Consent:

- A clear and concise statement that the study involves research;
- An explanation of the purpose of the research and the expected duration of the subject's participation;
- A description of the procedures to be followed and identification of any procedures which are experimental and the number of participants;
- A description of any foreseeable risks or discomforts to the subjects;
- A description of any benefits to the subject or others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained (also note that the study sponsor staff from DHHS or staff from the approving IRB may inspect the records);
- An explanation of whether compensation or medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

See Appendix 5 Informed Consent Template for more information.

If applicable, Additional elements of informed consent that may be included:

- A statement that the treatment or procedure may involve unforeseeable risks to the participant, embryo or fetus, if the subject is or may become pregnant;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the research may be related to the subject's willingness to continue participation;

Types and Ways to Document Informed Consent:

- Oral Informed Consent Procedures
- Abbreviated Written Informed Consent
- Written Narrative of Information Provided Orally to Participants or LAR
- Long Written Informed Consent
- Electronic Informed Consent
- Participants receive a copy of the Informed Consent Form or Information
-

Proposed survey instruments, questionnaires or recruitment notices

Changes in study after initiation

- Unexpected serious adverse events/unanticipated follow-ups, if applicable**
- Progress reports, if applicable**
- Final reports, if applicable**

APPENDIX 7: ON-LINE RESOURCES

<https://www.health.ny.gov/professionals/irb/> Department of Health's IRB Web Page

<http://www.fda.gov> Food and Drug Administration Home Page

<http://www.irbforum.org> The IRB Discussion Forum (known as "MCWIRB") promotes the discussion of ethical, regulatory and policy concerns with human subjects research

<http://www.naim.org> National Association of IRB Managers

<http://www.acrpnet.org/> Association of Clinical Research Professionals

<http://www.primr.org> Public Responsibility in Medicine and Research

<http://www.illuminata-inc.com/conteduc.html> A continuing education resource

<http://onlineethics.org> On-line resource addressing ethical issues in research

APPENDIX 8: CONFLICT OF INTEREST POLICY FOR PRINCIPAL INVESTIGATORS AND RESEARCHERS

INTRODUCTION

A conflict of interest, financial conflict of interest, or human subjects' conflict of interest may compromise or have the appearance of compromising, a researcher's professional judgment in conducting, evaluating, or reporting research results. Since such conflicts would affect not only the professional integrity of the individual but also the integrity of the Department of Health, it is necessary that all conflicts be identified and disclosed, plus managed, reduced, or eliminated.

POLICY

- The responsibility for identifying, understanding, and managing a conflict of interest, financial conflict of interest, or human subjects' conflict of interest rests primarily with the researcher.
- Researchers must complete and submit the NYSDOH and HRI DISCLOSURE OF SIGNIFICANT FINANCIAL INTEREST IN RESEARCH PROJECT (NYSDOH Form 3995), when appropriate, to Health Research, Inc.
- Researchers must disclose a conflict of interest to the Institutional Review Board (IRB) upon submission of the research proposal to the IRB for approval. It is understood that such disclosure may affect the IRB's determination regarding the proposal.
- Researchers must make human subjects recruited for research purposes aware of any conflict of interest. This must be done orally upon recruitment and in the consent document. Disclosure of financial conflicts of interests should be noted in the informed consent form found in Appendix 4 of the IRB's **Guidelines**.
- Researchers must follow the disclosure policies as outlined in this document in the section entitled, "DISCLOSURE REQUIREMENTS."
- Failure to disclose a conflict of interest, known by the individual, before or during the conduct of research may result in sanctions for the researcher and closure of the study, to be determined by the IRB and the NYSDOH. (APPM 250.1: Managing Conflicts on Interest in Research)

DISCLOSURE REQUIREMENTS

1. **Disclose financial information to the NYSDOH**-Individuals engaged in research should disclose all financial interests related to research and provide updated information when new financial circumstances may pose a conflict of interest and when grant applications are submitted on the HRI-50.
2. **Disclose financial information to publications**-When individuals engaged in research submit manuscripts for publication; they should disclose any financial interests that they have that are related to the research. Consistent with the policy established by the International

Committee of Medical Journal Editors, publications should print this information so that it is available to the public.

3. **Disclose financial information in oral presentations**-Individuals engaged in research should disclose to their audiences when presenting research results any financial interests that are related to the research on which they are reporting.
4. **Disclose financial information to federal agencies**-Federal regulations announced in the Federal Register on July 11, 1995, require institutions using PHS funds to report to the Department of Health and Human Services (DHHS) the existence of conflicting interests found by the institution and to assure DHHS that the institution has managed, reduced, or eliminated the conflicts prior to the expenditure. NIH and the FDA also require disclosure by researchers.
5. **Disclose financial information in the Institutional Review Board process**-The Institutional Review Board of the New York State Department of Health has jurisdiction over determining whether a relevant financial interest should be disclosed to human participants in research in the consent document. This information should be divulged before the research approval process is undertaken.
6. **Disclose human rights conflicts of interest**-An investigator who cannot maintain objectivity in the conduct of research with human subjects should make the problem known to the Institutional Review Board for determination of whether the investigator should be replaced, or the study closed.

IRB REVIEW OF PROPOSALS FOR CONFLICT OF INTEREST ISSUES

The IRB must be cognizant of the source of funding and funding arrangement for each protocol that they review. In dealing with studies with a conflict of interest or potential conflict of interest, the IRB should consider what modifications might need to be made to the protocol or consent form, and other approaches as appropriate. The IRB will consider the answers to the following questions in its deliberations:

- Who is the sponsor?
- Who designed the study?
- Who will analyze the safety and efficacy data?
- Is there a Data Safety Monitoring Board (DSMB)?
- What are the financial relationships between the Investigator and the sponsor?
- Is there any compensation that is affected by the study outcome?
- Does the Investigator have any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?
- Does the Investigator have equity interest in the company-publicly held company or non-publicly held company?
- Does the Investigator receive significant payments of other sorts? (e.g. Grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria)
- What are the specific arrangements for payment?
- Where does the payment go? To the Institution? To the Investigator?
- What is the payment per participant? Are there other arrangements?

The IRB will carefully consider the specific mechanisms proposed to minimize the potential adverse

consequences of the conflict in an effort to optimally protect the interests of the research subjects. If there are any financial conflicts of interest by the investigator, the investigator should not be engaged in aspects of the proposal that could be influenced inappropriately by that conflict. These aspects could include: the design of the study, monitoring of the study, obtaining informed consent, adverse event reporting, or analyzing the data.

TYPES OF CONFLICT OF INTEREST

Conflict of Interest: An individual, their spouse or dependent children, has a self-perceived private, personal, or professional interest sufficient to have the appearance or potential to influence the objective exercise of his or her official research duties.

Financial Conflict of Interest: An individual is considered to have a financial conflict of interest when any of his or her family (spouse or dependent children) or any associated entity possesses a financial interest in an activity or business which may have an inappropriate influence, or appear to have such an influence, on his or her activities as a researcher.

Human Subject's Conflict of Interest: An individual, their spouse or dependent children, is considered to have a human subject's conflict of interest when the researcher puts the academic premise, the article or journal publication, career advancement, or the satisfaction of accomplishment before the rights and welfare of study subjects. The protection of human subjects requires objectivity in communicating risks, selecting appropriate study subjects, the process of informed consent plus the gathering, analyzing and reporting of data.

The IRB will work closely with Objectivity in Research Committee to address and determine the extent of the Conflict of Interest.

POLICY

It is the policy of the Department and its facilities to maximize adherence to ethical principles and promote objectivity in research by establishing standards of conduct and procedures to eliminate any conflict of interest that would directly and significantly affect the design, conduct or reporting of research. Failure to comply with this APPM Item may lead to disciplinary action against a Department employee or termination of research at the Department.

SCOPE

This policy is applicable to any research that the Department of Health (NYSDOH), including the Department's Health Facilities, is engaged in and to each investigator participating in such research. This item is applicable to Health Research, Inc. employees, and may include all consultants, students, interns, and volunteers.

INFORMATION

The federal government has issued regulations requiring all institutions that apply for and receive research funding to implement and maintain a written, enforced policy on conflict of interest in research that is in compliance with the regulations. This APPM Item, together with the Department's document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards," comprise the Department's policy on financial conflicts of interest. The Department will enforce compliance with this APPM Item and will implement the provisions set out in "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards" by the Department and investigators.

DEFINITIONS

Conflict of Interest means a Reportable Interest that could directly and significantly affect the design, conduct or reporting of research.

Institutional Responsibilities means all professional responsibilities performed in the course of employment.

Investigator means the project director or principal investigator and any other person who is responsible in whole or in part for the design, conduct, or reporting of Research. The term "Investigator" includes the Investigator's spouse and dependent children.

Management Plan means a plan for eliminating, managing, or mitigating an Investigator's Conflict of Interest that the Objectivity in Research Committee determines to exist.

Objectivity in Research Committee means the group designated in accordance with the Department's document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards."

Reportable Interest means an interest the Investigator must disclose on the NYSDOH-3995 form and includes the following:

- A. Reportable Financial Interest means anything of monetary value, whether the value is readily ascertainable, as described below:
1. One or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's professional responsibilities:
 - a. Remuneration received from an entity or its affiliate whose product or process is involved in the Investigator's research or competes with such a product or process, during the twelve months preceding disclosure; or any equity interest in such entity or affiliate more than \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary including honoraria and consulting or speaking fees. An equity interest includes any stock, stock option or other ownership interest.
 - b. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights; and/or
 - c. Payment of the Investigator's travel-related or other expenses that are related to his/her Institutional Responsibilities by such an entity or affiliate.
 2. A Reportable Financial Interest does not include the following interests of the Investigator:
 - a. Salary, royalties, or other remuneration paid by the Department, HRI or through an affiliation agreement such as the one the Department maintains with NYPH;
 - b. Income from publicly traded investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles; or
 - c. Income from seminars, lectures, teaching and service on advisory panels only when the activity is sponsored or paid for only by one or more of the following: a governmental agency, an institution of higher education, an academic teaching hospital or a medical center.
- B. Reportable Non-Financial Interest means any other interest that might reasonably be expected to bias the design, conduct or reporting of research (e.g., when the Investigator or the Investigator's

spouse is an uncompensated board member or officer of an organization that advocates for or against a treatment involved in, or that competes with a treatment involved in, the research, or when the Investigator participated in the design, development, production or marketing of a product or process involved in the research but does not derive a financial interest in connection with the product or process)

Disclosure Obligations of All Investigators

Whenever an Investigator participates in or plans to participate in research, the Investigator shall submit a NYSDOH-3995, which identifies and provides all requested information about each Reportable Interest (financial or non-financial) that the Investigator has:

- A. Before an application for research funding is submitted; and
- B. Subsequently within 15 days of discovering or acquiring a previously undisclosed Reportable Interest.

An Investigator shall comply with a request for additional information about a Reportable Interest made by the relevant Objectivity in Research Committee, Institutional Review Board or the Department.

An Investigator who fails to disclose a Reportable Interest as provided above may be required to receive additional training or be disciplined. If the non-disclosing Investigator is not a Department employee, the Department may take appropriate remedial action, including, when the Department considers it necessary to protect the objectivity of the research, requiring the Investigator to withdraw from the research.

Contents of Agreements Pertaining to Investigators Who Are Not Members of the Department's Workforce (Investigators Outside the Department)

Every contract or other agreement under which an Investigator who is not a member of the Department's workforce (outside Investigator) will have language to ensure that any subrecipient Investigator complies with their institutions financial conflict of interest policy which must be consistent with 42 CFR Part 50 Subpart F and 45 CFR Part 94. The subrecipient shall certify as part of the agreement that its policy complies with the regulation. If the subrecipient cannot provide certification, the agreement shall state that subrecipient Investigators are obligated to comply with the provisions of this APPM Item. Such agreement shall also acknowledge that the non-Department signatory received a copy of this APPM Item and the Department's document entitled "Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards" and that the Department will follow the procedures set forth in such documents. A non-employee Investigator who fails to sign such an assurance shall not be permitted to participate in research in any way.

