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New York State
Department of Health
AIDS Institute
Office of the Medical Director

Request for Applications

HIV Provider Education
Clinical Guidelines Program

KEY DATES

RFA Release Date: September 2, 2010

Questions Due: September 14, 2010

**RFA Updates and
Questions and Answers Posted:** September 28, 2010

Letter of Interest Due: October 6, 2010

Applications Due: October 19, 2010

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**REQUEST FOR APPLICATIONS
HIV PROVIDER EDUCATION PROGRAM
CLINICAL GUIDELINES**

I. Introduction

The New York State Department of Health AIDS Institute is soliciting applications from organizations with the capacity, experience, and expertise to manage an HIV Provider Education Clinical Guidelines Program, which is intended to enhance the treatment of persons with HIV infection by meeting the clinical needs of service providers involved in patient treatment and care.

The program encompasses a wide range of activities associated with the development, dissemination, implementation and evaluation of HIV clinical practice guidelines. These guidelines will serve to improve the medical management and treatment needs of adults, adolescents and children with HIV infection and address the particular requirements of patients with mental health needs and substance use behaviors.

The selected contractor will manage eight distinct clinical committees comprised of physicians, pharmacists, nurse practitioners, care coordinators, dentists, mental health professionals, consumers of HIV services and other major stakeholders in the development of HIV clinical practices guidelines. The contractor will implement the process by which these committees will develop standards of care for patients in their areas of specialty. The committees will meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments. The contractor will develop strategies by which to improve and test these guidelines.

The continually changing nature of this epidemic makes it critical to offer a means of providing clinicians who care for HIV-infected patients with timely, state-of-the-art treatment information. Development, ongoing revision, dissemination and implementation of sound clinical practice guidelines are essential components of this program.

A. Description of Program

Guidelines development should involve the management and direction of the current guidelines committees and subcommittees (and additional committees if needed) in activities related to identifying pertinent guidelines topics, overseeing the process of writing and reviewing of chapters, ensuring peer reviews, and finalizing the completed document for AIDS Institute approval. Applicants should have proven capability to lend methodological expertise to the development of clinical guidelines documents. It is expected that the applicant will also be actively involved in the dissemination of the guidelines, and will identify objectives to expand the reach of the guidelines program and the materials it produces throughout New York State. The applicant will work under the guidance of the AIDS Institute in these efforts. A Steering Committee, composed of committee chairs, AIDS Institute staff and contractor staff, meets at least annually to address program processes, issues that involve multiple guidelines categories, and emerging scientific and policy topics. The contractor supports the Steering Committee by

providing background research on guidelines technical issues in order to ensure methodologic and process consistency in the program.

Implementation activities will involve, but will not be limited to, the creation of innovative formats for the guidelines to facilitate their adoption and use in HIV clinical practice, as well as the adaptation of guidelines and related materials for non-clinical audiences, such as support service providers and consumers. These activities will include updating information on the HIV Clinical Resource website, www.hivguidelines.org, maintaining web technology, producing informational brochures and printed materials, such as best practices booklets, and other companion documents for the guidelines. Other media, such as slides sets, videos, podcasts and webcasts will also be produced to meet the wide range of educational topics within the scope of HIV guidelines implementation. Guidelines evaluation activities to assess the extent of guidelines adoption will be conducted by the selected program with direction from the AIDS Institute.

B. Background

As the course of the HIV epidemic evolves, it continues to present new clinical challenges. Complex medication regimens, new testing technologies, and advances in understanding the basic science of HIV have increased both the longevity and quality of life of many patients with HIV infection. In conjunction with these welcome changes and increased life expectancy have also come the need for continuous innovation and reliable, relevant guidance on the treatment and management of co-morbidities and the need for an emphasis on secondary prevention strategies. In addition, the proportion of HIV patients with specialized care needs, such as adolescents, women, an aging population, substance users and those with mental illness, is increasing as the HIV prevalent population ages.

The AIDS Institute's Office of the Medical Director directly oversees the HIV clinical guidelines program. The written clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. The committees include representative experts in HIV care from across New York State. Committees meet regularly to identify needed guidelines topics, assess current recommendations, and review and update existing guidelines as necessary to keep information current with any emerging clinical and research developments.

To the extent possible, the Committees rely on evidence in formulating recommendations. When data from randomized clinical trials are not available, guidelines are developed based on consensus and relevant practice experience, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients. All guidelines are externally peer reviewed by at least two experts in that particular area of patient care, to ensure that varied opinions are included in the final recommendations in order to increase the depth and quality of the guidelines.

Current guidelines committees include:

- Medical Care Criteria Committee (Adult)

- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Medical Care of Women with HIV Infection
- Committee for the Medical Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee
- Steering Committee

In addition to being posted on the open access HIV Clinical Resource website, www.hivguidelines.org, all guidelines documents are currently disseminated to clinicians, support service providers and consumers via website emailing and through numerous AIDS Institute-sponsored educational programs, including the Clinical Education Initiative, the AIDS Educational Training Centers (AETC), the Education and Training Program and the HIV/AIDS Materials Initiative. Applicants should include discussion of specific strategies and methods they propose to use in the dissemination and implementation of all guidelines that are produced.

C. HIV Clinical Guidelines Program Goals

At the core of several AIDS Institute initiatives, the HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. As noted before, clinicians are targeted through the Clinical Education Initiative (CEI) and the AIDS Education and Training Centers (AETC). The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. Supportive service providers are targeted through the HIV Education and Training initiative, which provides training on important HIV topics to non-physician supportive service providers. Educational activities are carried out in trainings throughout the State as well as through video and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific aspects of the guidelines have been implemented.

Best practices booklets are developed that contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to promote activities related to HIV guidelines implementation and the highest level of HIV patient care possible.

II. Available Funding

A total of \$598,803 in New York State Department of Health appropriated funding is available to support one award statewide for the scope of services described in Section IV of this RFA. Annual renewal of the award made under this RFA is contingent upon satisfactory performance and the continued availability of funding.

III. Who May Apply

A. Minimum Eligibility Requirements

Eligible organizations are not-for-profit 501c(3) organizations and academic institutions.

B. Preference Factors

Preference will be given to applicants that can demonstrate the following:

- a. Demonstrated proficiency in HIV clinical guidelines development, and experience with a variety of guidelines dissemination and implementation strategies as well as an understanding of the relationship of clinical guidelines to public policy and a thorough understanding of the clinical and social issues relevant to HIV care.
- b. The organizational capacity to manage the current eight distinct clinical committees and coordinate all aspects of their guidelines activities.
- c. Access to clinicians, medical writers, editors, publication designers, public health specialists and/or others with expertise and relevant experience in medical education and in medical publishing and guidelines development and dissemination. Experience in working with medical professionals and with subcontractors and specialized consultants as needed to augment internal capacity.
- d. Substantial experience in website management, which includes technological expertise and familiarity with using electronic media. Should have expertise in overseeing the production of materials related to the guidelines, both as printed publications and website postings in various media.
- e. The applicant should be able, with guidance and in partnership with the AIDS Institute, to develop strategies to improve and test implementation of the HIV clinical guidelines. An involvement in evaluation strategies will be necessary to assess the effectiveness of the program. Applicants should have the ability to design and implement program evaluation.
- f. At least two (2) years of experience with administrative, fiscal and programmatic oversight of government contracts, including timely and accurate submission of fiscal and program reports.

IV. Project Requirements and Guidelines

The AIDS Institute expects the awardee to convene multiple standing guidelines committees, as well as subcommittees on specialized topics to develop HIV clinical practice guidelines. These committees may also provide expert advice and guidance on HIV policy issues, and identify and

address problems in the administration and delivery of care to HIV-infected persons. To prepare practice guidelines effectively, the committees require the leadership and support of an organization with methodologic expertise in guidelines development and knowledge of relevant evidence-based medicine. The selected organization will also need to possess excellent skills in medical writing and editing, and demonstrated proficiency in electronic media management. Knowledge and experience in design, production and printing of materials is also required. The AIDS Institute Contract Manager will coordinate activities with the selected organization and prioritize program effort. The selected organization will be responsible for routine reporting to the AIDS Institute Contract Manager utilizing mechanisms described in Section V.G. of this RFA and according to a schedule that will be specified by the AIDS Institute. Specific responsibilities and deliverables will include, but not be limited to, the following:

A. Provide Expertise in Clinical Guidelines Development

The selected program will support the clinical guidelines committees through provision of expert consultation in guidelines development leading to the formulation of systematically developed statements and recommendations to assist clinicians and patients with decisions about the best treatment and care practices in specific situations or circumstances. The organization will ensure that review drafts and revisions conform to Institute of Medicine recommendations. The selected program will be expected to provide expertise regarding the appropriate methods of guidelines formulation, including evidence-based approaches, appropriate use of consensus, and the use of rating systems to show the strength of recommendations and the quality of evidence to support them. The guidelines committees will consider the likelihood that other experts would reach comparable conclusions, with references to other sources such as the IAS, CDC, IDSA and DHHS.

The contractor should designate a Principal Investigator, with significant clinical or scientific experience in guidelines development and evidence-based medicine, expertise in HIV treatment, who is committed to the program a minimum of 5% F.T.E, who will have overall responsibility for the program. This individual must have significant clinical and or scientific experience and demonstrate expertise in guidelines development and evidence-based medicine; expertise in HIV care and treatment is preferred. The Principal Investigator will provide expert consultation in guidelines development and coordinate with DHHS and US Public Health Service Guidelines committees. The Principal Investigator will be involved in devising a rating system for evaluation of the individual recommendations within the guidelines. The Principal Investigator will serve on the Steering Committee and participate in other meetings as needed. It is also expected that the Principal Investigator will review all documents in draft and final forms for clarity, consistency, and accuracy and will compare with United States Public Health Service and DHHS Guidelines to emphasize any differences.

In addition, a Project Director, with guidelines experience, should be designated responsibility for overall management of the program, and who will guide the selected organization in providing process management for guidelines committees in determining priorities for new guidelines, updates and revisions, and will be responsible for contact and communication with committee chairs, designated lead authors, and guidelines peer reviewers. It is expected that there will be continuous leadership through all stages of the crafting of guidelines, and the

incorporation of recommendations concerning future review and updating of the guidelines. The selected organization is expected to ensure that all guidelines and materials are written in clear and unambiguous language and will edit, revise, and amend clinical guidelines as necessary to accomplish this goal. This process will also include revising guidelines based on discussions with the chapter authors, peer reviewers, and committee reviews, from rough drafts into clearly worded, formal practice guidelines. Professional writing and editing is an essential component of the guidelines process.

The selected organization is also expected to have the ability to conduct appropriate literature searches to assist the committees' efforts, and will ensure that guidelines contain a comprehensive review of the literature, that bibliographies for all guidelines chapters and any manuals are current and complete, and that accurate indices are included in designated publications. The awardee must be able to maintain active cross-referencing of topics and demonstrate the ability to update the relevant parts of guidelines that are affected by changes in scientific evidence.

Applicants should be able to demonstrate the expertise to prepare materials for printing, and include the ways they will ensure product quality. The awardee should have the ability to hire freelance medical editors/writers and indexers with specific expertise when necessary to assist in the timely completion of projects.