Training

Each Investigator shall complete the Department's Objectivity in Research Training and receive a copy of this APPM Item. During the training, the Department will inform each Investigator that it will maintain a publicly available web site on which it will promptly post the following information on disclosed Conflicts of Interest: Investigator's name, title and role in connection with the research; the name of the entity in which the Conflict of Interest is held; and the nature of the Conflict of Interest.

In addition, each Investigator is required to complete the National Institute of Health (NIH) Financial Conflict of Interest (FCOI) training tutorial prior to engaging in research related to any grant or contract and at least every four years. To accomplish this, investigators should go to the NIH training website at <http://grants.nih.gov/grants/policy/coi/tutorial2018/fcoi.htm> and follow the instructions. Once the Investigator has completed the tutorial, there is an option to print a certificate. Certificates

should be printed and forwarded to the designated Chair of the Objectivity in Research Committee. It will be the responsibility of each Investigator engaged in research to provide an initial certificate, as well as an updated certificate every four years, to maintain compliance with training requirements.

The Objectivity in Research Committee

A. Determining Whether a Reportable Interest is *Related* to the Research

In accordance with the procedures set out in “Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards,” the relevant Objectivity in Research Committee or its designee(s) shall review each completed NYSDOH-3995 and determine whether the disclosed Reportable Interests are related to the Investigator’s research. If the Committee determines that the Investigator has no Reportable Interest related to a research activity, it shall so inform the Investigator.

An Objectivity in Research Committee shall, at minimum, consider the following factors in determining whether a Reportable Interest is related to the Investigator’s research:

- Whether the Reportable Interest could be affected by the research; and
- Whether the research could affect the entity in which the Investigator has a Reportable Interest.

B. Determining Whether a Related Reportable Interest Creates a Conflict of Interest

When the Objectivity in Research Committee or its designee(s) determines that an Investigator’s Reportable Interest is related to research in which the Investigator is participating, such Committee or designee/s, shall determine whether the related Reportable Interest constitutes a Conflict of Interest. The Objectivity in Research Committee shall make such a determination before any funds are expended on the affected research, other than funds expended exclusively to prepare an application for approval of the research or to obtain funding for the research. If the Committee determines that the related Reportable Interest is not a Conflict of Interest, it shall so inform the Investigator.

An Objectivity in Research Committee shall determine that an Investigator has a Conflict of Interest when a related Reportable Interest could reasonably be expected to directly and significantly affect the design, conduct or reporting of the research. Such determination shall be made based on objective factors, not on the Investigator’s character, reputation or past conduct. The Objectivity in Research Committee may consider any information it deems relevant to its inquiry, and the Investigator shall cooperate fully with the Committee’s inquiries into the Investigator’s interests and research.

C. Timing of Determinations Concerning New, Amended or Unreviewed Disclosures

When an Investigator discloses a Reportable Interest after the initiation of the research, the Department otherwise becomes aware of such Reportable Interest, or the Department becomes aware that an Objectivity in Research Committee has not previously determined whether the Reportable Interest constitutes a Conflict of Interest, the relevant Objectivity in Research Committee shall, within 60 days of such disclosure or discovery, determine whether the Reportable Interest constitutes a Conflict of Interest.

D. Responsibilities Following a Finding that an Investigator Has a Conflict of Interest

Whenever an Objectivity in Research Committee finds that an Investigator has a Conflict of Interest, it shall manage that conflict through the development, implementation, monitoring and enforcement of a Management Plan.

Management Plans: In developing a Management Plan, the Objectivity in Research Committee may act on its own or in conjunction with the Investigator or another person. The Management Plan must state the specific actions to be taken and the person or organization responsible for each such action. The Objectivity in Research Committee shall require implementation of all the actions which, in its judgment, will eliminate or mitigate the bias that the identified Conflict of Interest has had or is likely to have on the design, conduct or reporting of the research. The following are examples of actions that an Objectivity in Research Committee may consider in preparing a Management Plan; they are not intended to be prescriptive or exclusive:

- Require public disclosure of Conflicts of Interest (e.g., when publishing or presenting the research or disclosure of Conflicts of Interest directly to human subjects involved in the research);
- Appoint an independent monitor empowered to take measures to protect the design, conduct or reporting of the research from bias;
- Modify the plan for conducting or reporting the research;
- Replace the Investigator, change his/her responsibilities for designing, conducting or reporting the research, or disqualify the Investigator from participating in all or part of the research;
- Reduce or eliminate the Reportable Interest;
- Require the Investigator to sever the relationship causing the Conflict of Interest.

A Management Plan that relates to federally-funded research shall require the Investigator to disclose each Conflict of Interest in each publication and presentation of the research and to request an addendum to previously published reports of the research to disclose such Conflict of Interest when the research was conducted to evaluate the safety or effectiveness for humans of a drug, medical device or treatment and the Department did not manage or report the Investigator's Conflict of Interest to the federal government.

Each Management Plan will include a plan by which the Department will monitor the Investigator's compliance with the Management Plan.

The Investigator must be given the opportunity to sign the Management Plan approved by the Objectivity in Research Committee. By signing the Management Plan, the Investigator agrees to comply with all its terms and the requirements of this APPM Item. A Management Plan concerning federally-funded research will be modified if required by the federal government even if the Investigator had agreed to the pre-modified Management Plan.

E. Consequences and Actions Following an Investigator's Failure to Sign or to Comply with a Management Plan:

An Investigator's failure to sign or his/her substantial non-compliance with a Management Plan, as determined by the Objectivity in Research Committee and/or the Investigator's supervisor, will result in disciplinary action for an Investigator who is a Department employee. Refusal to sign the Management Plan or non-compliance with a signed Management Plan by an Investigator, whether or not a researcher is a Department employee, can result in requiring the Investigator to withdraw from all or a part of the research. In the case of an Investigator, who is not a Department employee, research will be removed from the Department. The decision to require removal of the research from the Department must be approved by the Commissioner of Health or his/her designee.

PROCEDURES

Principal Investigator (PI)

1. Whenever an application for research funding is submitted,

completes and submits the NYSDOH-3995 form, which requires disclosures of Reportable Interests, as defined herein, applicable to the research project that he/she is proposing. The PI is responsible for assuring that any other Investigator involved with the project also completes the form.

2. Includes the completed form in the standard application package that is processed for NYSDOH and/or HRI approval.
 3. Files the completed form in the application file, if no Reportable Interest is reported.
 4. If a Reportable Interest is reported, forwards application to the appropriate Objectivity in Research Committee.
 5. Determines whether the Reportable Interest is related to the research and, if so, whether it constitutes a Conflict of Interest. If there is no Conflict of Interest, notifies the PI and grants administrator in writing.
 6. If there is a Conflict of Interest, develops a Management Plan to manage, reduce, or eliminate the Conflict of Interest. When a Management Plan has been agreed to, notifies any parties that will have a role in the plan and identifies the individual (usually the PI's supervisor) who is responsible for any oversight or monitoring required. Sends a copy of the Management Plan to the grant administrator.
 7. Sends a copy of the Management Plan to the PI.
 8. If in disagreement with the Objectivity in Research Committee, notifies the Center or Division Director of the disagreement and the reasons for the disagreement.
 9. Evaluates all information provided by the Objectivity in Research Committee and decides upon appropriate course of action. If necessary, modifies the Management Plan in a manner that is acceptable to the Objectivity in Research Committee.
 10. When the PI and other Investigators, if any, have agreed to the final Management Plan and it is signed by the PI, sends a copy of the final Management Plan to the grant administrator.
 11. Files the final Management Plan in the grant file. If an award is made, notifies the granting agency of the existence of a Conflict of Interest and provides assurance that the conflict is being managed, reduced or eliminated. If a Management Plan has not been agreed to, withdraws the application from further consideration.
- Grant Administrator (NYSDOH or HRI)
- Objectivity in Research Committee
- Principal Investigator
- Center or Division Director
- Grant Administrator

UPON OCCURRENCE OF A CONFLICT OF INTEREST AFTER RESEARCH IS INITIATED

- | | |
|-----------------------------------|--|
| Principal Investigator | 1. Reports Reportable Interest when it occurs, but not later than 15 calendar days after the occurrence, by filing form NYSDOH-3995 with the grant administrator. |
| Grant Administrator | 2. Forwards Form NYSDOH-3995 to the Objectivity in Research Committee. |
| Objectivity in Research Committee | 3. Proceeds with steps 5-7 above Management Plan must be developed and agreed to within 60 days. |
| Grant Administrator | 4. If a Management Plan has been agreed upon, notifies the granting agency of the existence of conflict and provides assurance that the conflict is being managed, reduced or eliminated. If a plan has not been agreed upon, notifies the sponsor that the grant will be terminated |

**DEPARTMENT OF HEALTH AND HEALTH RESEARCH, INC.
DISCLOSURE OF REPORTABLE INTEREST IN RESEARCH PROJECT**

Investigator: _____
Project: _____ Date: _____

I, my spouse, and my dependent children,

HAVE

DO NOT HAVE

A Reportable Interest. Attach a detailed description of the Reportable Interest, if applicable

Reportable Interest means:

A. Financial Interest:

1. one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's professional responsibilities:
 - a. Remuneration (including any payment) received from an entity or its affiliate whose product or process is involved in the Investigator's research or competes with such a product or process, during the twelve months preceding disclosure; or any equity interest in such entity or affiliate in excess of \$5,000;
 - b. Intellectual property rights (e.g., patents, copyrights) related to such an entity or affiliate; and/or
 - c. Payment of the Investigator's travel-related or other expenses by such an entity or affiliate.
2. A Reportable Interest does not include the following interests of the Investigator:
 - a. salary paid by the Department or HRI;
 - b. income from publicly traded investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; or
 - c. income from seminars, lectures, teaching and service on advisory panels or reimbursement of expenses from a governmental agency or an institution of higher education; or

B. Non-Financial Interest: any other interest that might reasonably be expected to bias the design, conduct or reporting of research (e.g., when the Investigator or the Investigator's spouse is an uncompensated board member or officer of an organization that advocates for or against a treatment involved in, or that competes with a treatment involved in, the research, or when the Investigator participated in the design, development, production or marketing of a product or process involved in the research but does not derive a financial interest in connection with the product or process).

I certify that the information provided herein is factual and complete, and agree to immediately report to the grant administrator any Reportable Interest that occurs hereafter during the term of this research project.

Signature: _____ Date: _____

NYSDOH-3995 (revised 8/2012)

NEW YORK STATE DEPARTMENT OF HEALTH INSTITUTIONAL RESPONSIBILITIES TO IMPLEMENT AND ENFORCE OBJECTIVITY IN RESEARCH STANDARDS

Application: Compliance with this set of procedures is mandatory for every institution and employee engaged in research. Together, this document and APPM Item 250.1 constitute the written and enforced policy required by 42 C.F.R. Part 50, subpart F and 45 C.F.R. Part 94.

Definitions

The definitions contained in APPM Item 250.1, which is attached, are adopted by reference. Defined terms are capitalized in this document.

Senior/Key Person for a research project means the project director or principal investigator and any other person whom the Department identifies as “senior/key personnel” or equivalent in any grant application, progress report or other report the Department submits to the PHS, the National Science Foundation or any other funding source.

Objectivity In Research Committees

Each institution at which research is planned or conducted and each division of the Department with employees who engage in research will have an Objectivity in Research Committee to perform the tasks APPM Item 250.1 sets out for such a committee and any other responsibilities assigned to it. One or more such institutions or Departmental divisions may have a joint Objectivity in Research Committee.

The director of each such institution and Departmental division shall appoint the members of the Objectivity in Research Committee and shall approve their written operating procedures. These responsibilities shall be performed cooperatively by the relevant directors in the case of joint Objectivity in Research Committees.

The written operating procedures of each Objectivity in Research Committee shall, at a minimum, establish the following:

- The number of persons to serve on the Committee, which should be an odd number, and the length of each term of service, including the initial terms of the original committee members established to achieve staggered terms if that outcome is desired;
- The number of persons needed to constitute a quorum;
- That a quorum is needed to determine whether a Reportable Interest is a Conflict of Interest, approve a management plan, determine whether an Investigator is not in substantial compliance with a management plan, and determine the sanctions to be imposed on an Investigator for failing to disclose a Reportable Interest in accordance with the schedule set out in APPM 250.1 or to be in substantial compliance with a management plan;
- Rules defining a conflict of interest for members of the Objectivity in Research Committee and governing members’ recusal from matters pending before the Committee due to such a conflict of interest.

Retrospective Reviews

The relevant Objectivity in Research Committee or other persons designated by the director, as applicable, shall undertake a retrospective review whenever one of the following events occurs:

- An Investigator does not disclose a Reportable Interest in accordance with the schedule for such disclosures set out in APPM Item 250.1 and the Objectivity in Research Committee determines it is a Conflicted Interest;

- The Objectivity in Research Committee does not review and make a determination in accordance with the relevant schedule set out in APPM Item 250.1 about whether a disclosed Reportable Interest is a Conflicted Interest;
- The Objectivity in Research Committee does not establish a management plan when one is required by APPM Item 250.1;
- The Objectivity in Research Committee does not determine whether an Investigator's failure to comply with a management plan constitutes substantial non-compliance;
- The Investigator is not in substantial compliance with a management plan to which he/she agreed; or
- The Objectivity in Research Committee or the Department, as relevant, does not take any action to enforce the Investigator's compliance with a management plan following such Committee's finding that the Investigator is not in substantial compliance with the Plan.

When the Objectivity in Research Committee's failure to act triggers the retrospective review, such review shall be performed by persons designated by the director who are not Committee members.

Each retrospective review will be completed within 120 days from when the non-compliance requiring the review is identified.

The purpose of the retrospective review is to determine whether, during the period of non-compliance, any of the affected research was biased in its design, conduct or reporting. The Objectivity in Research Committee or the director's designee, as applicable, shall document every retrospective review. Such record shall include at least the following:

- Project number;
- Project title;
- Project director or principal Investigator or where there is more than one such person, the contact project director or contact principal investigator;
- Name of the investigator with the Conflict of Interest;
- Name of the entity with which the investigator has a Conflict of Interest;
- Reason(s) for the retrospective review;
- Detailed description of the methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review;
- Conclusions of the review; and
- Where bias is found to have affected the design, conduct or reporting of research, a detailed action plan to eliminate or mitigate the effect of such bias.

Public Access to Information

The Department will post APPM 250.1 and this document (Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards) in a readily identifiable section of its public web site. The web site will state that taken together, these two documents comprise the Department's written, enforced policy required by 42 C.F.R. Part 50, subpart F and 45 C.F.R. Part 94.

The Department will also post the information set out in this section in the same readily identifiable portion of its public web site or provide this information to any person within five days of the Department's receipt of a written request for it. The public must have access to such information, by means of posting on a public web site or response to a written request, before any funds are expended in connection with the affected research.

The public shall have access to a record of an investigator's disclosed Conflicts of Interest where the Investigator is a Senior/Key Person and still holds the interest. The publicly accessible record shall include, at minimum, the investigator's name, title and role in connection with the research; the name of the entity in which the Financial Interest is held; the nature of the Conflict of Interest; and the amount of the Financial Interest, which may be reported by ranges, or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Information described in this section that is posted on the Department's web site must be updated in accordance with the following schedule:

- Annually;
- Within 60 days of when the Objectivity in Research Committee determines that a previously undisclosed interest of a Senior/Key Person is a Conflicted Interest;
- Within 60 days of when the Objectivity in Research Committee determines that an interest of a Senior/Key Person new to the research creates a Conflict of Interest.

Whether the publicly accessible information described in this section is provided on a web site or by written response to requests, the Department shall state the date as of which the information is current and describe the schedule for updating such information as set forth above. The Department shall retain such publicly accessible information for at least three years following the date on which it was most recently updated.

PHS Access to Information

The Department will promptly make available to the United States Department of Health and Human Services, PHS and the National Science Foundation all information in the Department's possession or to which it has a legal right that relates to any matter covered by APPM Item 250.1 or this Institutional Responsibilities to Implement and Enforce Objectivity in Research Standards document.

Reporting to PHS

This section on submitting reports to PHS applies **only** when **both** an Investigator's Reportable **Financial** Interest is at issue **and PHS-funded research** is involved.

Records Retention: With respect to Investigators working on PHS-funded research, the Department must retain all Investigators' NYSDOH-3995 forms, the findings of the Objectivity of Research Committees concerning the Reportable Financial Interest on each such form, and all actions such Committees and Department management take pursuant to APPM Item 250.1 for at least three years from the date the final expenditures report for the research is submitted to the PHS or, where, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, unless federal law supplies a different records retention rule.

Contents of Financial Conflict of Interest Reports: Each Financial Conflict of Interest report, whether the initial report for a research project or supplemental reports, shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of the relevant management plan. At minimum, such reports shall include the following:

- Project number;
- Name of the project director or principal investigator or, if more than one such person
- has been identified for a research project, the contact project director or principal
- investigator;
- Name of the investigator with the Financial Conflict of Interest;

- Name of the entity with which the investigator has a Financial Conflict of Interest;
- Nature of the Financial Interest the investigator has in the entity (e.g., equity, debt/bond, consulting fee, travel reimbursement, honorarium);
- Value of the Financial Interest the investigator has in the entity, which may be by ranges, or a statement that the value of the Reportable Financial Interest cannot be readily determined by reference to public prices or other reasonable measures;
- Description of how the Reportable Financial Interest relates to the PHS-Funded research and the basis for the Objectivity in Research Committee's determination that the Reportable Financial Interest conflicts with such research;
- Description of the key elements of the institution's management plan, including: the conflicted investigator's role and principal duties in the research, the conditions and requirements contained in the management plan, how the management plan is designed to safeguard objectivity in the research, confirmation of the investigator's agreement to the management plan, how the management plan will be monitored to ensure the investigator's compliance, and other information as needed.

Initial Financial Conflict of Interest Reports: Before any PHS-awarded funds are expended on a research project, the Department will make Financial Conflict of Interest reports to the PHS Awarding Component concerning any Financial Conflict of Interest the Objectivity in Research Committee determines an Investigator involved in such research has. The report shall include an assurance that the institution has implemented a management plan in compliance with APPM Item 250.1. The Department will not submit a Financial Conflict of Interest report when the investigator's Financial Conflict of Interest has been eliminated before the expenditure of any PHS-awarded funds.

Supplemental Financial Conflict of Interest Reports: When, subsequent to the expenditure of any PHS funds on a research project, the Objectivity in Research Committee finds that an investigator has a previously unidentified Financial Conflict of Interest, the Department will submit a Financial Conflict of Interest report to the relevant PHS awarding component within sixty days of such finding. The Department will also submit supplemental Financial Conflict of Interest reports to the relevant PHS awarding component in the following situations:

- Following a retrospective review, when appropriate, to specify the actions to be taken to manage the Financial Conflict of Interest going forward; and
- Annually for the duration of the PHS-funded research, including extensions with or without funds, with respect to any Financial Conflict of Interest previously reported to the PHS awarding component, which addresses the status of the Financial Interest and any changes to the management plan. The annual update shall state whether the Financial Conflict of Interest is still being managed or explain why the Financial Conflict of Interest no longer exists. The Department will comply with instructions from the PHS awarding component concerning the content and submission of these reports.

Mitigation Reports: Where bias is found through a retrospective review or otherwise, the Department will promptly notify and submit a mitigation report to the PHS Awarding Component, which must include, at minimum, the required elements of the record documenting the retrospective review set forth above as the second bulleted list under "Retrospective Review," a description of the impact of the bias on the research, and the Department's plan describing the action(s) to be taken to eliminate or mitigate the effect of the bias. The plan of action should address the impact of the bias on the research; the extent of any harm that has or is likely to occur, including any qualitative or quantitative data supporting any actual or future harm; and an analysis of whether the research project is salvageable.

APPENDIX 9: CONFLICT OF INTEREST POLICY FOR INSTITUTIONAL REVIEW BOARD MEMBERS AND ALTERNATES

Introduction

The purpose of this policy is to outline an approach that will foster both the conduct of unbiased review of research proposals and trust in the judgment of each individual reviewer by the identification and management of an actual or perceived conflict of interest by members of the Institutional Review Board of the New York State Department of Health. It is recognized that conflicts of interest can arise naturally from the Board member's engagement with the internal and external world and does not necessarily imply wrongdoing on anyone's part. It is, however, necessary for conflicts of interest to be recognized, disclosed, and eliminated.

Board Member Responsibilities Disclosure

Acknowledgement of a conflict of interest to the IRB Chair by a Board member or acknowledgement of a conflict of interest by the IRB Chair to the Board is mandatory. Such disclosure can be made prior to the next scheduled meeting, when asked to be a Principle Reviewer on a study, or upon the commencing of the full Board meeting.

Administrative Documentation

The minutes of a Board meeting must reflect the fact that a Board member was excused from discussing or voting on a research project with an acknowledged conflict of interest.

Meeting Procedure

The IRB members present at a Board meeting with an acknowledged conflict of interest regarding a research proposal cannot take part in the initial or continuing review of such proposal. The IRB member must be excused from the room prior to the discussion or voting on such proposal. The minutes should reflect the fact that the IRB member was out of the room for the discussion and vote. The IRB member may present factual information, without bias, to the IRB regarding the subject matter of the proposal if such information would assist in their decision-making process regarding the proposal.

Subsequent Discovery of A Conflict Of Interest

Discovery of an actual conflict of interest after a study has been approved and is active will result in the study being closed until it can be reviewed at the next Board meeting by a quorum of the members, barring the member with the conflict of interest. Should the study be approved once again, the study can resume. The IRB Chair will decide, after discussion with the Board, whether the member (failing to disclose the conflict of interest) should be removed from the Board for nondisclosure or should remain on the Board due to an unintentional violation. The Commissioner of Health will be advised if the Board member is removed for nondisclosure and will decide if further departmental actions should be taken.

Definitions

IRB Member: Any individual serving as a member of the Institutional Review Board that has been established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the New York State Department of Health.

Conflict of Interest: A situation in which a Board member has a self-perceived private, personal, financial, or professional interest sufficient so as to have the appearance or potential to influence the objective exercise of his or her official duties. It is not necessary for the member to reveal the reason for the conflict of interest; just that one does exist. Common indicators of a conflict of interest include:

the IRB member is a Principal Investigator or Key Personnel employee of the study being reviewed, has a financial interest in the conduct of the project, or would not be able to put the rights and welfare of the human subjects first due to a personal interest.

IRB members or consultants are defined when they have a conflicting interest as follows:

- Immediate Family means Spouse and Dependent children.
- “Financial Interest Related to the Research” means financial interest in the sponsor, product or service being tested.
- The definition considers non-financial issues.
- The definition is at least as stringent as the level of a researcher’s financial interest that requires evaluation as a possible conflict of interest.
- Involvement of the IRB member, consultant, or their immediate family in the design, conduct, or reporting of the research.

A financial conflict of interest means consisting of one or more of the following interests of the IRB member (and those of the IRB member’s spouse and dependent children) that reasonably appears to be related to the IRB or EC member’s institutional responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. (For purposes of this definition, remuneration includes salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices or other measures of fair market value);
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000 or when the IRB member (or the IRB or EC member spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interest (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

Appearance of Conflict of Interest: A situation in which a conflict of interest may appear to exist when in fact one does not. Since the appearance of a conflict of interest can call into question the integrity of the Board and the Department of Health, it is important that the Board member make the decision on whether to be removed from review of the study with the same rigorous evaluation process as a potential conflict.

APPENDIX 10: INSTITUTIONAL CONFLICT OF INTEREST

Introduction

New York State Department of Health (NYSDOH) and Health Research, Inc. (HRI) have an obligation to the people of the State of New York and to the public to conduct its/their activities properly. Accordingly, NYSDOH/HRI must provide clear standards aimed at preventing financial conflicts of interest from compromising its objectivity in the performance of its responsibilities. This policy on Institutional Conflict of Interest (the “Policy”) concerns conflicts that arise from NYSDOH/HRI’s financial relationships with external entities. It is intended to provide guidance to the NYSDOH/HRI staff to enable them to recognize and deal with institutional conflicts of interest, both real and perceived, that may arise during relationships between NYSDOH as an institution and private outside entities.