B. Guidelines Committee Management

The management of the guidelines committees will be the responsibility of the contractor. Guidelines committee membership, the annual work plans of each committee, contact with committee members as well as guidelines conference calls and meetings, will be arranged by the contractor. The current program structure includes active committees in the following areas: adult and pediatric medical care, dental services, mental health, woman's health, substance use, prevention, and pharmacy, and subcommittees for perinatal transmission and transitional health care. It should be noted that current committee structure will be altered to reflect the changing needs of the program over time. Each committee is governed by its own set of bylaws that delineate the process for determining committee structure, selecting chairs and vice-chairs and designating subcommittees (See example in Attachment 12).

Applicants should include how they will establish and maintain an editorial timetable for all committee efforts, and how they will manage the activities of the committees in an efficient manner to ensure that the time commitment and contributions of each committee member are utilized productively; and maximize the collective efforts of each committee so that new materials are being developed and existing materials are being updated concurrently, as appropriate.

1. Committee Meetings and Conference Call Management

Applicants should include specific plans to manage the activities of the existing guidelines committees. Applicants should include a general workplan with a description that includes the coordination of all committee activities, including) committee meetings, committee

conference calls, scheduling arrangements, advance notifications, follow up, preparation of minutes or meeting summaries (as specified) and other necessary arrangements. A proposed annual schedule for each committee should also be provided. Applicants should indicate how they will actively manage the work of the various committees simultaneously.

The selected organization will be expected to arrange and provide reimbursement for activities related to committee meetings and consultant services, including time spent at meetings, chapters/sections completed, and travel expenses in accordance with the AIDS Institute Stipend Rate Guidance (see Attachment 13). The selected organization will pay for committee and meeting expenses in a timely manner and will subsequently seek reimbursement from New York State only for previously paid, approved expenses.

The awardee will be responsible for coordinating a Guidelines Steering Committee meeting, held at least annually, to bring together all committee chairs and vice chairs to establish broad program goals and identify the direction for development, implementation and evaluation of their efforts. The selected organization will also be responsible to attend and present on the program at various AIDS Institute meetings, including the Consumer Advisory Committee, as requested.

Conference calls are scheduled to review updated or new guidelines chapters among the committees and subcommittees as well as with consumers; planning calls are used to finalize agendas before meetings and for general updating and planning with chairs. Policy discussion calls are on occasion convened at the request of the AIDS Institute on to seek the advice and opinions of guidelines committee members.

C. Guidelines Products and Materials

The successful applicant will work with the AIDS Institute to ensure that all publications and materials are professionally produced for wide distribution. The selected organization will provide creative and technical expertise regarding the presentation of information, graphic design, and layout of all publications and materials for publication. The contractor must ensure the accuracy of all products with professional level editing, and provide technical expertise and professional execution of all printing and production services; produce professionally printed materials and other informational products. These materials may include products of committees, subcommittees, work groups, and consultants. The selected organization will provide timetables for production, printing and distribution of all guidelines products and materials, and will meet any established deadlines.

The awardee will supervise processes related to the design and production of guidelines-related products, including clinical guidelines adaptations, best practices, consumer education materials, laminated reference cards, and other implementation-related products. Applicants should demonstrate knowledge and expertise in both print and web media, and must be capable of establishing timelines necessary for all pre-press work (sign-offs, design, layout) as well as printing, packaging, and shipping.

The selected organization will be expected to convert guidelines written for the clinical care

provider into language and formats appropriate for non-clinical service providers, consumers or consumer advocates, and the general public. Additionally, products will be reformatted to be used for teaching and presentations. The contractor will assist in the drafting, editing, design and production of supporting materials for the clinical guidelines according to AIDS Institute models that may include standards of care, policy manuals, diagnostic and treatment methodologies, organizational models of care, quality improvement models and algorithms. Publication may be in English or Spanish. All materials must be approved by the New York State Department of Health prior to any printing or distribution.

The selected organization will pay for printing and distribution of publications, and other media, in a timely manner. It is expected that the chosen organization will augment current methods and also explore new ways to distribute materials to reach wider clinical audiences. The selected organization will seek reimbursement from New York State only for previously paid, approved expenses. Please note: These costs should be included as part of the total award, and should NOT be construed as over and above the \$598,803 maximum award.

Examples of recent program printed materials and guidelines should be included as an attachment to the application.

D. Website Maintenance and Enhancement

A major function of the guidelines program is to maintain and update the HIV Clinical Resource website, www.hivguidelines.org, where all guidelines materials will be available in html and pdf format. The contractor will ensure timely posting of all materials to the website and update the website with new material on a regular basis; the capacity must exist to update it daily. The website must include a search engine with the ability to search and display site content in a useful manner. Attention will be paid to site design, which should combine ease of use with functionality. In addition to clinical guidelines materials, quality program, best practices and clinical education documents will need to be posted as well. The site also contains space to list upcoming HIV related events, such as conferences, and to display public health news and alerts. Applicants should indicate how they will maintain the website in their proposed workplan.

The contractor must have the technical ability to adapt guidelines documents so they may be downloaded onto hand-held electronic devices, such as personal digital assistants (PDAs). There must be the capacity to archive all website materials. The AIDS Institute expects that the contractor will continue to explore using new media options on the guidelines website, and add any enhancements needed to create the website capacity to ensure that this occurs. The AIDS Institute is exploring the possibility of merging its current websites, and expects the contractor to participate in this process.

The contractor should arrange for hosting of the website, and will be responsible for monitoring this process. The AIDS Institute will direct the program to explore ways to increase the number of those registered at the site who will receive broadcast emails when new guidelines or materials have been finalized. It is expected that the contractor will develop website enhancements and will work with the AIDS Institute to promote the website and identify ways for placing website content/links to related media and other relevant websites, as well as establish goals for website usage. The awardee will be expected to expand the internal and

external website linkages, and work to broaden the scope of the site. The selected organization will work with the CEI Tech Center on issues of guidelines content, and the two sites will mutually support one another's efforts.

The program should track and report website statistics and other site information as requested and consider ways to obtain knowledge about website access and the reasons visitors are using the site. In addition, the contractor will perform a comprehensive annual review of each webpage to ensure its accuracy and currency, test links to ensure that they are active; and check consistency of all posted documents.

E. Distribution/Dissemination of Guidelines

The AIDS Institute regards the dissemination of clinical guidelines as a critical component of the program and one for which it expects the successful applicant to be prepared to bring new strategies and identify methodologies to increase the availability and awareness of guidelines for providers. Active dissemination encompasses a wide range of educational strategies that target different groups of users. The contractor will work with the AIDS Institute to review all new products and existing documents and examine possibilities for new methods of dissemination. Applicants should include a dissemination plan in their proposal, indicating the specific methods that it intends to use in disseminating various kinds of materials and products.

The contractor will assist the AIDS Institute in specific dissemination efforts and will work with the NYS Department of Health Distribution Center to ensure that all printed materials can be ordered in sufficient quantities to meet distribution needs. The contractor will participate in internal AIDS Institute meetings and specifically the monthly Guidelines Workgroup to keep current in AI projects in order to provide guidelines-related input as needed for AI projects and campaigns.

F. Guidelines Implementation

Implementation constitutes a crucial step in the guidelines process, as even the best guidelines are unlikely to produce significant change in clinical practice without carefully designed strategies to achieve their implementation. Therefore, the successful applicant will assist the AI in developing implementation materials and in evaluating their impact. The selected organization must have the capacity to critically review implementation materials to ensure that content is consistent with guidelines. The contractor will use the website homepage and broadcast emails to assist in implementation strategies. The contractor will also develop ways to target website guidelines users and determine how they are using this content as well as solicit user feedback.

Guidelines recommendations will be implemented more effectively when they are disseminated through a coordinated plan to reach their appropriate target audiences, which may include clinicians, support service providers, and consumers. Although it may involve changing systems and addressing barriers, effective guidelines implementation is necessary to achieve improved clinical outcomes. With guidance from the AI, the program will ensure that each committee discusses implementation strategies and develops an implementation plan that includes, but is not limited to, provider education activities, printed materials, and website utilization. This effort

will be achieved most successfully by allotting time devoted to implementation on agendas for all committee meetings, and scheduling follow-up calls and email requests as appropriate.

The selected organization should have the ability to translate materials written for the clinical care provider into language appropriate for the non-clinical service provider, the consumer and advocate. The contractor should also have the skills to reformat materials into products to be used for teaching and clinical education.

It is expected that all HIV clinical guidelines materials will be listed on the National Guideline Clearinghouse databases as they are published, and other such repositories as appropriate.

G. Evaluation of Guidelines

The selected organization is expected to develop strategies and methods to evaluate the effectiveness of HIV clinical guidelines. Evaluation activities will increase because the program has matured; applicants should demonstrate, either by using staff members or consultants, the necessary expertise to implement program evaluation. These efforts will involve various sections of participants in the AI; however, the contractor will play a substantial role in coordinating and moving them forward. The selected organization is also expected to work with each committee to establish evaluation methods and to determine the use of the guidelines by providers in New York State. The evaluation component will also be used to measure the effectiveness of guidelines dissemination endeavors, and particularly the effectiveness of the program's website for currency of information, ease of use, and its ability to meet the needs of providers for HIV clinical information.

Applicants should include evaluation strategies in their proposal responses, and should address methods and suggest plans to conduct guidelines program evaluation. These plans should include both evaluation of the existing guidelines program as well as a broader review of the effects of these evidence based guidelines on patient care in New York State. The proposals should consider ways the current guidelines program could be improved.

V. Administrative Requirements

A. Issuing Agency

This RFA is issued by the NYS Department of Health AIDS Institute, Office of the Medical Director. The Department is responsible for the requirements specified herein and for the evaluation of all applications.

B. Question and Answer Phase:

All substantive questions must be submitted in writing to:

Tracy Hatton
New York State Department of Health
AIDS Institute, Office of the Medical Director
90 Church Street, 13th Floor
New York, NY 10007
teh04@health.state.ny.us

To the degree possible, each inquiry should cite the RFA section and paragraph to which it refers. Written questions will be accepted until the date posted on the cover of this RFA.

Questions of a technical nature can be addressed to Tracy Hatton in writing or via email. Questions are of a technical nature if they are limited to how to prepare your application (e.g., formatting) rather than relating to the substance of the application. Prospective applicants should note that all clarification and exceptions, including those relating to the terms and conditions of the contract, are to be raised prior to the submission of an application.

This RFA has been posted on the Department of Health's public website at: <http://www.nyhealth.gov/funding/>. Questions and answers, as well as any updates and/or modifications, will also be posted on the Department of Health's website. All such updates will be posted by the date identified on the cover sheet of this RFA.

If prospective applicants would like to receive notification when updates/modifications are posted (including responses to written questions) please complete and submit a letter of interest (see Attachment 2). Prospective applicants may also use the letter of interest to request actual (hard copy) documents containing update information.

C. Applicant Conference and Letter of Interest

An Applicant Conference will not be held for this project.

Submission of a Letter of Interest is encouraged but not mandatory. The Letter of Interest must be received by the date posted on the cover of this RFA at the address shown in Section D below in order to automatically receive any updates or modifications to this RFA. Failure to submit a Letter of Interest will NOT preclude the submission of an application. A sample Letter of Interest is included as Attachment 2 of this RFA.

D. How to File an Application

Applications must be **received** at the following address by 5:00 PM on the date posted on the cover sheet of this RFA. Late applications will not be accepted*.