Consistent with its obligation to uphold the public trust, NYSDOH is committed to extending the reach of its research and public health activities. NYSDOH’s mission of research and service is well served through the creation of collaborations with people and entities outside of NYSDOH that are better able to meet the challenges of an increasingly complex world. Collaboration, particularly where external financial sponsorship is involved, may result in the creation of inherent tensions between NYSDOH’s role as a public health facilitator and the interest of the parties to the collaboration in achieving a positive outcome. Where such tensions have or appear to have the potential to interfere with independent decision making on the part of NYSDOH staff, or to compromise the objectivity of research, NYSDOH must examine whether a conflict of interest exists.

Such conflicts of interest may be conflicts of interest involving the personal financial relationships of NYSDOH employees with entities that conduct business with NYSDOH. Individual financial conflicts of interest are regulated by the *Policy on Conflicts of Interest* and generally are outside the scope of this Policy except in cases where NYSDOH employees with administrative authority possess personal financial interests that intersect with their official NYSDOH duties. In addition, this Policy does not address nor attempt to regulate ideological differences that may arise in, and that may in fact be necessary.

This Policy defines institutional conflicts of interest, provides examples and sets out rules for the guidance of NYSDOH/HRI staff. It is hoped that by increasing awareness of the potential for such conflicts and providing a process to address them, this Policy will both protect the integrity of NYSDOH/HRI and will encourage NYSDOH research staff to enter into and conduct research activities involving engagement with outside entities with transparency, confidence and integrity.

Definitions

Institutional Conflict of Interest: An institutional conflict of interest exists where a financial relationship between NYSDOH/HRI and an external entity compromises the integrity of institutional decision making. Such conflicts may arise in situations where 1) NYSDOH/HRI enters into a financial or business relationship at the institutional level with an external entity that may bring financial gain to the institution or any of its units; or 2) a NYSDOH/HRI staff member holds administrative or decision-making authority of such a scope that NYSDOH cannot engage in a questioned activity or relationship independent of his or her involvement, and at the same time that person has personal financial interests that relate to the proposed activity or relationship. For purposes of application of this Policy, such personal financial interests may be deemed to be NYSDOH financial interests.

Institutional conflicts of interest may involve a NYSDOH activity carried out in the pursuit of

NYSDOH's mission. Of concern are conflicts that arise in the conduct of research involving human subjects, but any activity in which the judgment of those involved becomes affected by NYSDOH financial relationships may lead to a violation of this Policy.

NOTE: For purposes of this Policy, personal financial interests shall include anything of monetary value, including salary or other payments for services, equity interests, and intellectual property rights of the NYSDOH Staff or of his or her family members. (*Family members shall include dependent children or spouse. Spouse shall include a person with whom the employee lives together in the same residence and with whom the employee shares responsibility for each other's welfare and shares financial obligations.*) Interests in mutual funds where the NYSDOH employee has no control over the selection of holdings shall not be considered a personal financial interest under this Policy.

Covered Individuals

This Policy covers all NYSDOH staff who are in a position to make decisions for NYSDOH that affect the following:

- the conduct of research, especially research involving human subjects,
- the use of NYSDOH resources, including decisions involving expenditures, purchasing, investments, equity and technology transfer,
- the execution of contracts and grants, or
- the licensing of NYSDOH intellectual property to external parties.

NYSDOH Staff who hold Executive positions or are IRB Members should be especially vigilant.

POLICY

It is the Policy of NYSDOH that in pursuing its mission NYSDOH must conduct its business free of improper influence resulting from external institutional financial relationships.

Potential institutional conflicts of interest must be identified promptly and resolved appropriately. NYSDOH must strive to isolate decisions involving NYSDOH research from decisions regarding the management of financial investments made by or on behalf of NYSDOH/HRI.

In determining whether a potential institutional conflict of interest in fact constitutes an impermissible institutional conflict of interest, NYSDOH will employ the following test: a financial relationship with an external entity will give rise to an impermissible institutional conflict of interest when the objectivity of the decision making process or the allocation of resources is influenced in ways that (1) compromise the integrity of NYSDOH in fulfilling its mission, and (2) would not occur but for the expectation of financial gain to one if NYSDOH's internal units from an anticipated external financial relationship.

Collaborations with external entities and public engagement in general are NYSDOH's strategic objectives. This Policy regulates those collaborations that may be determined to be actual institutional conflicts of interest. A relationship that may initially appear to result in an institutional conflict of interest may not in fact do so. Determining whether such a conflict exists requires careful consideration of all available relevant information.

POLICY IMPLEMENTATION

Strategies for Resolution of Potential Institutional Conflicts

Potential institutional conflicts of interest may be resolved in a variety of ways, including but not limited to the following mechanisms:

(1) Where NYSDOH proposes to conduct business with an entity with which it has a financial

relationship, the entire transaction between the parties must be included in a written contract or Memorandum of Understanding (MOU). Inclusion of all points of agreement between NYSDOH and the entity is critical to avoiding the appearance, whether or not warranted, that NYSDOH may have conferred improper benefits on an entity with which it has a financial relationship.

(2) Where a contract or MOU is appropriate to the relationship, such contracts or MOUs should be awarded through use of transparent procedures for solicitation and award of contracts, such as those used by the Office of the State Comptroller or HRI's Office of Subcontracts. However, this approach may not be feasible.

(3) All covered individuals must report any potential institutional conflict of interest arising from their personal financial interests to their immediate supervisors at the earliest opportunity. Where such a potential institutional conflict meets, the test set forth above, employees should, where feasible, recuse themselves from involvement in NYSDOH business involving entities with whom those officers have financial relationships. An employee's supervisor must concur in the employee's decision to recuse himself or herself. In some cases, it will be impossible for officers to recuse themselves and conduct their research duties effectively, and in such instances, they must divest themselves of the personal financial interest creating the institutional conflict. Both the disclosure to the employee's supervisor and the decision to recuse or divest should be documented.

(4) In all instances, NYSDOH must segregate decisions involving the management of its investments and the solicitation of contributions from decisions regarding NYSDOH research that is or may be affected by those investments or contributions.

Procedures for Reporting Concerns of Potential Institutional Conflicts

Any NYSDOH employee who has concerns about the permissibility of any relationship or activity on the part of NYSDOH involving an external relationship should consult the Conflict of Interest Officer. If, after examination of the situation, the Conflict of Interest Officer determines that a potential institutional conflict of interest may exist or that a situation poses significant potential for public perception of an institutional conflict of interest, the Conflict of Interest Officer shall refer the matter to the Objectivity in Research Committee.

The committee shall evaluate potential conflicts of interest that are referred by the Conflict of Interest Officer. Following evaluation, the committee shall make a recommendation concerning the disposition of the potential institutional conflict of interest.

Any use of this Policy to report in bad faith an alleged potential institutional conflict of interest shall be a violation of this Policy. Any act of retaliation or reprisal against an individual for reporting in good faith a potential institutional conflict of interest or a breach of this Policy shall be found in violation of this Policy. Such violations will be dealt with through regular administrative processes.

Examples of Institutional Conflict of Interest

Financial relationships with external entities give rise to impermissible institutional conflicts of interest when, in the interests of financial gain to NYSDOH's internal units, the objectivity of the decision-making process or the allocation of resources is influenced in ways that (1) compromise the integrity of fulfilling NYSDOH's mission, and (2) would not occur but for the existence of the external financial relationship.

The following examples are not intended to be exhaustive.

Examples of Institutional Conflict of Interest:

1. Seeking to influence the NYSDOH research review committee (Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB)) to grant concessions or exceptions in reviewing or monitoring a research project.
2. Seeking to influence the NYSDOH research review committee (IACUC or IRB) to grant concessions or exceptions in reviewing or monitoring a research project sponsored by an external entity in which NYSDOH or HRI has a financial interest.
3. Where a NYSDOH employee has made a personal financial investment in a NYSDOH Staff Member's start-up company, involvement by that official in decisions affecting the terms and conditions of that NYSDOH Staff Member's NYSDOH employment.
4. Where a IRB Member has made a personal financial investment in a NYSDOH Staff Member's start-up company, involvement by that IRB Member in decisions affecting the terms and conditions of NYSDOH research or business relationships with that start-up company.

APPENDIX 11: SPECIAL PROCEDURES FOR HUMAN SUBJECTS RESEARCH

All human subjects research protocols submitted for regular or expedited review to any IRB must indicate 1) the nature and source of all drugs, devices or biologics to be used in the proposed research, 2) the source of all funding and 3) whether the proposed project involves the use of an invention or technology that is owned by NYSDOH/HRI or has been invented by a NYSDOH/HRI employee.

The IRB shall refer a proposed research project to the Conflict of Interest Officer for further review under this Policy where:

- (1) The proposed research studies involve an invention or technology owned by NYSDOH or invented by a NYSDOH/HRI employee.

APPENDIX 12: HIPAA – NYSDOH COVERED PROGRAMS

Covered Programs means the components of the Department of Health that perform Covered Functions, including:

- A. Medicaid Program, including:
 - (i) Medicaid; Family Health Plus; and Medicaid Managed Care
 - (ii) Medicaid; Family Health Plus; and Medicaid Managed Care
 - (iii) Family Planning Extension Program (FPEP)
 - (iv) Patient Review Instrument (PRI) Unit
 - (v) HIV Special Needs Plan
 - B. Child Health Plus
 - C. Elderly Pharmaceutical Insurance Coverage (EPIC) Program
 - D. Adult Cystic Fibrosis Assistance Program (ACFAP)
 - E. American Indian Health Program (AIHP)
 - F. HIV Uninsured Care Programs
 - (i) AIDS Drug Assistance Program (ADAP)
 - (ii) ADAP Plus (Primary Care)
 - (iii) HIV Home Care Program
 - G. Health Facilities Management and State operated facilities:
 - (i) Helen Hayes Hospital and Nursing Home
 - (ii) Veterans' Home at Batavia
 - (iii) Veterans' Home at Montrose
 - (iv) Veterans' Home at Oxford
 - (v) Veterans' Home at St. Albans
 - H. Lead Poisoning/Trace Elements Laboratory within the Wadsworth Center
- Non-Covered Programs means the remaining components of the Department of Health that do not perform Covered Functions, including, but not limited to, all the programs that function as a Health Oversight Agency or Public Health Authority.

APPENDIX 13: IRB APPROVAL CONDITIONS & INVESTIGATOR'S RESPONSIBILITY

NEW YORK STATE DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD (IRB)

IRB APPROVAL CONDITIONS & INVESTIGATOR'S RESPONSIBILITY

In accordance with the NYSDOH's policies and procedures, filed with the Office for Human Research Protections, Federalwide Assurance, it is the responsibility of all researchers and study personnel to comply with the following:

- This approval applies only to the protocol referenced in the attached letter. If you have any questions concerning the determinations, you have the option of requesting further review by the IRB. The IRB may request a full review to reconsider any protocol approved under expedited review. You agree to abide by the decisions of the IRB.
- Research studies have the resources necessary to protect participants:
 - Adequate time for the researchers to conduct and complete the research;
 - Adequate number of qualified staff;
 - Adequate facilities;
 - Access to a population that will allow recruitment of the necessary number of participants;
 - Availability of medical or psychosocial resources that participants may need because of the research.

For the safety of participants to be appropriate, the IRB may determine that the research plan makes adequate provisions for data and safety monitoring. The IRB might consider provisions such as:

What safety information will be collected, including serious adverse events.