Valerie J. White
Deputy Director, Administration and Data Systems
New York State Department of Health AIDS Institute
ESP, Corning Tower Room 478
Albany, New York 12237

Applicants shall submit 1 original, signed application and 8 copies. Application packages should be clearly labeled with the name and number of the RFA as listed on the cover of this document. Applications WILL NOT be accepted via fax or e-mail.

Applicants should pay close attention to Attachment 3, the Application Checklist, to ensure that submission requirements have been met. Applicants should review this attachment before writing and prior to submitting the application.

* It is the applicant's responsibility to see that applications are delivered to the address above prior to the date and time specified. Late applications due to a documentable delay by the carrier may be considered at the Department of Health's discretion.

E. The Department of Health Reserves the Right To:

1. Reject any or all applications received in response to this RFA.
2. Withdraw the RFA at any time, at the Department's sole discretion.
3. Make an award under the RFA in whole or in part.
4. Disqualify any applicant whose conduct and/or proposal fails to conform to the requirements of the RFA.
5. Seek clarifications and revisions of applications.
6. Use application information obtained through site visits, management interviews and the state's investigation of an applicant's qualifications, experience, ability or financial standing, and any material or information submitted by the applicant in response to the agency's request for clarifying information in the course of evaluation and/or selection under the RFA.
7. Prior to application opening, amend the RFA specifications to correct errors or oversights, or to supply additional information, as it becomes available.
8. Prior to application opening, direct applicants to submit proposal modifications addressing subsequent RFA amendments.
9. Change any of the scheduled dates.
10. Waive any requirements that are not material.
11. Award more than one contract resulting from this RFA.
12. Conduct contract negotiations with the next responsible applicant, should the Department be unsuccessful in negotiating with the selected applicant.
13. Utilize any and all ideas submitted with the applications received.
14. Unless otherwise specified in the RFA, every offer is firm and not revocable for a

period of 60 days from the bid opening.

15. Waive or modify minor irregularities in applications received after prior notification to the applicant.
16. Require clarification at any time during the procurement process and/or require correction of arithmetic or other apparent errors for the purpose of assuring a full and complete understanding of an offeror's application and/or to determine an offerer's compliance with the requirements of the RFA.
17. Negotiate with successful applicants within the scope of the RFA in the best interests of the State.
18. Eliminate any mandatory, non-material specifications that cannot be complied with by all applicants.
19. Award grants based on geographic or regional considerations to serve the best interests of the state.

F. Term of Contract

Any contract resulting from this RFA will be effective only upon approval by the New York State Office of the Comptroller.

Contracts will be awarded under this RFA for a 12-month term, with an anticipated start date on or about March 1, 2011. Awards may be renewed for up to four additional one-year periods based on satisfactory performance and the availability of funds.

G. Payment & Reporting Requirements of Grant Awardees

1. The Department may, at its discretion, make an advance payment to not for profit grant contractors in an amount not to exceed twenty-five (25) percent.
2. The grant contractor will be required to submit quarterly invoices and required reports of expenditures to the State's designated payment office:

AIDS Institute-Office of the Medical Director
NYS Department of Health
90 Church Street, 13th Floor
New York, NY 10007

Grant contractors shall provide complete and accurate billing vouchers to the Department's designated payment office in order to receive payment. Billing vouchers submitted to the Department must contain all information and supporting documentation required by the Contract, the Department and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall only be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the

Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-474-4032. CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

Payment of such vouchers by the State (NYS Department of Health) shall be made in accordance with Article XI-A of the New York State Finance Law. Payment terms will be: quarterly vouchers.

3. The grant contractor will be required to submit a narrative monthly progress report.

All payment and reporting requirements will be detailed in Appendix C of the final grant contract.

H. Vendor Responsibility Questionnaire

New York State Procurement Law requires that state agencies award contracts only to responsible vendors. Vendors are invited to file the required Vendor Responsibility Questionnaire online via the New York State VendRep System or may choose to complete and submit a paper questionnaire. To enroll in and use the New York State VendRep System, see the VendRep System Instructions available at www.osc.state.ny.us/vendrep or go directly to the VendRep system online at <https://portal.osc.state.ny.us>. For direct VendRep System user assistance, the OSC Help Desk may be reached at 866-370-4672 or 518-408-4672 or by email at helpdesk@osc.state.ny.us. Vendors opting to file a paper questionnaire can obtain the appropriate questionnaire from the VendRep website www.osc.state.ny.us/vendrep or may contact the Department of Health or the Office of the State Comptroller for a copy of the paper form. Applicants should also complete and submit the Vendor Responsibility Attestation (Attachment 9).

I. General Specifications

1. By signing the "Application Cover Sheet" (Attachment 4) each applicant attests to its express authority to sign on behalf of the applicant.
2. Contractor will possess, at no cost to the State, all qualifications, licenses and permits to engage in the required business as may be required within the jurisdiction where the work specified is to be performed. Workers to be employed in the performance of this contract will possess the qualifications, training, licenses and permits as may be required within such jurisdiction.

3. Submission of an application indicates the applicant's acceptance of all conditions and terms contained in this RFA, including the terms and conditions of the contract. Any exceptions allowed by the Department during the Question and Answer Phase (Section V.B.) must be clearly noted in a cover letter attached to the application.
4. An applicant may be disqualified from receiving awards if such applicant or any subsidiary, affiliate, partner, officer, agent or principal thereof, or anyone in its employ, has previously failed to perform satisfactorily in connection with public bidding or contracts.
5. Provisions Upon Default
 - a. The services to be performed by the Applicant shall be at all times subject to the direction and control of the Department as to all matters arising in connection with or relating to the contract resulting from this RFA.
 - b. In the event that the Applicant, through any cause, fails to perform any of the terms, covenants or promises of any contract resulting from this RFA, the Department acting for and on behalf of the State, shall thereupon have the right to terminate the contract by giving notice in writing of the fact and date of such termination to the Applicant.
 - c. If, in the judgement of the Department of Health, the Applicant acts in such a way which is likely to or does impair or prejudice the interests of the State, the Department acting on behalf of the State, shall thereupon have the right to terminate any contract resulting from this RFA by giving notice in writing of the fact and date of such termination to the Contractor. In such case the Contractor shall receive equitable compensation for such services as shall, in the judgement of the State Comptroller, have been satisfactorily performed by the Contractor up to the date of the termination of this agreement, which such compensation shall not exceed the total cost incurred for the work which the Contractor was engaged in at the time of such termination, subject to audit by the State Comptroller.

J. Appendices included in DOH Grant Contracts

The following will be incorporated as appendices into any contract(s) resulting from this Request for Applications (See Attachment 1 Standard State Contract with Appendices).

APPENDIX A	Standard Clauses for New York State Contracts
APPENDIX A-1	Agency Specific Clauses
APPENDIX A-2	Standard Clauses for All AIDS Institute Contracts
APPENDIX B	Budget
APPENDIX C	Payment and Reporting Schedule
APPENDIX D	Workplan
APPENDIX E	Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof,

completed by the CONTRACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for:

Workers' Compensation, for which one of the following is incorporated into this contract as Appendix E-1:

- **CE-200** - Certification of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **C-105.2** -- Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the **U-26.3**; OR
- **SI-12** -- Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** - Certificate of Participation in Workers' Compensation Group Self Insurance.

Disability Benefits coverage, for which one of the following is incorporated into this contract as **Appendix E-2**:

- **CE-200** - Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **DB-120.1** -- Certificate of Disability Benefits Insurance OR
- **DB-155** -- Certificate of Disability Benefits Self-Insurance

NOTE: Do not include the Workers' Compensation and Disability Benefits forms with your application. These documents will be requested as a part of the contracting process should you receive an award.

APPENDIX F	AIDS Institute Policy/Access to and Disclosure of Personal Health Related Information
APPENDIX G	Notifications

VI. Completing the Application

Application Format and Content

Applications should not exceed twenty-one (21) double-spaced pages, using a 12-pitch type font with one-inch margins on all sides. Pages should be numbered consecutively, including all attachments. The program summary, budget and budget justification, examples of guidelines, publications, and materials requested in E. below, and all attachments are *not included* in the 21 page limitation. **Failure to follow these guidelines may result in a deduction of up to five (5) points.**

Please respond to each of the following statements and questions. Be specific and complete in your responses, as they comprise your application. **Number/letter your narrative to correspond to each statement and/or question in the order presented.** Indicate if a statement or question is not relevant to your agency or application. The value assigned to each section is an indication of the relative weight that will be given to that section when your application is scored.

All applications are required to demonstrate support for the proposed program by including a signed Letter of Commitment from the applicant's Board of Directors or Equivalent Official (see Attachment 5).

A. Program Summary

**(Up to 2 pages, not counted in page total)
Not scored**

Applicants should provide a summary of the application and include a brief description of the specific activities to be undertaken and demonstrate how they will effectively meet program goals and utilize their funding request.

B. Applicant Organization and Capacity

**(3-5 pages)
(Maximum Score: 20 points)**

(1) Describe the organization's capacity to fulfill all functions of the guidelines program; include related experience and expertise that will be utilized in managing the scope of work. Provide a description of the staffing pattern your organization proposes to carry out the scope of work. **Preference will be given to applicants that have the organizational capacity to manage the current eight distinct clinical committees and coordinate all aspects of their guidelines activities.**

(2) Describe how the organization has demonstrated the following characteristics in previous work:

- Capacity to provide leadership and management of the program staff to ensure accomplishment of program activities and scope of work in a professional and timely manner and;

- Provide methodology, expertise and design of program evaluation.

(3) Minimum staffing requirements:

- Describe the role of the Principal Investigator and demonstrate that this position will meet the project requirements set forth in section IV. A of this RFA. Include the individual's background, professional experience in HIV treatment, and all relevant experience. Describe in detail the Principal Investigator's involvement in the Program. Please include a CV with the application.
- Describe the duties and expertise of the Project Director, who will be responsible for the overall management of the program and the primary contact person for the AIDS Institute. Please include a CV/resume with the application.
- Describe the duties and background of the remaining project staff, as well as ability to access and augment staff efforts in order to ensure sufficient capacity of clinicians, medical writers, editors or public health specialists who have experience in clinical guidelines development, experience in medical education, experience in medical publishing, and website development and maintenance. Please include any relevant CVs/resumes with the application. **Preference will be given to applicants that have access to clinicians, medical writers, editors, publication designers, public health specialists and/or others with expertise and relevant experience in medical education and in medical publishing and guidelines development and dissemination.**

(4) Describe the applicant's ability to design and implement program evaluation.

(5) Describe the applicant organization's administrative capacity, including fiscal management, information systems, board involvement, and organizational structure and how the organization's administrative capacity will support the proposed program. **Provide information to demonstrate that the applicant meets the preference factor of having at least two (2) years experience with administrative, fiscal, and programmatic oversight of government contracts, including timely and accurate submission of fiscal and program reports.**
Complete Attachment 6.

(6) Attach a copy of your most recent Yearly Independent Audit.

C. Applicant Experience and Expertise

(3-5 pages)

(Maximum Score: 20 points)

(1) Describe the organization's experience in the clinical aspects of guidelines content and ability to ensure the following:

- Specific experience in the methodology and language of guidelines development and familiarity with evidence-based medicine and medical/scientific literature; capacity to comprehend, articulate and communicate the medical/scientific issues covered in guidelines;
- Ability to direct committees through the process of guidelines development including appropriate language for recommendations; ensure that guidelines encompass common clinical scenarios, and acknowledge common exceptions;
- Experience in medical writing and editorial management to oversee all aspects of the editorial process and ensure timely and professional completion of written products;

Preference will be given to applicants that can demonstrate proficiency in HIV clinical guidelines development, and experience with a variety of guidelines dissemination and implementation strategies as well as an understanding of the relationship of clinical guidelines to public policy and a thorough understanding of the clinical and social issues relevant to HIV care.

(2) Describe the experience of the organization in addressing the following areas:

- Experience in website maintenance that includes the ability to post materials in a variety of formats, manage website design and content, and possess the ability to make changes and enhancements when needed. **Preference will be given to applicants that can demonstrate substantial expertise in website management, which includes technological expertise and familiarity with using electronic media, as well as expertise in overseeing the production of materials related to the guidelines, both as printed publications and website postings in various media;**
- Capability and experience in conducting dissemination of materials in various electronic media and in print;
- Ability to provide technical assistance, specifically regarding the use of information technology, to the AIDS Institute to ensure realization of projects;
- Expertise in graphic design/layout; and preparing documents for website posting;

- The ability to oversee printing and distribution of materials related to clinical guidelines.

D. Goals, Objectives, and Work Plan

(6-8 pages)

(Maximum Score: 20 points)

Points for this section will be assigned based on the description of the goals, objectives, activities, and the time in which these activities will be achieved. Applicants should explain the process through which specific program activities will be carried out, including the staff that will be utilized, and the time frames.

At a minimum, the narrative should include the following:

- (1) Program structure and administrative responsibilities;
- (2) Services related to the development of evidence-based clinical guidelines;
- (3) Plans to manage the work of all the guidelines committees, consultants, and peer reviewers;
- (4) The process to be used writing and content editing of the guidelines and other materials;
- (5) Plans to ensure that the final guidelines and other program materials will be made available in various formats, on the HIV Clinical Resource website,
- (6) Design, production and distribution of printed materials;
- (7) Methods to ensure wide dissemination of guidelines and related materials;
- (8) Methodology and plan for evaluation of dissemination strategies, and for conducting program evaluation and research regarding the effectiveness of guidelines implementation in New York State

E. Program Assessment and Guidelines Evaluation

(2-3 pages)

(Maximum Score: 10 points)

- (1) Describe the evaluation strategies that your organization will use to assess the effectiveness of HIV clinical guidelines.
- (2) Include the specific methods to be utilized to conduct guidelines program evaluation. This plan should include both evaluation of the existing guidelines program as well as a broader review of the effects of these evidence-based guidelines on patient care in New York State and the effectiveness of the program's website and its ability to meet the needs of clinical providers. Please include systems that allow for collecting information and monitoring usage in an ongoing manner.
- (3) The proposals should consider ways the current guidelines program could be improved and describe the approach that would be taken to implement any needed changes.
Preference will be given to applicants that are able, with guidance and in partnership with the AIDS Institute, to develop strategies to improve and test implementation of the HIV clinical guidelines.

F. Examples of Guidelines, Publications, Materials (paper/electronic)

(Up to 50 pages, not counted in page total)

(Maximum Score: 10 points)

Applicants should include the following examples that they have developed, designed and/or produced:

- Guidelines that demonstrate the ability to target the needs of clinical providers;
- Sample publications that show the ability to produce professional level educational materials that contain language and formats appropriate for clinical providers, supportive service providers, and consumers;
- Web page designs and related electronic formats that demonstrate the ability to target an audience of clinical providers using new media.

All examples should be of a professional level and contain clinical content. This should not exceed a total of 50 pages of material.

G. Budget and Justification

(Use budget forms; not counted in page total)

(Maximum Score: 20 points)

- (1) Complete the attached budget forms (Attachment 7) assuming a 12-month budget. All costs must be directly related to the activities described in the application, necessary to the guidelines project, reasonable and cost effective. Justification for each cost should be submitted in narrative form.
- (2) The project budget should include a breakdown of the proposed budget for development of the following projects. The actual projects may vary slightly but will represent the equivalent size and cost of those listed below:
 - The budget should reflect the development and dissemination of 20 guidelines in a year, with at least one guideline from each committee.
 - All program staff salary costs including fringe; the budget should reflect staff duties and the amount of time needed to complete these activities,
 - Reimbursement to guidelines committee members for time and travel
 - Any consultant and subcontractor expenses including services and functions
 - Website maintenance and related costs
 - Program staff travel and meeting expenses

- Any production and printing related costs
- If subcontracting is requested, applicants are expected to describe the activities they will perform.

(3) Financial Capacity

Note: This program requires that the contractor have the financial capacity to pay committee, consultant, printing, production, distribution, and other expenses on a reimbursement basis. The contractor may submit vouchers to New York State only for paid expenses. The contractor is required to pay approved expenses in a timely manner.

- Describe your organization's business history and capacity to account for and track prompt payment of approved expenses.
- Provide documentation of your organization's capacity to pay approved expenses prior to reimbursement by New York State. This would include documentation of capital reserves on hand to satisfy the financial requirements of this contract. This documentation should include showing organizational fiscal capacity to meet payroll and fund Other than Personnel Services as the need occurs.
- The contractor must be able to substantiate all vouchers to New York State with paid invoices for approved expenses.
- The organization must show the ability to make such payments in advance of reimbursement by New York State for those expenses and independent of receipt of reimbursement by New York State for expenses during any prior period.

Ineligible budget items will be removed from the budget before the budget is scored. Ineligible items are those items determined by NYSDOH personnel to be inadequately justified in relation to the proposed workplan or not fundable under existing state and federal guidance (OMB circulars). The budget amount requested will be reduced to reflect the removal of the ineligible items.

Funding may support a fair proportion of the overall organizational structure to an extent that it allows the funded applicant to implement program activities. This includes funding for administrative staff, supervisors and support personnel, and other-than-personnel costs such as a share of space, supplies, telephone, and other expenses associated with program implementation and service delivery. Agencies without a federally approved administrative rate may request up to 10% of total direct costs for administrative expenses. Agencies with a federally approved rate greater than or equal to 20% may request up to 20%; agencies with a federally approved rate of less than 20% may request their approved rate.

H. Required Attachments to the Application

The following should be submitted with your application and are not counted towards the application's overall page limitation:

- Application Checklist (Attachment 3)
- Application Cover Sheet (Attachment 4)
- Letter of Commitment from Board of Directors or Equivalent Official (Attachment 5)
- Budget Forms and Narrative (Attachment 7)
- Vendor Responsibility Questionnaire (Attachment 8) (if you choose not to submit on-line)
- Vendor Responsibility Attestation (Attachment 9)
- Copy of your most recent Yearly Independent Audit
- Curriculum Vitae/resumes for all program staff
- Agency Capacity Information (Attachment 6)
- Examples of recent printed program materials and guidelines

VII. Review and Award Process

Applications meeting the eligibility requirements will be reviewed and evaluated competitively using an objective rating system reflective of the required items specified for each section, and the maximum points for each section specified above. A panel convened by the AIDS Institute will conduct a review of applications from eligible applicants.

The reviewers will consider the following factors: (1) overall merit and clarity of the application; (2) responsiveness to this Request for Applications; (3) agency capacity and experience; (4) applicant's catchment area and innovative approaches to reaching the target population; (5) comprehensive, creative and sound program design; (6) quality of the evaluation strategy; (7) relevance, justification and cost-effectiveness of budgeted costs; and (8) agency experience in the effective administrative, fiscal, and programmatic oversight of government contracts, including timely and accurate submission of fiscal and program reports.

The application with the highest acceptable score (70 or above) will receive the award. If there are no applications scoring 70 or above, the NYSDOH reserves the right to funding the highest scoring applicant.

Where two or more applicants for funding are judged, on the basis of their written applications, to be equal in quality, such applicants may be invited to meet with AIDS Institute staff. Such meetings, to be conducted in a fashion comparable to employment interviews, are for the purpose of helping to distinguish between or among the applicants based on their response to structured questions.

A visit to an applicant's service site may be appropriate when the agency and its facilities are not familiar to the AIDS Institute. The purpose of such a visit would be to verify that the agency has appropriate facilities to carry out the work plan described in its application for funding.

It is anticipated that there may be more worthy applications than can be funded with available resources. Applications will be deemed to fall in one of three categories: 1) approved and funded, 2) approved but not funded, 3) not approved. Should additional funding become available, the AIDS Institute may select a contractor from the pool of applicants deemed approved but not funded. If it is determined that the needed expertise/services are not available among these organizations, the AIDS Institute reserves the right to establish additional competitive solicitations or to award funds on a sole source basis.

Following the awarding of contracts from this RFA, applicants may request a debriefing from the NYSDOH no later than three months from the date of the awards announcement. This debriefing will be limited to the positive and negative aspects of the subject application.

ATTACHMENT 1
STANDARD GRANT CONTRACT WITH
APPENDICES

GRANT CONTRACT (STANDARD)

STATE AGENCY (Name and Address): _____	.	NYS COMPTROLLER'S NUMBER: _____
	.	
	.	ORIGINATING AGENCY CODE: _____
	.	
CONTRACTOR (Name and Address): _____	.	TYPE OF PROGRAM(S) _____
	.	
	.	
FEDERAL TAX IDENTIFICATION NUMBER: _____	.	INITIAL CONTRACT PERIOD _____
	.	
MUNICIPALITY NO. (if applicable): _____	.	FROM: _____
	.	
	.	TO: _____
	.	
CHARITIES REGISTRATION NUMBER: ____ - ____ - ____ or () EXEMPT: (If EXEMPT, indicate basis for exemption): _____	.	FUNDING AMOUNT FOR INITIAL PERIOD: _____
	.	
	.	MULTI-YEAR TERM (if applicable): FROM: TO: _____
	.	
CONTRACTOR HAS() HAS NOT() TIMELY FILED WITH THE ATTORNEY GENERAL'S CHARITIES BUREAU ALL REQUIRED PERIODIC OR ANNUAL WRITTEN REPORTS. _____	.	
	.	
CONTRACTOR IS() IS NOT() A SECTARIAN ENTITY CONTRACTOR IS() IS NOT() A NOT-FOR-PROFIT ORGANIZATION _____	.	

APPENDICES ATTACHED AND PART OF THIS AGREEMENT

_____	APPENDIX A	Standard clauses as required by the Attorney General for all State contracts.
_____	APPENDIX A-1	Agency-Specific Clauses (Rev 10/08)
_____	APPENDIX B	Budget
_____	APPENDIX C	Payment and Reporting Schedule
_____	APPENDIX D	Program Workplan
_____	APPENDIX G	Notices
_____	APPENDIX X	Modification Agreement Form (to accompany modified appendices for changes in term or consideration on an existing period or for renewal periods)

OTHER APPENDICES

_____	APPENDIX A-2	Program-Specific Clauses
_____	APPENDIX E-1	Proof of Workers' Compensation Coverage
_____	APPENDIX E-2	Proof of Disability Insurance Coverage
_____	APPENDIX H	Federal Health Insurance Portability and Accountability Act Business Associate Agreement
_____	APPENDIX _____	_____
_____	APPENDIX _____	_____

STATE OF NEW YORK

AGREEMENT

This AGREEMENT is hereby made by and between the State of New York agency (STATE) and the public or private agency (CONTRACTOR) identified on the face page hereof.