How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

- The frequency of data collection, including when safety data collection starts.
 - The frequency or periodic review of cumulative safety data.
 - The plan might include use of the NYSDOH Data Protection Review Board and a plan for reporting data monitoring committee findings to the IRB and the sponsor, including the frequency of reporting.
 - For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB needs to carefully review the data and safety monitoring plan and determine whether the NYSDOH Data Protection Review Board is needed.
 - If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring;
 - Provisions for the oversight of safety data (e.g., by the Data Protection Review Board).
 - Conditions that trigger an immediate suspension of the research, if applicable.
- Researchers **MUST** be cognizant that when following Department of Defense regulations, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or

tests” shall NOT be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

- When following Department of Defense regulations, the IRB considers the appointment of a research monitor:
 - Required for research involving greater than minimal risk, although the IRB can require this for a portion of the research or studies involving no more than minimal risk if appropriate.
 - The research monitor is appointed by name and shall be independent of the team conducting the research.
 - There may be more than one research monitor (e.g. if different skills or experience are needed).
 - The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.
 - The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.
 - The duties of the research monitor are determined on the basis of specific risks or concerns about the research.
 - The research monitor can "take any steps to protect the safety and well-being of participants until the IRB can assess.
- May perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).
- May discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
- Report observations and findings to the IRB or a designated official.
 - The research monitor has the authority to:
 - Stop a research study in progress.
 - Remove individuals from study.
- You acknowledge and accept your responsibility to protect the rights and welfare of human research participants, and for complying with all applicable federal, state and local regulations, including but not limited to: Code of Federal Regulations (CFR) Title 45 CFR Part 46, HIPAA, NYS Law, NYSDOH policies and procedures and IRB guidelines*.
- All study staff have received the required human subjects protection training provided by the IRB, or other appropriate institution, prior to conducting your research, and understand the ethical principles articulated in the Belmont Report. (The Belmont Report can be obtained on the website: <http://ohsr.od.nih.gov/guidelines/belmont.html>). Training must be updated periodically. It is the responsibility of the principal investigator to ensure that all study staff possess a current and valid training certificate. If a training certificate expires before completion of the study, all study activities must cease until an updated training certificate has been obtained.
- You are to provide a copy of the IRB approved informed consent document to each participant at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents (and research records) are to be retained in a manner approved by the IRB.

- You will promptly report proposed changes/modifications to approved studies to the IRB. The changes will not be initiated without IRB review and approval.
- You must immediately report to the IRB any adverse events (injury, unanticipated problems, continuous anticipated problems, subject complaints, etc.) that arise in connection with your use of human subjects and follow up with actions taken.
- All approved studies are subject to compliance audits as the IRB sees fit.
- The continuation of research after expiration of IRB approval is a violation of federal regulations. There are no provisions for any grace period beyond the termination date. If IRB approval has expired, research activities must stop, and no new subjects may be enrolled in the study, until IRB review and approval has been obtained.

APPENDIX 14: ESSENTIAL REQUIREMENTS FOR ENVIRONMENTAL PROTECTION AGENCY, DEPARTMENT OF EDUCATION & DEPARTMENT OF DEFENSE – SPONSORED RESEARCH

Environmental Protection Agency

The following are essential requirements when conducting research sponsored by the Environmental Protection Agency.

- EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
- The EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.
- EPA policy requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.
- For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
 - EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

The EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

Department of Education

The following are essential requirements when conducting research sponsored by the Department of Education.

- Access to instructional material used in a research or experimentation program:
 - All instructional material--including teachers' manuals, films, tapes, or other supplementary instructional material--which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.
 - Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
 - Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under NYS law.

Department of Defense

The following are essential requirements when conducting research sponsored by the Department of Defense.

- Determinations of serious or continuing non-compliance of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.
- Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

APPENDIX 15: MEDICAL CARE FOR PARTICIPANTS

In NYSDOH/HRI sponsored research, medical care for participants is addressed by:

- Including in its standard contract template a provision that the sponsor provides for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to a participant, without regard as to the fault of the sponsor (see Standard NYS Boilerplate Contract language: Indemnification; Appendix E Proof of Worker's Compensation Coverage and E-1 Proof of Disability Insurance Coverage)
- Asking for the inclusion of such a provision in any proposed contract that does not use NYS' standard template
- Including the substance of any such provision in the consent form
- Including a statement in the consent form that participants do not waive any liability rights for personal injury by signing the consent form

VA Research Collaborations:

In VA research collaborations at Stratton VA Hospital, medical care for participants is addressed by complying with the applicable VA laws and policy that currently:

- Require pursuant to [38 CFR 17.85](#) that the VA provide free medical care to both veteran and non-veteran participants for those injuries, except for: (a) treatment for injuries due to noncompliance with study procedures, or (b) research conducted for VA under a contract with an individual or a non-VA institution
- Require pursuant to [38 USC 1151](#) that if a participant who is a veteran be eligible for dependency and indemnity compensation for a qualifying additional disability or a qualifying death in the same manner as if such additional disability or death were service-connected, if the disability or death was not the result of willful misconduct and was caused by hospital care, medical or surgical treatment, or examination furnished to the participant and the proximate cause of the disability or death was either; (a) carelessness, negligence, lack of proper skill, error in judgment, or similar instance of fault on the part of the department in furnishing the hospital care, medical or surgical treatment, or examination; or (b) an event not reasonably foreseeable
- Allowing pursuant to [28 USC 1346\(b\)](#) and [2671-2680](#) claims under the Federal Torts Claims Act for both veteran and non-veteran participants who consider the VA to be at fault for their injuries.

In collaborative research at Stratton VA Hospital, NYSDOH and HRI in its sponsored agreements addresses medical care for participants by:

- Abiding by the same laws and policy as specified above.

On behalf of Stratton VA Hospital, the IRB requires that the VA Protocol Director include a statement in the VA consent form:

- Explaining the above-described possible benefits for participants, and
- Explaining that participants do not waive any liability rights for personal injury by signing the consent form.

APPENDIX 16: PARTICIPANTS CONCERNS & COMMENTS

OBJECTIVE

To provide guidance in handling concerns, complaints, or questions received regarding a research study involving human subjects.

GENERAL DESCRIPTION

The right of research subjects to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. The IRB Administrative Director or designee in the IRB Administrative Office is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. These issues will be handled in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone, in writing, or via email to the IRB Administrative Office. Each IRB approved informed consent document includes the IRB Administrative Director's contact information and telephone number. The telephone number is also listed on the NYSDOH and IRB websites.

RESPONSIBILITY

IRB Administrative Director, IRB Administrative Staff, IRB Chair, Principal Investigator (PI)/Study Personnel

PROCEDURES

Concerns/Complaints/Questions

1. A research subject or anyone with a concern, complaint, or question regarding a research study involving human subjects may raise the concern, complaint, or question with the IRB Administrative Office. Upon receipt of a concern (e.g., allegation), complaint, or question, the IRB Administrative Director gathers the following information from the complainant as appropriate:
 - Subject's (or complainant's) name, address, and phone number (This information is NOT MANDATORY, and an individual may report an incident anonymously; however, the IRB Administrative Director will advise the individual that a thorough review may not be possible, and that, without this information, follow-up responses to the individual are not feasible.);
 - Study protocol title (or IRB Number) and the name of the Principal Investigator;
 - Date(s) of the incident, and;
 - An explanation of the concern, complaint, or question.
2. The IRB Administrative Director will assure the individual (or complainant) that he/she will inquire into the circumstances and that the IRB will take appropriate measures to address the issue. Furthermore, the IRB Administrative Director informs the individual that a response to him or her will be forthcoming as quickly as possible provided that contact information is given (e.g., if possible, within 5 to 7 days if the issue is a complaint). The IRB Administrative Director also explains to the individual the limits to confidentiality.
3. The IRB Administrative Director handles the concern, complaint, or question in a confidential manner to the extent allowed by law. The IRB Administrative Office limits access to information concerning the contact to employees with responsibilities that require knowledge of the concern, complaint, or question.
4. The IRB Administrative Director conveys the information regarding the concern, complaint, or question to the Principal Investigator of the study at issue, and the IRB Chair in a timely manner.

5. The IRB Administrative Director promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issue(s) at the administrative level.
6. If the alleged impropriety involves potential harm to subjects or others, the IRB Administrative Director notifies the IRB for immediate action pending formal inquiry. The IRB Administrative Director reports concerns, complaints, or questions involving serious issues immediately to the IRB Chair, the Institutional Official (IO), and, if appropriate, the NYSDOH Division of Legal Affairs.
7. The IRB Administrative Director manages the inquiry, preparing related correspondence, and maintaining documentation of the review for up to seven years from completion of the inquiry or close out of the IRB file, whichever is longer.
8. The IRB Chair or IRB Vice Chair, in collaboration with the IRB Administrative Director, ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature such as an incentive issue, the IRB Chair or the IRB Administrative Director may resolve the issue without bringing it to the IRB. The IRB Chair, or the IRB Administrative Director refers major issues such as failure to obtain signed informed consent from potential subjects (if required) to the IRB and the IRB votes on any actions the IRB takes. All actions taken are by the IRB, are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings.
9. Depending on the nature of the event or circumstances, the IRB may take the following actions but is not limited to:
 - Further inquiry;
 - Administrative action;
 - Details and recommendations forwarded to the appropriate Center, Division or Departmental Heads for consideration and action as appropriate;
 - Details and recommendations forwarded to the Institutional Official and/or NYSDOH Division of Legal Affairs for action;
 - Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable, and;
 - Other actions as deemed appropriate.
10. The IRB Administrative Office and IRB monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The IRB Administrative Director brings issues involving noncompliance to the attention of the IRB Chair, the IRB, and the Institutional Official.

REFERENCES

45 CFR 46.116(a)
21 CFR 50.25(a)

APPENDIX 17: OUTREACH & EVALUATION

Participant inquiries about research studies are handled by the IRB Administration. Inquiries received by IRB Administrative staff are forwarded to Research Staff, if they cannot be addressed by the IRB Administrative Staff. All answers to queries flow back through the IRB Administrative Office to the participants. IRB Administrative Staff use a relational database of studies that provides contact information to prospective participants for active research being conducted by the NYSDOH.

Outreach

NYSDOH is committed to assuring that all of its research activities are conducted in a way that promotes the rights and welfare of its participants. If you are considering participating in research, are currently involved in research, or want to find out more about research from the viewpoint of a participant. General information is provided on the conduct and oversight of research and the protection of human subjects.

By taking part in a research study, you can also contribute to better understanding of how the treatment or intervention works in people of different ethnic backgrounds and genders. To speak with an informed individual who is unaffiliated with specific research call Tony Watson, the IRB Administrative Director at (518) 474-8539 for questions, concerns, or complaints about the research, research related injury and questions about your rights as a research participant.

Evaluation

Evaluations take place in an ongoing manner. The many different Centers, Divisions, Departments and Sections of the Health Department evaluate their impact on an ongoing basis. For instance, Program Evaluation surveys are routinely used as part of the Department's vision to protect the health of NYS residents. The Health Department conducts surveys regarding public opinion on research, public health surveillance and public health responses to epidemics and outbreaks on a regular basis, and makes their results available through <https://health.data.ny.gov/> All IRB Administrative staff, IRB members and the Chair are requested to report both positive and negative feedback about all outreach activities, (wherever the feedback originates), to the IRB Administrative Director for presentation to the Institutional Official. IRB Administration track this input to make changes to our educational program and improve outreach activities.

Evaluation and Program Feedback

Your feedback is important to us. Below are some links to how you can provide feedback, give suggestions, or express concerns or complaints. **Program and/or Website Feedback** (There is only one link provided, should there be more?)

The IRB Administrative Office welcomes your feedback about our performance, as well as your suggestions on ways in which we can continue to improve the quality of our operations and services.

We appreciate your suggestions or comments about this website. Please provide your input on any or all the following:

- Additional topics or specific items you would like added to the website
- Items you found difficult to locate
- Corrections or broken links
- Any other comments you may have.

You may provide feedback to us by contacting any of the following individuals directly by e-mail, phone, fax, or postal mail. If you wish, you may provide feedback to us **anonymously** by not including your name when you call, fax, or write this office.

- Administrative Director – IRB Administration (Tony Watson)
- IRB Chair (Dr. James Tesoriero)
- Institutional Official (Brad Hutton, OPH Deputy Commissioner)

Contact Information:
Institutional Review Board
New York State Department of Health
ESP Corning Tower, Room 474
Albany, NY 12237-0001
(518) 474-8539

Concerns and Complaints

The IRB Administrative Office is concerned about the safety, rights and welfare of all individuals participating in or associated with research projects conducted at the NYSDOH or conducted by NYSDOH researchers, regardless of the site of the research. All research-related concerns or complaints reported to IRB Administration are taken very seriously.

- If you are a research subject, please refer to the section on the website called [Where can I get more information about my rights or if I have a problem?](#) You may also contact any of the people listed above by mail, phone, or email IRBBML@health.state.ny.us.
- You may submit your complaint or concern by calling Tony Watson at (518) 474-8539 or emailing him at tony.watson@health.ny.gov.
- If you are an investigator or on the research staff, please refer to the Program Feedback information above. You may also contact any of the people listed above by mail, e-mail, or phone.

On a yearly basis, the IRB Director of Administration and IRB Chair will review all feedback received by the IRB Administrative Office. This information will then be used to make changes to outreach materials, including but not limited to, corrections to the website and providing additional materials to address frequently asked questions.

Thank you for taking the time to provide your feedback, comments and concerns to the IRB Administrative Office

APPENDIX 18: HUMAN SUBJECTS RESEARCH WEBPAGE

The NYSDOH Institutional Review Board's webpage can be found at <https://www.health.ny.gov/professionals/irb/> and contains:

A Human Subject Participant Page, which will provide information and resources about participating in research for participants, prospective participants, and community members, including:

- Frequently asked questions (FAQs)
<https://www.health.ny.gov/professionals/irb/faq.htm>
- Application Forms and Instructions
<https://www.health.ny.gov/professionals/irb/forms.htm>
- Annual Meeting Schedule <https://www.health.ny.gov/professionals/irb/meetings.htm>
- List of IRB Members, Their Specialties and Contact Information
https://www.health.ny.gov/professionals/irb/board_members.htm
- Definitions of Research terms (e.g. clinical trials, including the various phases and informed consent) <https://www.health.ny.gov/professionals/irb/resources.htm>
- General information on the rights of research participants and questions to ask before agreeing to participate in research
<https://www.health.ny.gov/professionals/irb/participants.htm>
- A Link to OHRP brochures: [Becoming a Research Volunteer](#): It's Your Decision (in English and Spanish)
- A Links to the Office of Human Research Protections, Food and Drug Administration, National Cancer Institute, and Office of Research Integrity
<https://www.health.ny.gov/professionals/irb/resources.htm>

APPENDIX 19: NOTIFICATION OF FINDINGS BY SPONSOR

Provisions should be included in standard sponsored research contract templates that the sponsor will within 72 hours of becoming aware of an Issue of Non-Compliance, Serious Adverse Event, Unanticipated Problem or other reportable circumstances will notify the Protocol Director or the IRB of:

- A. Non-compliance with the protocol or applicable laws, particularly those laws related to participants, that could impact the safety or welfare of the participants.
- B. Serious adverse events that have been reported to the FDA or other governmental agency in relation to the protocol at NYSDOH or any other site participating in a multisite study.
- C. Unanticipated problems in the protocol at NYSDOH or any other site that could relate to risks to participating participants, and
- D. Circumstances that could affect participants' willingness to continue to participate in the protocol or the IRB's continuing approval of the protocol.

When non-standard contract templates are used, the sponsor is asked to include equivalent statements.

APPENDIX 20: IRB CHAIR/ VICE CHAIR SELF-EVALUATION FORM

New York State Department of Health
Institutional Review Board
IRB Chair/Vice Chair Self-Evaluation Worksheet

Print Name: [Click or tap here to enter text.](#)

Date: [Click or tap to enter a date.](#)

The purpose of this form is to obtain information about your experience as an IRB Chair and IRB Vice Chair to improve our education and training program and to ensure that you have the tools needed to perform this important function. This self-evaluation form will also be used by the NYSDOH Institutional Official to annual assess your performance. Please evaluate yourself in the following areas:

DESCRIPTION	RATING	COMMENTS/SUGGESTIONS
Knowledge and application of the federal regulations and ethical principles	<input type="checkbox"/> Expert Knowledge <input type="checkbox"/> Working Knowledge <input type="checkbox"/> Familiar <input type="checkbox"/> Need Education	
Knowledge and application of IRB policies and procedures	<input type="checkbox"/> Expert Knowledge <input type="checkbox"/> Working Knowledge <input type="checkbox"/> Familiar <input type="checkbox"/> Need Education	
Ability to lead IRB members in a thorough review of a protocol abiding by all policies, procedures and applicable federal, state, and local laws, rules and regulations	<input type="checkbox"/> Facilitate discussion <input type="checkbox"/> Actively participate in discussions <input type="checkbox"/> Participate only as needed <input type="checkbox"/> Overbearing in directing the discussion	
Meeting management and time management skills	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Need help	
Attendance in last calendar year	<input type="checkbox"/> Attended 10 – 12 meetings <input type="checkbox"/> Attended 8-9 meetings <input type="checkbox"/> Attended fewer than 8 meetings	
Comfort level for contacting investigators and study staff and/or IRB Staff for additional information prior to the	<input type="checkbox"/> Comfortable <input type="checkbox"/> Hesitant, but will contact <input type="checkbox"/> Uncomfortable	

meeting

TRAINING and EDUCATIONAL ACTIVITIES

DATE COMPLETED

(Please select the activities completed below)

- Initial IRB Member Orientation
- Completion of CITI IRB Member Training
- Completion of other human subjects protection training
- Continuing Education
 - OHRP Seminar Series
 - IRB Forum Member
 - Relevant local, regional, or National Conferences (please list below)

Additional Comments: (Continue on a separate sheet of paper if necessary)

APPENDIX 21: IRB MEMBER SELF-EVALUATION FORM

New York State Department of Health
 Institutional Review Board
 IRB Member Self-Evaluation Worksheet

Print Name: _____ Date: _____

The purpose of this form is to obtain information about your experience as an IRB Member to improve our education and training program and to ensure that you have the tools needed to perform this important function. This self-evaluation form will also be used by the NYSDOH Institutional Official to annual assess your performance. Please evaluate yourself in the following areas:

DESCRIPTION	RATING	COMMENTS/SUGGESTIONS
Knowledge and application of the federal regulations and ethical principles	<input type="checkbox"/> Expert Knowledge <input type="checkbox"/> Working Knowledge <input type="checkbox"/> Familiar <input type="checkbox"/> Need Education	
Knowledge and application of IRB policies and procedures	<input type="checkbox"/> Expert Knowledge <input type="checkbox"/> Working Knowledge <input type="checkbox"/> Familiar <input type="checkbox"/> Need Education	
Active participation in the meeting discussions	<p>Check all that apply</p> <input type="checkbox"/> Facilitate discussion as primary reviewer <input type="checkbox"/> Actively participate in Discussions <input type="checkbox"/> Willing to disagree with consensus or majority opinion <input type="checkbox"/> Participate only as needed <input type="checkbox"/> Uncomfortable participating in discussion	
Adheres to subcommittee schedule and provides thorough and timely expedited reviews	<input type="checkbox"/> Always <input type="checkbox"/> Often <input type="checkbox"/> Need help	
Attendance in last calendar year	<input type="checkbox"/> Attended 10 – 12 meetings <input type="checkbox"/> Attended 8-9 meetings <input type="checkbox"/> Attended fewer than 8 meetings	
Comfort level for contacting investigators and study staff and/or IRB staff for additional information prior to the meeting	<input type="checkbox"/> Comfortable <input type="checkbox"/> Hesitant, but will contact <input type="checkbox"/> Uncomfortable	

TRAINING and EDUCATIONAL ACTIVITIES

DATE COMPLETED

(Please select the activities completed below)

- Initial IRB Member Orientation
- Completion of CITI Training
- Completion of other human subjects protection training
- Continuing Education
 - OHRP Seminar Series
 - IRB Forum Member
 - Relevant local, regional, or National Conferences (please list below)

Additional Comments: (Continue on a separate sheet of paper if necessary)

APPENDIX 22: EXPEDITED REVIEW OF RESEARCH INVOLVING VULNERABLE POPULATIONS

New York State Department of Health Expedited Review of Research Involving Vulnerable Populations

- Pregnant Women, Human Fetuses or Neonates are Involved in Research. If yes, fill out questions for Subpart B.**
 - Prisoners are involved in this research. If yes, contact staff. Review of prisoner research requires review by the full committee.**
 - Children are involved in this research. If yes, complete questions for Subpart D.**
-

Subpart B: Research Involving Pregnant Women or Human Fetuses (all conditions must be met)

- 1) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women:
- A. have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
 - B. preclinical studies are not indicated or are not scientifically appropriate

Describe preclinical studies, or explain why they are not indicated or are not scientifically appropriate (for example, for non-biomedical research that is not greater than minimal risk) with reference to specific elements of the protocol or other study documents.

Type your description here

- 2) The risk to the fetus is caused solely by (only 1 of the following options a or b)
- A. interventions or procedures that hold out the prospect of direct benefit for the women or fetus; or
 - B. if there is no prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

3) Any risk is the least possible for achieving the objectives of the research;

- Yes
- No

4) Describe the risks involved in the research for the pregnant women and human fetuses with reference to specific elements of the protocol or other study documents.

Type your description here

- 5) The research holds out the prospect of
- A. direct benefit to the pregnant women only,
 - B. direct benefit to both the pregnant women and the fetus,
 - C. no prospect of benefit to the woman nor fetus but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be gained by any other means (the pregnant woman's consent is required);

- D. direct benefit to the fetus only and no benefit to the pregnant woman. (Consent of the pregnant woman and the father is required; consent by the father need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest);

6) Describe the reasonably foreseeable impact of the research on the pregnant women and human fetuses with reference to specific elements of the protocol or other study documents.

Type your description here

7) Check the option that best describes the consent process concerning Subpart B Pregnant Women, Human Fetuses and Neonates

- A. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus (for children who are pregnant, assent and permission must be obtained in accordance with Subpart D, below)
- B. No inducements, monetary or otherwise, have been offered to terminate the pregnancy for the purposes of the research activity; and
- C. Individuals engaged in the research will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy
- D. Individuals engaged in the research will have no part in determining the viability of the fetus at the termination of the pregnancy

8) Describe how the pregnant women and human fetus participants are selected/recruited with reference to specific elements of the protocol or other study documents

Type your description here

9) Research not approvable based on the above requirements

Review by the convened IRB required

- End of review section for research involving pregnant women and human fetuses.
- Save this document
- Proceed to determine whether research involves neonates and children

10) There are no neonates in the research

- If children are enrolled, skip to the Children section.
- If no children are enrolled, save this file and upload.

11) Neonates will be enrolled in the study; convened IRB review required.

- End of review section for research involving neonates
 - Save this document
 - Proceed to determine whether research involves children
-

Subpart D: Research Involving Children

Section 1: Classify the research according to anticipated risks and potential benefits.

§46.404 - No greater than minimal risk to children is presented.

Describe how the risk is no greater than minimal
Type your description here

Describe how adequate provisions are made for soliciting the assent of the children and the permission (parental/guardian informed consent) of their parents or guardians.
Type your description here

§46.405, §46.406, §46.407 – Greater than minimal risks to children is presented. Study needs to be reviewed by the convened IRB.

Type your description of why the research is greater than minimal risk here

Describe the consent and assent process for research involving children
Type your description here

Section 2: Determine whether the provisions for parental permission and minor assent are adequate

Describe the provisions that are present for soliciting permission of the parents or legal guardians.
Type your description here

- Parents/Legal guardian's permission must be obtained (§46.408(b)).
- Permission by one parent is sufficient even if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child.
 - Permission must be sought from both parents if both parents are alive, known, competent, reasonably available, and have legal responsibility for the care and custody of the child. Otherwise the permission of one parent is required.
- Documentation of parents/legal guardian's permission is in accordance with §46.117.
- Language of the parental consent form is appropriate for the expected educational level of the parent.
- Waiver of parents/legal guardian's permission is appropriate under one of the following options:

Option #1

- The research is conducted by or subject to the approval of state or local government officials.
- The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs.
 - Procedures for obtaining benefits or services under those programs.
 - Possible changes in or alternatives to those programs or procedures.
 - Possible changes in methods or levels of payment for benefits or services under those programs.
- The research cannot practicably be carried out without the waiver or alteration.
- The research is not FDA-regulated.