WITNESSETH:

WHEREAS, the STATE has the authority to regulate and provide funding for the establishment and operation of program services and desires to contract with skilled parties possessing the necessary resources to provide such services; and

WHEREAS, the CONTRACTOR is ready, willing and able to provide such program services and possesses or can make available all necessary qualified personnel, licenses, facilities and expertise to perform or have performed the services required pursuant to the terms of this AGREEMENT;

NOW THEREFORE, in consideration of the promises, responsibilities and covenants herein, the STATE and the CONTRACTOR agree as follows:

- I. Conditions of Agreement
 - A. This AGREEMENT may consist of successive periods (PERIOD), as specified within the AGREEMENT or within a subsequent Modification Agreement(s) (Appendix X). Each additional or superseding PERIOD shall be on the forms specified by the particular State agency, and shall be incorporated into this AGREEMENT.
 - B. Funding for the first PERIOD shall not exceed the funding amount specified on the face page hereof. Funding for each subsequent PERIOD, if any, shall not exceed the amount specified in the appropriate appendix for that PERIOD.
 - C. This AGREEMENT incorporates the face pages attached and all of the marked appendices identified on the face page hereof.
 - D. For each succeeding PERIOD of this AGREEMENT, the parties shall prepare new appendices, to the extent that any require modification, and a Modification Agreement (The attached Appendix X is the blank form to be used). Any terms of this AGREEMENT not modified shall remain in effect for each PERIOD of the AGREEMENT.

To modify the AGREEMENT within an existing PERIOD, the parties shall revise or complete the appropriate appendix form(s). Any change in the amount of consideration to be paid, or change in the term, is subject to the approval of the Office of the State Comptroller. Any other modifications shall be processed in accordance with agency guidelines as stated in Appendix A1.
 - E. The CONTRACTOR shall perform all services to the satisfaction of the STATE. The CONTRACTOR shall provide services and meet the program objectives summarized in the Program Workplan (Appendix D) in accordance with: provisions of the AGREEMENT; relevant laws, rules and regulations, administrative and fiscal

guidelines; and where applicable, operating certificates for facilities or licenses for an activity or program.

- F. If the CONTRACTOR enters into subcontracts for the performance of work pursuant to this AGREEMENT, the CONTRACTOR shall take full responsibility for the acts and omissions of its subcontractors. Nothing in the subcontract shall impair the rights of the STATE under this AGREEMENT. No contractual relationship shall be deemed to exist between the subcontractor and the STATE.
- G. Appendix A (Standard Clauses as required by the Attorney General for all State contracts) takes precedence over all other parts of the AGREEMENT.

II. Payment and Reporting

- A. The CONTRACTOR, to be eligible for payment, shall submit to the STATE's designated payment office (identified in Appendix C) any appropriate documentation as required by the Payment and Reporting Schedule (Appendix C) and by agency fiscal guidelines, in a manner acceptable to the STATE.
- B. The STATE shall make payments and any reconciliations in accordance with the Payment and Reporting Schedule (Appendix C). The STATE shall pay the CONTRACTOR, in consideration of contract services for a given PERIOD, a sum not to exceed the amount noted on the face page hereof or in the respective Appendix designating the payment amount for that given PERIOD. This sum shall not duplicate reimbursement from other sources for CONTRACTOR costs and services provided pursuant to this AGREEMENT.
- C. The CONTRACTOR shall meet the audit requirements specified by the STATE.
- D. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-474-4032. CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

In addition to the Electronic Payment Authorization Form, a Substitute Form W-9, must be on file with the Office of the State Comptroller, Bureau of Accounting Operations. Additional information and procedures for enrollment can be found at <http://www.osc.state.ny.us/epay>.

Completed W-9 forms should be submitted to the following address:

NYS Office of the State Comptroller
Bureau of Accounting Operations
Warrant & Payment Control Unit
110 State Street, 9th Floor
Albany, NY 12236

III. Terminations

- A. This AGREEMENT may be terminated at any time upon mutual written consent of the STATE and the CONTRACTOR.
- B. The STATE may terminate the AGREEMENT immediately, upon written notice of termination to the CONTRACTOR, if the CONTRACTOR fails to comply with the terms and conditions of this AGREEMENT and/or with any laws, rules and regulations, policies or procedures affecting this AGREEMENT.
- C. The STATE may also terminate this AGREEMENT for any reason in accordance with provisions set forth in Appendix A-1.
- D. Written notice of termination, where required, shall be sent by personal messenger service or by certified mail, return receipt requested. The termination shall be effective in accordance with the terms of the notice.
- E. Upon receipt of notice of termination, the CONTRACTOR agrees to cancel, prior to the effective date of any prospective termination, as many outstanding obligations as possible, and agrees not to incur any new obligations after receipt of the notice without approval by the STATE.
- F. The STATE shall be responsible for payment on claims pursuant to services provided and costs incurred pursuant to terms of the AGREEMENT. In no event shall the STATE be liable for expenses and obligations arising from the program(s) in this AGREEMENT after the termination date.

IV. Indemnification

- A. The CONTRACTOR shall be solely responsible and answerable in damages for any and all accidents and/or injuries to persons (including death) or property arising out of or related to the services to be rendered by the CONTRACTOR or its subcontractors pursuant to this AGREEMENT. The CONTRACTOR shall indemnify and hold harmless the STATE and its officers and employees from claims, suits, actions, damages and costs of every nature arising out of the provision of services pursuant to this AGREEMENT.
- B. The CONTRACTOR is an independent contractor and may neither hold itself out nor claim to be an officer, employee or subdivision of the STATE nor make any claims, demand or application to or for any right based upon any different status.

V. Property

Any equipment, furniture, supplies or other property purchased pursuant to this AGREEMENT is deemed to be the property of the STATE except as may otherwise be governed by Federal or State laws, rules and regulations, or as stated in Appendix A-2.

VI. Safeguards for Services and Confidentiality

- A. Services performed pursuant to this AGREEMENT are secular in nature and shall be performed in a manner that does not discriminate on the basis of religious belief, or promote or discourage adherence to religion in general or particular religious beliefs.
- B. Funds provided pursuant to this AGREEMENT shall not be used for any partisan political activity, or for activities that may influence legislation or the election or defeat of any candidate for public office.
- C. Information relating to individuals who may receive services pursuant to this AGREEMENT shall be maintained and used only for the purposes intended under the contract and in conformity with applicable provisions of laws and regulations, or specified in Appendix A-1.

APPENDIX A-1
(REV 10/08)

AGENCY SPECIFIC CLAUSES FOR ALL
DEPARTMENT OF HEALTH CONTRACTS

1. If the CONTRACTOR is a charitable organization required to be registered with the New York State Attorney General pursuant to Article 7-A of the New York State Executive Law, the CONTRACTOR shall furnish to the STATE such proof of registration (a copy of Receipt form) at the time of the execution of this AGREEMENT. The annual report form 497 is not required. If the CONTRACTOR is a business corporation or not-for-profit corporation, the CONTRACTOR shall also furnish a copy of its Certificate of Incorporation, as filed with the New York Department of State, to the Department of Health at the time of the execution of this AGREEMENT.
2. The CONTRACTOR certifies that all revenue earned during the budget period as a result of services and related activities performed pursuant to this contract shall be used either to expand those program services funded by this AGREEMENT or to offset expenditures submitted to the STATE for reimbursement.
3. Administrative Rules and Audits:
 - a. If this contract is funded in whole or in part from federal funds, the CONTRACTOR shall comply with the following federal grant requirements regarding administration and allowable costs.
 - i. For a local or Indian tribal government, use the principles in the common rule, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments," and Office of Management and Budget (OMB) Circular A-87, "Cost Principles for State, Local and Indian Tribal Governments".
 - ii. For a nonprofit organization other than
 - ◆ an institution of higher education,
 - ◆ a hospital, or
 - ◆ an organization named in OMB Circular A-122, "Cost Principles for Non-profit Organizations", as not subject to that circular,use the principles in OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-profit Organizations," and OMB Circular A-122.
 - iii. For an Educational Institution, use the principles in OMB Circular A-110 and OMB Circular A-21, "Cost Principles for Educational Institutions".
 - iv. For a hospital, use the principles in OMB Circular A-110, Department of Health and Human Services, 45 CFR 74, Appendix E, "Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals" and, if not covered for audit purposes by OMB Circular A-133, "Audits of States Local Governments and Non-profit Organizations", then subject to program specific audit requirements following Government Auditing Standards for financial audits.
 - b. If this contract is funded entirely from STATE funds, and if there are no specific administration and allowable costs requirements applicable, CONTRACTOR shall adhere to the applicable principles in "a" above.

- c. The CONTRACTOR shall comply with the following grant requirements regarding audits.
 - i. If the contract is funded from federal funds, and the CONTRACTOR spends more than \$500,000 in federal funds in their fiscal year, an audit report must be submitted in accordance with OMB Circular A-133.
 - ii. If this contract is funded from other than federal funds or if the contract is funded from a combination of STATE and federal funds but federal funds are less than \$500,000, and if the CONTRACTOR receives \$300,000 or more in total annual payments from the STATE, the CONTRACTOR shall submit to the STATE after the end of the CONTRACTOR's fiscal year an audit report. The audit report shall be submitted to the STATE within thirty days after its completion but no later than nine months after the end of the audit period. The audit report shall summarize the business and financial transactions of the CONTRACTOR. The report shall be prepared and certified by an independent accounting firm or other accounting entity, which is demonstrably independent of the administration of the program being audited. Audits performed of the CONTRACTOR's records shall be conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States covering financial audits. This audit requirement may be met through entity-wide audits, coincident with the CONTRACTOR's fiscal year, as described in OMB Circular A-133. Reports, disclosures, comments and opinions required under these publications should be so noted in the audit report.
 - d. For audit reports due on or after April 1, 2003, that are not received by the dates due, the following steps shall be taken:
 - i. If the audit report is one or more days late, voucher payments shall be held until a compliant audit report is received.
 - ii. If the audit report is 91 or more days late, the STATE shall recover payments for all STATE funded contracts for periods for which compliant audit reports are not received.
 - iii. If the audit report is 180 days or more late, the STATE shall terminate all active contracts, prohibit renewal of those contracts and prohibit the execution of future contracts until all outstanding compliant audit reports have been submitted.
4. The CONTRACTOR shall accept responsibility for compensating the STATE for any exceptions which are revealed on an audit and sustained after completion of the normal audit procedure.
5. FEDERAL CERTIFICATIONS: This section shall be applicable to this AGREEMENT only if any of the funds made available to the CONTRACTOR under this AGREEMENT are federal funds.
- a. LOBBYING CERTIFICATION
 - 1) If the CONTRACTOR is a tax-exempt organization under Section 501 (c)(4) of the Internal Revenue Code, the CONTRACTOR certifies that it will not engage in lobbying activities of any kind regardless of how funded.