Option #2

- The research involves no more than minimal risk to the participants.
- The waiver or alteration does not adversely affect the rights and welfare of the participants.
- The research cannot practicably be carried out without the waiver or alteration.
- When appropriate, the participants will be provided with additional pertinent information after participation.

Option #3

- The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants.
- An appropriate mechanism for protecting the children who will participate as participants in the research is substituted.
- The research is not FDA-regulated.

Describe the mechanism for protecting the children who will participate as subjects in the research. The waiver may not be granted if in violation of Federal, state and local laws.

Type your description here

Describe the provisions for obtaining assent of the children.

Type your description here

Children are NOT capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research (§46.408(a)).

Children are capable of providing assent. In determining whether children are capable of assenting, the IRB should take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child as the IRB deems appropriate (§46.408(a)).

Documentation of child assent is required (§46.409(e)).

- Written Form
- Short Form
- Script

Signature of child is required for assent.

Investigator may consider appropriateness of signature on a case-by-case bases taking into consideration the age, maturity, and psychological state of the child.

Language of the assent is appropriate for the age, maturity, and psychological state of the child.

Describe the process for obtaining assent/consent and identifying dissent.

Type your description here

Does the research involve wards of the state?

If yes, is the research approved under §46.406 or §46.407?

If yes, determine that the research:

- Is related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- An advocate for each child who is a ward has been appointed.

The advocate serves in addition to any other individual acting on behalf of the child

as guardian or *in loco parentis*.

- The advocate has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research.
- The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Thank you for completing your review.

Please save and forward this file to the NYSDOH IRB

as an attachment to your review

APPENDIX 23: NON-RESEARCH DETERMINATION APPLICATION & REVIEWER FORM

NEW YORK STATE DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD NON-RESEARCH DETERMINATION APPLICATION & REVIEWER FORM

Principal Investigator Name: Click or tap here to enter text. Date: Click or tap to enter a date.

Project Title: Click or tap here to enter text.

Only complete the section that is applicable to the activity you are submitting to the IRB for a Non-Research Determination.

SECTION 1: DETERMINATION IF PUBLIC HEALTH NON-RESEARCH

1. Is the purpose of the activity to identify and control a health problem? Yes No
If Yes, please explain in detail the purpose of the activity: Click or tap here to enter text.
2. Is the purpose of the activity to improve a public health program or service? Yes No
If Yes, please explain how this activity will improve a public health program or service? Be sure to name the program or service and provide specific details. Click or tap here to enter text.
3. Are the benefits of the project primarily or exclusively for the participants or the participants' community? Yes No Please explain in detail the benefits of the project and who will benefit from them. Click or tap here to enter text.
4. Is the data collected needed to assess or improve the program or service? Yes No
Please explain specifically why the data is needed to assess or improve the program or service. Click or tap here to enter text.
5. The knowledge that is generated does not extend beyond the scope of the activity. Yes No
Be specific and explain how the knowledge generate is only applicable to the scope of the activity and cannot be generalized. Click or tap here to enter text.
6. Are the activities experimental? Yes No If No, explain how the activities are not experimental. Click or tap here to enter text.

If Yes to questions 1-5 and No to question 6 then this is a Public Health Non-Research Activity.

SECTION 2: DETERMINATION IF ACTIVITY IS PUBLIC HEALTH SURVEILLANCE (NON-RESEARCH)

1. Does the activity involve regular, on-going collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population? Yes No N/A If Yes, please explain. Click or tap here to enter text.

2. Is the data being used to manage public health programs? Yes No N/A
If yes, please explain how the data is being used to manage public health programs.
[Click or tap here to enter text.](#)
3. Does the activity have the capability to invoke public health mechanisms to prevent or control disease or injury in response to an event? Yes No N/A
If yes, please explain in detail including what the mechanisms are to prevent or control disease or injury.
4. Is the purpose of this activity to prevent or control disease or injury in a defined population?
 Yes No N/A If yes, please explain in detail the purpose, the disease or injury and the defined population. [Click or tap here to enter text.](#)

If Yes to answers 1-4, then it is a Public Health Surveillance Activity (Non-Research)

SECTION 3: DETERMINATION IF ACTIVITY IS EMERGENCY RESPONSE (NON-RESEARCH)

1. Will this activity identify, characterize and solve an immediate health crisis? Yes No N/A If yes, please explain in detail. [Click or tap here to enter text.](#)
2. Will the knowledge gained directly benefit those participants involved in the investigation or communities? Yes No N/A
If yes, please explain those benefits. [Click or tap here to enter text.](#)

If Yes is answered to both questions, it is an Emergency Response (Non-Research) Yes No

SECTION 4: DETERMINATION IF ACTIVITY IS PROGRAM EVALUATION (NON-RESEARCH)

1. Is the purpose of this activity is to test new modified or previously untested intervention, service or program to determine if it is effective? Yes No N/A if yes, please explain the intervention
2. Is the purpose of this activity is to assess the success of an established program in achieving objectives in a specific population and information learned will be used to provide feedback to the program? Yes No N/A

If you answered No to #1 and Yes to #2 then it is non-research.

SECTION 5: DETERMINATION OF ACTIVITIES INVOLVING HUMAN SPECIMENS

1. Does this activity involve only coded human biological specimens or coded private information/data from living individuals? Yes No N/A If Yes, please explain which the activity is using and how it is coded. [Click or tap here to enter text.](#)
2. The specimens or private information/data collected were not collected specifically for this activity from living human participants. Yes No N/A
If Yes, please explain. [Click or tap here to enter text.](#)
3. The investigator is not able to identify the individuals the private information/data or specimens originated from. Yes No N/A If Yes, please explain. [Click or tap here to enter text.](#)

4. Activities involving specimens or information/data from a repository/database does not constitute human subjects research if it meets one of the following:
- The repository/database obtains the specimens or data without identifiers.
 - The repository/database obtains the specimens or data with identifiers, but is prevented by law to from providing identifiers that link to the individuals.
 - The investigators and the repository that holds the key that links coded specimens/data to living identifiable, individuals enter into an agreement prohibiting the release of the key to the investigators under any circumstances until the specimen/data donors are deceased.
 - There are IRB-Approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the specimen or data donors are deceased.

If answer Yes to any of numbers 1 – 3 (and the others are N/A) or if criteria from #4 is checked then it is not human subjects research.

Researcher DO NOT complete below this line!

Reviewer: please complete the information below.

Reviewer Name: Click or tap here to enter text.

IRBNet #: Click or tap here to enter text.

Conflict of Interest Disclosure:

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study? Yes* No *If yes, please do not perform the review and contact the IRB Office: 518-474-8539

DETERMINATION OF HUMAN SUBJECTS RESEARCH

- The proposed activity as described **DOES NOT constitute research**. IRB review is not required. This determination only applies to the activities described in this request. If there are any changes that may alter this determination the investigator may request another written determination.
- The proposed activity as described constitutes human subjects research. Submission of an IRB Application IS REQUIRED. IRB Approval must be obtained before the research can begin. Please complete and submit an IRB Application with the appropriate protocol narrative. All forms are available on the Forms & Instructions page on the IRB web site. If you have questions or needs additional guidance on the IRB submission process, please contact IRB staff for guidance at 518-474-8539.

Reviewer's Comments (optional):

Reviewer: Click or tap here to enter text.

Date: Click or tap here to enter text.

APPENDIX 24: RESEARCH POST-APPROVAL MONITORING REVIEW POLICY

NEW YORK STATE DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD POST-APPROVAL MONITORING POLICY

I. Purpose of Post-Approval Monitoring (PAM) Reviews

The purpose of a PAM is to:

- A. Determine that the rights and safety of human subjects have been and are being protected.
- B. Assess adherence to federal and state regulations.
- C. Assess adherence to IRB guidelines.
- D. Provide education to research professionals.
- E. Identify potential compliance issues that can be used to strengthen existing IRB policies.

II. Types of Post-Approval Monitoring Reviews

Two specific types of PAM Reviews are performed: Random Reviews and Review for Cause that are triggered by an adverse event or problem(s) brought to the attention of the IRB.

- A. Randomly-Selected Reviews - The researcher will be notified in writing that the PAM Review is to take place. The purpose of this PAM Review is to provide a more comprehensive examination of both the documents and procedures of the study.
- B. Review for Cause – This type of PAM Review will be performed as the result of a serious adverse event or in response to a professional request by research staff or an institutional official for a review.

III. Post-Approval Monitoring Review Notification

Notification procedures are as follows:

- A. The Principal Investigator will receive written notification at least one-week before a Random Post-Approval Monitoring Review asking to schedule a time for a Pre-Audit Review and Review time.
- B. The Principal Investigator will receive written notification before a Review for Cause Post-Approval Monitoring Review unless a serious adverse event necessitates an Immediate review.

IV. Post-Approval Monitoring Review

The Compliance Officer reviews the following information in the package submission via IRBNet and any submitted documentation to IRB:

- A. The names of all individuals responsible for protocol related activities including the investigators and key personnel
- B. Verification of Principal and Co-Investigator training status

- C. The number of subjects enrolled in the study
- D. The location(s) of the recruitment sites
- E. Review of exclusion/inclusion criteria
- F. The occurrence of adverse events or receipt of participant complaints
- G. The presence of data and safety monitoring plans
- H. The methods of maintaining data confidentiality
- I. Any difficulties in subject recruitment or retention
- J. Clarification of any questions regarding the conduct of the study

V. Selection of Studies

Studies will be selected at random for review. Studies involving more than minimal risk will have a higher probability of being selected. Studies will be selected primarily from those that were originally reviewed as full board review and expedited.

VI. Post-Approval Monitoring Review with Research Personnel

Review includes:

- A. Informed consent document/s.
- B. Adherence to study procedures as outlined in IRB approved protocol.
- C. Occurrence and reporting of adverse events.
- D. Adherence to ethical principles-respect for persons, beneficence, and justice.
- E. Selection and recruitment of subjects.
- F. Confidentiality of subjects.
- G. Storage of documents, data files, secure server, etc.
- H. Maintenance and organization of records which includes: protocol, informed consent documents, monitoring/log reports, brochures, serious adverse event reports, and the study reports.
- I. Participants' research records and signed consent forms

VII. Review of Research Project Regulatory File

It is recommended that all Principal Investigators maintain a Research Project Regulatory File associated with each approved protocol. This file should contain all supportive study documentation. These records will be reviewed during a PAM Review.

The following is the list of recommended documents to be maintained in a Research Project Regulatory File:

- A. Grant announcement
- B. Protocol
- C. Informed consent document-approved and stamped
- D. All IRB correspondence
- E. Participant screening log
- F. Correspondence relating to serious adverse events, unanticipated problems or complaints
- G. Sponsor correspondence, if applicable
- H. Sponsor monitoring reports, if applicable
- I. Laboratory certifications, if used
- J. Range of normal values, if blood work is done

- K. Investigator's CV and Training Certificate
- L. Copies of signed confidentiality statements of staff
- M. Copies of all research staff's training certificates
- N. Final study report
- O. Copy of staff titles and responsibilities on project.
- P. Research participant's records

VIII. Selection of Research Participants' Records

The Compliance Officer will randomly select a representative sample from approved research projects Random Reviews. Access to all selected subjects' records and associated documents should be provided.

In the case of Reviews for Cause, the Compliance Officer may review all the research participants' records.

IX. Post-Approval Monitoring Review of Research Participant Records

The Research Compliance Officer will:

- A. Evaluate the investigator's raw data file for organization, completeness, condition, and legibility.
- B. Determine if there is adequate documentation to verify the participation of each study participant.
- C. Determine if procedures performed on the research subject were as outlined in the protocol.
- D. Determine if inclusion/exclusion criteria were met.
- E. Determine if any adverse events occurred and were reported.