- 2) The CONTRACTOR acknowledges that as a recipient of federal appropriated funds, it is subject to the limitations on the use of such funds to influence certain Federal contracting and financial transactions, as specified in Public Law 101-121, section 319, and codified in section 1352 of Title 31 of the United States Code. In accordance with P.L. 101-121, section 319, 31 U.S.C. 1352 and implementing regulations, the CONTRACTOR affirmatively acknowledges and represents that it is prohibited and shall refrain from using Federal funds received under this AGREEMENT for the purposes of lobbying; provided, however, that such prohibition does not apply in the case of a payment of reasonable compensation made to an officer or employee of the CONTRACTOR to the extent that the payment is for agency and legislative liaison activities not directly related to the awarding of any Federal contract, the making of any Federal grant or loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan or cooperative agreement. Nor does such prohibition prohibit any reasonable payment to a person in connection with, or any payment of reasonable compensation to an officer or employee of the CONTRACTOR if the payment is for professional or technical services rendered directly in the preparation, submission or negotiation of any bid, proposal, or application for a Federal contract, grant, loan, or cooperative agreement, or an extension, continuation, renewal, amendment, or modification thereof, or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan or cooperative agreement.
- 3) This section shall be applicable to this AGREEMENT only if federal funds allotted exceed \$100,000.
- a) The CONTRACTOR certifies, to the best of his or her knowledge and belief, that:
- ◆ No federal appropriated funds have been paid or will be paid, by or on behalf of the CONTRACTOR, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal amendment or modification of any federal contract, grant, loan, or cooperative agreement.
 - ◆ If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the CONTRACTOR shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying" in accordance with its instructions.
- b) The CONTRACTOR shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including

subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

- c) The CONTRACTOR shall disclose specified information on any agreement with lobbyists whom the CONTRACTOR will pay with other Federal appropriated funds by completion and submission to the STATE of the Federal Standard Form-LLL, "Disclosure Form to Report Lobbying", in accordance with its instructions. This form may be obtained by contacting either the Office of Management and Budget Fax Information Line at (202) 395-9068 or the Bureau of Accounts Management at (518) 474-1208. Completed forms should be submitted to the New York State Department of Health, Bureau of Accounts Management, Empire State Plaza, Corning Tower Building, Room 1315, Albany, 12237-0016.
 - d) The CONTRACTOR shall file quarterly updates on the use of lobbyists if material changes occur, using the same standard disclosure form identified in (c) above to report such updated information.
- 4) The reporting requirements enumerated in subsection (3) of this paragraph shall not apply to the CONTRACTOR with respect to:
- a) Payments of reasonable compensation made to its regularly employed officers or employees;
 - b) A request for or receipt of a contract (other than a contract referred to in clause (c) below), grant, cooperative agreement, subcontract (other than a subcontract referred to in clause (c) below), or subgrant that does not exceed \$100,000; and
 - c) A request for or receipt of a loan, or a commitment providing for the United States to insure or guarantee a loan, that does not exceed \$150,000, including a contract or subcontract to carry out any purpose for which such a loan is made.

b. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE:

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by federal programs either directly or through State or local governments, by federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol

treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a monetary penalty of up to \$1000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this AGREEMENT, the CONTRACTOR certifies that it will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act. The CONTRACTOR agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

c. CERTIFICATION REGARDING DEBARMENT AND SUSPENSION

Regulations of the Department of Health and Human Services, located at Part 76 of Title 45 of the Code of Federal Regulations (CFR), implement Executive Orders 12549 and 12689 concerning debarment and suspension of participants in federal programs and activities. Executive Order 12549 provides that, to the extent permitted by law, Executive departments and agencies shall participate in a government-wide system for non-procurement debarment and suspension. Executive Order 12689 extends the debarment and suspension policy to procurement activities of the federal government. A person who is debarred or suspended by a federal agency is excluded from federal financial and non-financial assistance and benefits under federal programs and activities, both directly (primary covered transaction) and indirectly (lower tier covered transactions). Debarment or suspension by one federal agency has government-wide effect.

Pursuant to the above-cited regulations, the New York State Department of Health (as a participant in a primary covered transaction) may not knowingly do business with a person who is debarred, suspended, proposed for debarment, or subject to other government-wide exclusion (including any exclusion from Medicare and State health care program participation on or after August 25, 1995), and the Department of Health must require its prospective contractors, as prospective lower tier participants, to provide the certification in Appendix B to Part 76 of Title 45 CFR, as set forth below:

1) APPENDIX B TO 45 CFR PART 76-CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION-LOWER TIER COVERED TRANSACTIONS

Instructions for Certification

- a) By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
- b) The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered and erroneous certification, in addition to other remedies available to the Federal Government the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
- c) The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the

prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.

- d) The terms *covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded*, as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
 - e) The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
 - f) The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transaction," without modification, in all lower tier covered transactions.
 - g) A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded From Federal Procurement and Non-procurement Programs.
 - h) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
 - i) Except for transactions authorized under paragraph "e" of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
- 2) Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion – Lower Tier Covered Transactions
- a) The prospective lower tier participant certifies, by submission of this

proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department agency.

- b) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.
6. The STATE, its employees, representatives and designees, shall have the right at any time during normal business hours to inspect the sites where services are performed and observe the services being performed by the CONTRACTOR. The CONTRACTOR shall render all assistance and cooperation to the STATE in making such inspections. The surveyors shall have the responsibility for determining contract compliance as well as the quality of service being rendered.
 7. The CONTRACTOR will not discriminate in the terms, conditions and privileges of employment, against any employee, or against any applicant for employment because of race, creed, color, sex, national origin, age, disability, sexual orientation or marital status. The CONTRACTOR has an affirmative duty to take prompt, effective, investigative and remedial action where it has actual or constructive notice of discrimination in the terms, conditions or privileges of employment against (including harassment of) any of its employees by any of its other employees, including managerial personnel, based on any of the factors listed above.
 8. The CONTRACTOR shall not discriminate on the basis of race, creed, color, sex, national origin, age, disability, sexual orientation or marital status against any person seeking services for which the CONTRACTOR may receive reimbursement or payment under this AGREEMENT.
 9. The CONTRACTOR shall comply with all applicable federal, State and local civil rights and human rights laws with reference to equal employment opportunities and the provision of services.
 10. The STATE may cancel this AGREEMENT at any time by giving the CONTRACTOR not less than thirty (30) days written notice that on or after a date therein specified, this AGREEMENT shall be deemed terminated and cancelled.
 11. Where the STATE does not provide notice to the NOT-FOR-PROFIT CONTRACTOR of its intent to not renew this contract by the date by which such notice is required by Section 179-t(1) of the State Finance Law, then this contract shall be deemed continued until the date that the agency provides the notice required by Section 179-t, and the expenses incurred during such extension shall be reimbursable under the terms of this contract.
 12. Other Modifications
 - a. Modifications of this AGREEMENT as specified below may be made within an existing PERIOD by mutual written agreement of both parties:
 - ◆ Appendix B - Budget line interchanges; Any proposed modification to the contract which results in a change of greater than 10 percent to any budget category, must be submitted to OSC for approval;
 - ◆ Appendix C - Section II, Progress and Final Reports;
 - ◆ Appendix D - Program Workplan will require OSC approval.
 - b. To make any other modification of this AGREEMENT within an existing PERIOD, the parties shall revise or complete the appropriate appendix form(s), and a

Modification Agreement (Appendix X is the blank form to be used), which shall be effective only upon approval by the Office of the State Comptroller.

13. Unless the CONTRACTOR is a political sub-division of New York State, the CONTRACTOR shall provide proof, completed by the CONTRACTOR's insurance carrier and/or the Workers' Compensation Board, of coverage for

Workers' Compensation, for which one of the following is incorporated into this contract as **Appendix E-1**:

- **CE-200** - Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **C-105.2** -- Certificate of Workers' Compensation Insurance. PLEASE NOTE: The State Insurance Fund provides its own version of this form, the **U-26.3**; OR
- **SI-12** -- Certificate of Workers' Compensation Self-Insurance, OR **GSI-105.2** -- Certificate of Participation in Workers' Compensation Group Self-Insurance

Disability Benefits coverage, for which one of the following is incorporated into this contract as **Appendix E-2**:

- **CE-200** - Certificate of Attestation For New York Entities With No Employees And Certain Out Of State Entities, That New York State Workers' Compensation And/Or Disability Benefits Insurance Coverage is Not Required; OR
- **DB-120.1** -- Certificate of Disability Benefits Insurance OR
- **DB-155** -- Certificate of Disability Benefits Self-Insurance

14. Contractor shall comply with the provisions of the New York State Information Security Breach and Notification Act (General Business Law Section 899-aa; State Technology Law Section 208). Contractor shall be liable for the costs associated with such breach if caused by Contractor's negligent or willful acts or omissions, or the negligent or willful acts or omissions of Contractor's agents, officers, employees or subcontractors.
15. All products supplied pursuant to this agreement shall meet local, state and federal regulations, guidelines and action levels for lead as they exist at the time of the State's acceptance of this contract.
16. Additional clauses as may be required under this AGREEMENT are annexed hereto as appendices and are made a part hereof if so indicated on the face page of this AGREEMENT.

APPENDIX C

PAYMENT AND REPORTING SCHEDULE

I. Payment and Reporting Terms and Conditions

A. The STATE may, at its discretion, make an advance payment to the CONTRACTOR, during the initial or any subsequent PERIOD, in an amount to be determined by the STATE but not to exceed _____ percent of the maximum amount indicated in the budget as set forth in the most recently approved Appendix B. If this payment is to be made, it will be due thirty calendar days, excluding legal holidays, after the later of either:

- ❶ the first day of the contract term specified in the Initial Contract Period identified on the face page of the AGREEMENT or if renewed, in the PERIOD identified in the Appendix X, OR
- ❶ if this contract is wholly or partially supported by Federal funds, availability of the federal funds;

provided, however, that a STATE has not determined otherwise in a written notification to the CONTRACTOR suspending a Written Directive associated with this AGREEMENT, and that a proper voucher for such advance has been received in the STATE's designated payment office. If no advance payment is to be made, the initial payment under this AGREEMENT shall be due thirty calendar days, excluding legal holidays, after the later of either:

- ❶ the end of the first <monthly or quarterly> period of this AGREEMENT; or
- ❶ if this contract is wholly or partially supported by federal funds, availability of the federal funds:

provided, however, that the proper voucher for this payment has been received in the STATE's designated payment office.

B. No payment under this AGREEMENT, other than advances as authorized herein, will be made by the STATE to the CONTRACTOR unless proof of performance of required services or accomplishments is provided. If the CONTRACTOR fails to perform the services required under this AGREEMENT the STATE shall, in addition to any remedies available by law or equity, recoup payments made but not earned, by set-off against any other public funds owed to CONTRACTOR.

C. Any optional advance payment(s) shall be applied by the STATE to future payments due to the CONTRACTOR for services provided during initial or subsequent PERIODS. Should funds for subsequent PERIODS not be appropriated or budgeted by the STATE for the purpose herein specified, the STATE shall, in accordance with Section 41 of the State Finance Law, have no liability under this AGREEMENT to the CONTRACTOR, and this AGREEMENT shall be considered terminated and cancelled.