X. Compliance Review of Participants' Consent Forms

The informed consent document will be reviewed for the presence of the following documentation:

- A. The signature of the participant or the participant's legal representative.
- B. The signature of the interviewer.
- C. The signature of a witness, if applicable.
- D. Dates are written adjacent to each signature.
- E. The initials of the subject are on multi-page documents.
- F. Presence of the IRB approval dates and expiration.
- G. Listing of appropriate NYSDOH and IRB contact information and collaborators.
- H. Utilization of the current approved consent form.
- I. Consistency between the risks listed and actual risks encountered.
- J. Any modification to the informed consent form.
- K. Determination that informed consent was obtained prior to research.
- L. Implementation of all study procedures outlined.

XI. Observation of the Informed Consent Procedure

Protocols will be chosen for observation of the informed consent process by one of the following methods:

- A. The Compliance Officer or IRB Administration or Member may request to observe the informed consent process at any time that the protocol is reviewed. The level of risk to study subjects will determine the possibility of selection.
- B. The Compliance Officer, IRB Administration or Member may request to observe the informed consent process as a result of a problem that has been reported to the IRB.
- C. The Compliance Officer, IRB Administration or Member may randomly choose a study to observe the informed consent process.

The Compliance Officer will discuss with the Principal Investigator the details of the observation of the Informed Consent Process. The Principal Investigator will inform the Compliance Officer of a date and time for the observation. The Compliance Officer will be introduced to the potential subject who will be provided with an explanation for the Compliance Officer's presence and the potential subject will be assured that confidentiality will be maintained. The potential subject will need to grant permission for the observation. The Compliance Officer will observe and record their de-identified observations including the appropriateness of study personnel/s response to participant's questions for the IRB compliance files.

XII. Post-Approval Monitoring Review of Informed Consent Forms for Contact Information

The Compliance Officer will evaluate that the informed consent form has clear and concise language that provides instruction in case of an emergency, injury, or an adverse event, that there are valid contact numbers for study personnel and it has the correct number for the Institutional Review Board Administration. As well as, If there are after business hours and weekend contact information available for high risk studies.

XIII. Reporting Requirements

All PAM Reviews will be presented and reviewed by the IRB. Minor violations will be presented to the IRB Chair for review. Minor violations will be sanctioned according to IRB Guidelines and Federal Regulations in accordance the Federalwide Assurance.

Major violation, along with any minor violations that are determined to be major violations will be reviewed at the next regularly scheduled full board meeting. Any sanctions to be imposed will be determined by the full Institutional Review Board.

Principal Investigator will be notified in writing within 10 business days of the Research Compliance Officer's findings.

XIV. Protocol Violations 45 CFR 46.113; 21 CFR 56.108(b)(2) & 56.113

A protocol violation occurs when there is a variance in a research study between the

protocol that has been reviewed and approved by the Institutional Review Board (IRB) and the actual activities that are being performed by the research personnel. Protocol violations may be major or minor as defined below. A violation also occurs when IRB, state or federal regulations or institutional policy is not observed.

A. Minor Protocol Violations:

1. The violation has no substantive effect on the risks to the research participants.
2. The violation has no substantive effect on the value of the data collected.
3. The violation did not result from willful or knowing misconduct on the part of the researcher.

B. Major Protocol Violations:

1. The violation has harmed or posed a significant risk of substantive harm to research participants.
2. The violation has damaged the scientific integrity of the data collected for the study.
3. There is evidence of willful or knowing misconduct on the part of the researcher.
4. The research demonstrated other serious or continuing noncompliance with federal, state, or local research regulations.

IRB Administration will be made aware of protocol violations, as a result of, an adverse event submission, a PAM review, or a professional reporting the violation. The IRB Members will be made aware of both minor and major protocol violations. Minor Violations will be handled by the IRB Chair or Vice Chair, if Chair is not available.

C. Process for Minor Protocol Violations:

1. An inquiry and fact-finding process is initiated by the IRB Chair, in cooperation with the IRB Administrative Director and IRB Compliance Officer.
2. The IRB Chair, IRB Administrative Director and IRB Compliance Officer assess all information related to the protocol violation, contrast the violation with the approved protocol and make a conclusion regarding the seriousness of the violation. Consultation with scientists with relevant expertise or the Division of Legal Affairs will occur as needed.
3. If the findings support a violation, the IRB Chair will issue a memo to the Principal Investigator (PI) identifying corrective action that must be taken and any action in relation to participants that may need to be made, if necessary.
4. The IRB Chair or IRB Administrative Director will present a summary of the violation, process, facts and recommendations at the next scheduled meeting of the IRB.
5. If the findings do not support a minor violation, the matter will be treated as a major violation.
6. The PI will have an opportunity to respond to the findings in person and in writing for inclusion in the study file.

D. Process for Major Protocol Violations:

1. An inquiry and fact-finding process is initiated by the IRB Chair, in cooperation with the IRB Administrative Director and IRB Compliance Officer.
2. The IRB Chair convenes a hearing meeting with the full Institutional Review Board and the Principal Investigator.
3. If the Board's findings support a major violation, the protocol will be suspended or

terminated per the IRB determinations.

4. If suspension of the study would be harmful to study participants, the Center Director or Division Director will appoint a replacement PI to continue the study temporarily at the approval of the IRB.
5. The IRB will report the violations to New York State Department of Health, Health Research Inc., the study sponsor and Office for Human Research Protections.
6. If the findings support the conclusion of scientific misconduct has also occurred, the matter will be remanded to the Commissioner of Health.
7. A written summary of the findings will be sent to the PI and retained in the IRB office if the findings are substantiated.

Protection of Human Subjects 45 CFR 46.109:

An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but no less than once a year, and shall have authority to observe or have a third party observe the consent process and the research.

APPENDIX A: POST-APPROVAL MONITROING REVIEW NOTIFICATION LETTER



Department
of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D.,
J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Date

To:

From:

Subject: Post-Approval Monitoring Review Program Audit

Study:

Dear PI's name:

The Institutional Review Board (IRB) of the New York State Department of Health (NYSDOH) is committed to the improvement of the quality, efficiency, and integrity of our research environment and activities. In keeping with this commitment, the IRB has instituted a compliance program as a means of quality assessment of the research conducted under our Federalwide Assurance agreement with the Office of Human Research protections (OHRP).

The objective of this Post-Approval Monitoring (PAM) Review Program is to ensure that proper scientific, ethical and regulatory requirements are followed in IRB approved protocols. The program is also designed to encourage compliance by detecting errors and/or emissions that might inadvertently occur when implementing research activities. This program serves as a useful educational purpose and enhances research activities at NYSDOH.

Protocols are chosen at random throughout NYSDOH. However, long-term projects, those involving vulnerable populations, and those with significant adverse events may, at times, be given higher priority. All active studies that receive NYSDOH IRB approval, regardless of review designation, are eligible for review. Your protocol has been selected for Random PAM Review which means your study was selected randomly and there is no cause (adverse event or violation) for reviewing it. You will be contacted by me, the Compliance Officer, to arrange for a mutually agreeable time to conduct a Pre-Audit Interview, as well as schedule a date to complete the Post-Approval Monitoring Program review.

The Pre-Audit Interview will be conducted with you and/or the study coordinator to discuss the research personnel responsibilities and other study related issues. This can be done telephonically if research is located off-site. This interview will involve approximately 15-20 minutes of your time. The PAM Review will be performed in person at the site of your research, depending on the study, this could last from 2-4 hours. It would be beneficial if there is a conference room available or a quiet area for the day of the review, as I will be reviewing the study records. I will also like to witness the consent process, that is watch research personnel consent a participant. Hopefully this could be included in the time I am visiting your site. Enclosed you will find a brief outline of the documentation that will be reviewed, if applicable to your study.

APPENDIX B: NEW YORK STATE DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD POST-APPROVAL MONITORING REVIEW PROGRAM INFORMATION FOR PRINCIPAL INVESTIGATORS

During the Post-Approval Monitoring (PAM) Review, the Compliance Officer will review current study procedures (in comparison to IRB-approved protocol study procedures) and will also review research records and observe the informed consent process.

I. Information Reviewed during a PAM Review

1. The informed consent documents
2. Adherence to IRB approved study procedures
3. Occurrence and reporting of adverse events and unanticipated problems
4. Adherence to ethical principles: respect for persons, beneficence and justice
5. Selection and recruitment of subjects
6. Confidentiality of subject data
7. Storage of documents, data files, secure server, etc.
8. Maintenance and organization of records (Regulatory File Management)
9. Participant's research records and signed consent/assent forms.

II. Review of Research Study Regulatory File

It is recommended that Principal Investigators maintain a Research Study Regulatory File associated with each approved protocol which contains all supportive study documentation. These records may be reviewed at the time of Post-Approval Monitoring depending upon the type of review being conducted. The following is a list of recommended documents to be maintained in the Research Study Regulatory File:

1. Grant announcement
2. Study Protocol
3. Informed consent/assent document affixed with the IRB expiration date
4. All written correspondence with the IRB
5. All Protocol change requests
6. Participant screening log
7. Documents related to adverse events
8. Sponsor correspondence, if applicable
9. Sponsor monitoring reports, if applicable
10. Laboratory certifications, if applicable
11. Range of normal values, if lab work is done
12. Investigator's CV and human subjects' protection training certificate for all study staff
13. Copies of signed confidentiality statements of all study staff
14. Final study report, if applicable
15. Copy of staff titles and responsibilities on the project
16. Research participant's records

III. Selection of Research Participants' Records

1. The IRB will randomly select a representative sample of records of the participant population for review during the scheduled Compliance Review. Access to all selected participants records and associated documents should be available for review.
2. In the case of Review for Cause Compliance Reviews, and at the discretion of the IRB, the IRB may review all of the research participants' records.

IV. Review of Research Participant Records

This will include the following:

1. Review of the investigator's raw data file for organization, completeness, condition and legibility
2. Determination if there is adequate documentation to verify the agreement of each subject to participate in the research
3. Determination if procedures performed on the research participants were as outlined in the IRB-approved protocol
4. Determination if inclusion/exclusion criteria were met
5. Determination if any adverse events or unanticipated problems occurred and were reported.

V. Compliance Review of Subject Informed Consent/Assent Forms

The informed consent/assent document will be reviewed for the presence of the following:

1. The signature of the subject or the subject's legal representative
2. The signature of the interviewer
3. The signature of a witness, if applicable
4. Dates are written adjacent to each signature
5. Presence of the IRB approval dates and expiration date
6. Inclusion of appropriate study staff and IRB contact information
7. Use of the most recently IRB approved consent form
8. Determination that consent was obtained prior to research intervention
9. Consistency between the risks listed and actual risks encountered
10. Any modifications to the consent procedures or consent form
11. Implementation of study procedures as outlined
12. The Informed Consent and/or Assent documentation is on NYSDOH letterhead
13. Copies of signed confidentiality statements of all study staff
14. Final study report, if applicable
15. Copies of staff titles and responsibilities on the project
16. Research participant's records

APPENDIX C: POST-APPROVAL MONITORING REVIEW PRE-AUDIT INTERVIEW

A Pre-Audit Interview is to be scheduled prior to the conduct of an investigator site audit with the Principal Investigator or member(s) of the respective research staff.

This interview is performed to identify the names of individual research staff that are responsible for the various protocol related activities:

- Preparing IRB protocol submissions
- Obtaining Informed Consent from participants
- Recruiting study participants
- Reporting Adverse Events/Unanticipated Problems or complaints
- Maintaining study documentation
- Analyzing Study Data

During the Pre-Audit Interview the following information is also obtained:

- Number of subjects screened and enrolled into the study
- Number of sites involved, if study is multi-center
- Occurrence of Adverse Events or Unanticipated Problems
- Occurrence of site monitoring visits
- Presence of data and safety monitoring plans
- Difficulties in study recruitment or in study conduct

The Pre-Audit Interview is to be utilized as an opportunity to clarify any questions or issues that the Compliance Officer or IRB Administration may have regarding the conduct of the study.