- D. The CONTRACTOR will be entitled to receive payments for work, projects, and services rendered as detailed and described in the program workplan, Appendix D. All payments shall be in conformance with the rules and regulations of the Office of the State Comptroller. The CONTRACTOR shall provide complete and accurate billing vouchers to the Agency's designated payment office in order to receive payment. Billing vouchers submitted to the Agency must contain all information and supporting documentation required by the Contract, the Agency and the State Comptroller. Payment for vouchers submitted by the CONTRACTOR shall be rendered electronically unless payment by paper check is expressly authorized by the Commissioner, in the Commissioner's sole discretion, due to extenuating circumstances. Such electronic payment shall be made in accordance with ordinary State procedures and practices. The CONTRACTOR shall comply with the State Comptroller's procedures to authorize electronic payments. Authorization forms are available at the State Comptroller's website at www.osc.state.ny.us/epay/index.htm, by email at epunit@osc.state.ny.us or by telephone at 518-474-4032. The CONTRACTOR acknowledges that it will not receive payment on any vouchers submitted under this contract if it does not comply with the State Comptroller's electronic payment procedures, except where the Commissioner has expressly authorized payment by paper check as set forth above.

In addition to the Electronic Payment Authorization Form, a Substitute Form W-9, must be on file with the Office of the State Comptroller, Bureau of Accounting Operations. Additional information and procedures for enrollment can be found at <http://www.osc.state.ny.us/epay>.

Completed W-9 forms should be submitted to the following address:

NYS Office of the State Comptroller
Bureau of Accounting Operations
Warrant & Payment Control Unit
110 State Street, 9th Floor
Albany, NY 12236

- E. The CONTRACTOR will provide the STATE with the reports of progress or other specific work products pursuant to this AGREEMENT as described in this Appendix below. In addition, a final report must be submitted by the CONTRACTOR no later than ____ days after the end of this AGREEMENT. All required reports or other work products developed under this AGREEMENT must be completed as provided by the agreed upon work schedule in a manner satisfactory and acceptable to the STATE in order for the CONTRACTOR to be eligible for payment.
- F. The CONTRACTOR shall submit to the STATE <monthly or quarterly> voucher claims and reports of expenditures on such forms and in such detail as the STATE shall require. The CONTRACTOR shall submit vouchers to the State's designated payment office located in the _____.

All vouchers submitted by the CONTRACTOR pursuant to this AGREEMENT shall be submitted to the STATE no later than _____ days after the end date of the period for which reimbursement is being claimed. In no event shall the amount received by the CONTRACTOR exceed the budget amount approved by the STATE, and, if actual expenditures by the CONTRACTOR are less than such sum,

the amount payable by the STATE to the CONTRACTOR shall not exceed the amount of actual expenditures. All contract advances in excess of actual expenditures will be recouped by the STATE prior to the end of the applicable budget period.

- G. If the CONTRACTOR is eligible for an annual cost of living adjustment (COLA), enacted in New York State Law, that is associated with this grant AGREEMENT, payment of such COLA, or a portion thereof, may be applied toward payment of amounts payable under Appendix B of this AGREEMENT or may be made separate from payments under this AGREEMENT, at the discretion of the STATE.

Before payment of a COLA can be made, the STATE shall notify the CONTRACTOR, in writing, of eligibility for any COLA. If payment is to be made separate from payments under this AGREEMENT, the CONTRACTOR shall be required to submit a written certification attesting that all COLA funding will be used to promote the recruitment and retention of staff or respond to other critical non-personal service costs during the State fiscal year for which the cost of living adjustment was allocated, or provide any other such certification as may be required in the enacted legislation authorizing the COLA.

II. Progress and Final Reports

Insert Reporting Requirements in this section. Provide detailed requirements for all required reports including type of report, information required, formatting, and due dates. Please note that at a minimum, expenditure reports (to support vouchers) and a final report are required. Other commonly used reports include:

Narrative/Qualitative: This report properly determines how work has progressed toward attaining the goals enumerated in the Program Workplan (Appendix D).

Statistical/Qualitative Report: This report analyzes the quantitative aspects of the program plan - for example: meals served, clients transported, training sessions conducted, etc.

APPENDIX D

PROGRAM WORKPLAN (sample format)

A well written, concise workplan is required to ensure that the Department and the contractor are both clear about what the expectations under the contract are. When a contractor is selected through an RFP or receives continuing funding based on an application, the proposal submitted by the contractor may serve as the contract's work plan if the format is designed appropriately. The following are suggested elements of an RFP or application designed to ensure that the minimum necessary information is obtained. Program managers may require additional information if it is deemed necessary.

I. CORPORATE INFORMATION

Include the full corporate or business name of the organization as well as the address, federal employer identification number and the name and telephone number(s) of the person(s) responsible for the plan's development. An indication as to whether the contract is a not-for-profit or governmental organization should also be included. All not-for-profit organizations must include their New York State charity registration number; if the organization is exempt AN EXPLANATION OF THE EXEMPTION MUST BE ATTACHED.

II. SUMMARY STATEMENT

This section should include a narrative summary describing the project which will be funded by the contract. This overview should be concise and to the point. Further details can be included in the section which addresses specific deliverables.

III. PROGRAM GOALS

This section should include a listing, in an abbreviated format (i.e., bullets), of the goals to be accomplished under the contract. Project goals should be as quantifiable as possible, thereby providing a useful measure with which to judge the contractor's performance.

IV. SPECIFIC DELIVERABLES

A listing of specific services or work projects should be included. Deliverables should be broken down into discrete items which will be performed or delivered as a unit (i.e., a report, number of clients served, etc.) Whenever possible a specific date should be associated with each deliverable, thus making each expected completion date clear to both parties.

Language contained in Appendix C of the contract states that the contractor is not eligible for payment "unless proof of performance of required services or accomplishments is provided." The workplan as a whole should be structured around this concept to ensure that the Department does not pay for services that have not been rendered.

Appendix G

NOTICES

All notices permitted or required hereunder shall be in writing and shall be transmitted either:

- (a) via certified or registered United States mail, return receipt requested;
- (b) by facsimile transmission;
- (c) by personal delivery;
- (d) by expedited delivery service; or
- (e) by e-mail.

Such notices shall be addressed as follows or to such different addresses as the parties may from time to time designate:

State of New York Department of Health

Name:

Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

[Insert Contractor Name]

Name:

Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

Any such notice shall be deemed to have been given either at the time of personal delivery or, in the case of expedited delivery service or certified or registered United States mail, as of the date of first attempted delivery at the address and in the manner provided herein, or in the case of facsimile transmission or email, upon receipt.

The parties may, from time to time, specify any new or different address in the United States as their address for purpose of receiving notice under this AGREEMENT by giving fifteen (15) days written notice to the other party sent in accordance herewith. The parties agree to mutually designate individuals as their respective representative for the purposes of receiving notices under this AGREEMENT. Additional individuals may be designated in writing by the parties for purposes of implementation and administration/billing, resolving issues and problems, and/or for dispute resolution.

Agency Code 12000
APPENDIX X

Contract Number: _____

Contractor: _____

Amendment Number X-_____

This is an AGREEMENT between THE STATE OF NEW YORK, acting by and through NYS Department of Health, having its principal office at Albany, New York, (hereinafter referred to as the STATE), and _____ (hereinafter referred to as the CONTRACTOR), for amendment of this contract.

This amendment makes the following changes to the contract (check all that apply):

- _____ Modifies the contract period at no additional cost
- _____ Modifies the contract period at additional cost
- _____ Modifies the budget or payment terms
- _____ Modifies the work plan or deliverables
- _____ Replaces appendix(es) _____ with the attached appendix(es) _____
- _____ Adds the attached appendix(es) _____
- _____ Other: (describe) _____

This amendment *is* / *is not* a contract renewal as allowed for in the existing contract.

All other provisions of said AGREEMENT shall remain in full force and effect.

Prior to this amendment, the contract value and period were:

\$ _____ From ____/____/____ to ____/____/____.
(Value before amendment) (Initial start date)

This amendment provides the following modification (complete only items being modified):

\$ _____ From ____/____/____ to ____/____/____.

This will result in new contract terms of:

\$ _____ From ____/____/____ to ____/____/____.
(All years thus far combined) (Initial start date) (Amendment end date)

Signature Page for:

Contract Number: _____

Contractor: _____

Amendment Number: X-_____

IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT as of the dates appearing under their signatures.

CONTRACTOR SIGNATURE:

By: _____ Date: _____
(signature)

Printed Name: _____

Title: _____

STATE OF NEW YORK)
) SS:
County of _____)

On the ___ day of _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is(are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their/ capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

(Signature and office of the individual taking acknowledgement)

STATE AGENCY SIGNATURE

"In addition to the acceptance of this contract, I also certify that original copies of this signature page will be attached to all other exact copies of this contract."

By: _____ Date: _____
(signature)

Printed Name: _____

Title: _____

ATTORNEY GENERAL'S SIGNATURE

By: _____ Date: _____

STATE COMPTROLLER'S SIGNATURE

By: _____ Date: _____

STANDARD CLAUSES FOR NYS CONTRACTS

The parties to the attached contract, license, lease, amendment or other agreement of any kind (hereinafter, "the contract" or "this contract") agree to be bound by the following clauses which are hereby made a part of the contract (the word "Contractor" herein refers to any party other than the State, whether a contractor, licenser, licensee, lessor, lessee or any other party):

1. EXECUTORY CLAUSE. In accordance with Section 41 of the State Finance Law, the State shall have no liability under this contract to the Contractor or to anyone else beyond funds appropriated and available for this contract.

2. NON-ASSIGNMENT CLAUSE. In accordance with Section 138 of the State Finance Law, this contract may not be assigned by the Contractor or its right, title or interest therein assigned, transferred, conveyed, sublet or otherwise disposed of without the previous consent, in writing, of the State and any attempts to assign the contract without the State's written consent are null and void. The Contractor may, however, assign its right to receive payment without the State's prior written consent unless this contract concerns Certificates of Participation pursuant to Article 5-A of the State Finance Law.

3. COMPTROLLER'S APPROVAL. In accordance with Section 112 of the State Finance Law (or, if this contract is with the State University or City University of New York, Section 355 or Section 6218 of the Education Law), if this contract exceeds \$50,000 (or the minimum thresholds agreed to by the Office of the State Comptroller for certain S.U.N.Y. and C.U.N.Y. contracts), or if this is an amendment for any amount to a contract which, as so amended, exceeds said statutory amount, or if, by this contract, the State agrees to give something other than money when the value or reasonably estimated value of such consideration exceeds \$10,000, it shall not be valid, effective or binding upon the State until it has been approved by the State Comptroller and filed in his office. Comptroller's approval of contracts let by the Office of General Services is required when such contracts exceed \$85,000 (State Finance Law Section 163.6.a).

4. WORKERS' COMPENSATION BENEFITS. In accordance with Section 142 of the State Finance Law, this contract shall be void and of no force and effect unless the Contractor shall provide and maintain coverage during the life of this contract for the benefit of such employees as are required to be covered by the provisions of the Workers' Compensation Law.

5. NON-DISCRIMINATION REQUIREMENTS. To the extent required by Article 15 of the Executive Law (also known as the Human Rights Law) and all other State and Federal statutory and constitutional non-discrimination provisions, the Contractor will not discriminate against any employee or applicant for employment because of race, creed, color, sex, national origin, sexual orientation, age, disability, genetic predisposition or carrier status, or marital status. Furthermore, in accordance with Section 220-e of the Labor Law, if this is a contract for the construction, alteration or repair of any public building or public work or for the manufacture, sale or distribution of materials, equipment or supplies, and to the extent that this contract shall be performed within the State of New York, Contractor agrees that neither it nor its subcontractors shall, by reason of race, creed, color, disability, sex, or national origin: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the performance of work under this contract. If this is a building service contract as defined in Section 230 of the Labor Law, then, in accordance with Section 239 thereof, Contractor agrees that neither it nor its subcontractors shall by reason of race, creed, color, national origin, age, sex or disability: (a) discriminate in hiring against any New York State citizen who is qualified and available to perform the work; or (b) discriminate against or intimidate any employee hired for the

performance of work under this contract. Contractor is subject to fines of \$50.00 per person per day for any violation of Section 220-e or Section 239 as well as possible termination of this contract and forfeiture of all moneys due hereunder for a second or subsequent violation.

6. WAGE AND HOURS PROVISIONS. If this is a public work contract covered by Article 8 of the Labor Law or a building service contract covered by Article 9 thereof, neither Contractor's employees nor the employees of its subcontractors may be required or permitted to work more than the number of hours or days stated in said statutes, except as otherwise provided in the Labor Law and as set forth in prevailing wage and supplement schedules issued by the State Labor Department. Furthermore, Contractor and its subcontractors must pay at least the prevailing wage rate and pay or provide the prevailing supplements, including the premium rates for overtime pay, as determined by the State Labor Department in accordance with the Labor Law.

7. NON-COLLUSIVE BIDDING CERTIFICATION. In accordance with Section 139-d of the State Finance Law, if this contract was awarded based upon the submission of bids, Contractor affirms, under penalty of perjury, that its bid was arrived at independently and without collusion aimed at restricting competition. Contractor further affirms that, at the time Contractor submitted its bid, an authorized and responsible person executed and delivered to the State a non-collusive bidding certification on Contractor's behalf.

8. INTERNATIONAL BOYCOTT PROHIBITION. In accordance with Section 220-f of the Labor Law and Section 139-h of the State Finance Law, if this contract exceeds \$5,000, the Contractor agrees, as a material condition of the contract, that neither the Contractor nor any substantially owned or affiliated person, firm, partnership or corporation has participated, is participating, or shall participate in an international boycott in violation of the federal Export Administration Act of 1979 (50 USC App. Sections 2401 et seq.) or regulations thereunder. If such Contractor, or any of the aforesaid affiliates of Contractor, is convicted or is otherwise found to have violated said laws or regulations upon the final determination of the United States Commerce Department or any other appropriate agency of the United States subsequent to the contract's execution, such contract, amendment or modification thereto shall be rendered forfeit and void. The Contractor shall so notify the State Comptroller within five (5) business days of such conviction, determination or disposition of appeal (2NYCRR 105.4).

9. SET-OFF RIGHTS. The State shall have all of its common law, equitable and statutory rights of set-off. These rights shall include, but not be limited to, the State's option to withhold for the purposes of set-off any moneys due to the Contractor under this contract up to any amounts due and owing to the State with regard to this contract, any other contract with any State department or agency, including any contract for a term commencing prior to the term of this contract, plus any amounts due and owing to the State for any other reason including, without limitation, tax delinquencies, fee delinquencies or monetary penalties relative thereto. The State shall exercise its set-off rights in accordance with normal State practices including, in cases of set-off pursuant to an audit, the finalization of such audit by the State agency, its representatives, or the State Comptroller.

10. RECORDS. The Contractor shall establish and maintain complete and accurate books, records, documents, accounts and other evidence directly pertinent to performance under this contract (hereinafter, collectively, "the Records"). The Records must be kept for the balance of the calendar year in which they were made and for six (6) additional years thereafter. The State Comptroller, the Attorney General and any other person or entity authorized to conduct an examination, as well as the agency or agencies involved in this contract, shall have access to the Records during normal business hours at an office of the Contractor

within the State of New York or, if no such office is available, at a mutually agreeable and reasonable venue within the State, for the term specified above for the purposes of inspection, auditing and copying. The State shall take reasonable steps to protect from public disclosure any of the Records which are exempt from disclosure under Section 87 of the Public Officers Law (the "Statute") provided that: (i) the Contractor shall timely inform an appropriate State official, in writing, that said records should not be disclosed; and (ii) said records shall be sufficiently identified; and (iii) designation of said records as exempt under the Statute is reasonable. Nothing contained herein shall diminish, or in any way adversely affect, the State's right to discovery in any pending or future litigation.

11. IDENTIFYING INFORMATION AND PRIVACY NOTIFICATION.

(a) FEDERAL EMPLOYER IDENTIFICATION NUMBER and/or FEDERAL SOCIAL SECURITY NUMBER. All invoices or New York State standard vouchers submitted for payment for the sale of goods or services or the lease of real or personal property to a New York State agency must include the payee's identification number, i.e., the seller's or lessor's identification number. The number is either the payee's Federal employer identification number or Federal social security number, or both such numbers when the payee has both such numbers. Failure to include this number or numbers may delay payment. Where the payee does not have such number or numbers, the payee, on its invoice or New York State standard voucher, must give the reason or reasons why the payee does not have such number or numbers.

(b) PRIVACY NOTIFICATION. (1) The authority to request the above personal information from a seller of goods or services or a lessor of real or personal property, and the authority to maintain such information, is found in Section 5 of the State Tax Law. Disclosure of this information by the seller or lessor to the State is mandatory. The principal purpose for which the information is collected is to enable the State to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liabilities and to generally identify persons affected by the taxes administered by the Commissioner of Taxation and Finance. The information will be used for tax administration purposes and for any other purpose authorized by law.

(2) The personal information is requested by the purchasing unit of the agency contracting to purchase the goods or services or lease the real or personal property covered by this contract or lease. The information is maintained in New York State's Central Accounting System by the Director of Accounting Operations, Office of the State Comptroller, 110 State Street, Albany, New York 12236.

12. EQUAL EMPLOYMENT OPPORTUNITIES FOR MINORITIES AND WOMEN.

In accordance with Section 312 of the Executive Law, if this contract is: (i) a written agreement or purchase order instrument, providing for a total expenditure in excess of \$25,000.00, whereby a contracting agency is committed to expend or does expend funds in return for labor, services, supplies, equipment, materials or any combination of the foregoing, to be performed for, or rendered or furnished to the contracting agency; or (ii) a written agreement in excess of \$100,000.00 whereby a contracting agency is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon; or (iii) a written agreement in excess of \$100,000.00 whereby the owner of a State assisted housing project is committed to expend or does expend funds for the acquisition, construction, demolition, replacement, major repair or renovation of real property and improvements thereon for such project, then:

(a) The Contractor will not discriminate against employees or applicants for employment because of race, creed, color, national origin, sex, age, disability or marital status, and will undertake or continue existing programs of affirmative action to ensure that minority group members and women are afforded equal employment opportunities without discrimination. Affirmative action shall mean recruitment,

employment, job assignment, promotion, upgradings, demotion, transfer, layoff, or termination and rates of pay or other forms of compensation;

(b) at the request of the contracting agency, the Contractor shall request each employment agency, labor union, or authorized representative of workers with which it has a collective bargaining or other agreement or understanding, to furnish a written statement that such employment agency, labor union or representative will not discriminate on the basis of race, creed, color, national origin, sex, age, disability or marital status and that such union or representative will affirmatively cooperate in the implementation of the contractor's obligations herein; and

(c) the Contractor shall state, in all solicitations or advertisements for employees, that, in the performance of the State contract, all qualified applicants will be afforded equal employment opportunities without discrimination because of race, creed, color, national origin, sex, age, disability or marital status.

Contractor will include the provisions of "a", "b", and "c" above, in every subcontract over \$25,000.00 for the construction, demolition, replacement, major repair, renovation, planning or design of real property and improvements thereon (the "Work") except where the Work is for the beneficial use of the Contractor. Section 312 does not apply to: (i) work, goods or services unrelated to this contract; or (ii) employment outside New York State; or (iii) banking services, insurance policies or the sale of securities. The State shall consider compliance by a contractor or subcontractor with the requirements of any federal law concerning equal employment opportunity which effectuates the purpose of this section. The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall waive the applicability of Section 312 to the extent of such duplication or conflict. Contractor will comply with all duly promulgated and lawful rules and regulations of the Governor's Office of Minority and Women's Business Development pertaining hereto.

13. CONFLICTING TERMS. In the event of a conflict between the terms of the contract (including any and all attachments thereto and amendments thereof) and the terms of this Appendix A, the terms of this Appendix A shall control.

14. GOVERNING LAW. This contract shall be governed by the laws of the State of New York except where the Federal supremacy clause requires otherwise.

15. LATE PAYMENT. Timeliness of payment and any interest to be paid to Contractor for late payment shall be governed by Article 11-A of the State Finance Law to the extent required by law.

16. NO ARBITRATION. Disputes involving this contract, including the breach or alleged breach thereof, may not be submitted to binding arbitration (except where statutorily authorized), but must, instead, be heard in a court of competent jurisdiction of the State of New York.

17. SERVICE OF PROCESS. In addition to the methods of service allowed by the State Civil Practice Law & Rules ("CPLR"), Contractor hereby consents to service of process upon it by registered or certified mail, return receipt requested. Service hereunder shall be complete upon Contractor's actual receipt of process or upon the State's receipt of the return thereof by the United States Postal Service as refused or undeliverable. Contractor must promptly notify the State, in writing, of each and every change of address to which service of process can be made. Service by the State to the last known address shall be sufficient. Contractor will have thirty (30) calendar days after service hereunder is complete in which to respond.

18. PROHIBITION ON PURCHASE OF TROPICAL HARDWOODS. The Contractor certifies and warrants that all wood products to be used under this contract award will be in accordance with, but not limited to, the specifications and provisions of State Finance Law §165. (Use of Tropical Hardwoods) which prohibits purchase and use of tropical hardwoods, unless specifically exempted, by the State or any governmental agency or political subdivision or public benefit corporation. Qualification for an exemption under this law will be the responsibility of the contractor to establish to meet with the approval of the State.

In addition, when any portion of this contract involving the use of woods, whether supply or installation, is to be performed by any subcontractor, the prime Contractor will indicate and certify in the submitted bid proposal that the subcontractor has been informed and is in compliance with specifications and provisions regarding use of tropical hardwoods as detailed in §165 State Finance Law. Any such use must meet with the approval of the State; otherwise, the bid may not be considered responsive. Under bidder certifications, proof of qualification for exemption will be the responsibility of the Contractor to meet with the approval of the State.

19. MACBRIDE FAIR EMPLOYMENT PRINCIPLES. In accordance with the MacBride Fair Employment Principles (Chapter 807 of the Laws of 1992), the Contractor hereby stipulates that the Contractor either (a) has no business operations in Northern Ireland, or (b) shall take lawful steps in good faith to conduct any business operations in Northern Ireland in accordance with the MacBride Fair Employment Principles (as described in Section 165 of the New York State Finance Law), and shall permit independent monitoring of compliance with such principles.

20. OMNIBUS PROCUREMENT ACT OF 1992. It is the policy of New York State to maximize opportunities for the participation of New York State business enterprises, including minority and women-owned business enterprises as bidders, subcontractors and suppliers on its procurement contracts.

Information on the availability of New York State subcontractors and suppliers is available from:

NYS Department of Economic Development
Division for Small Business
30 South Pearl St -- 7th Floor
Albany, New York 12245
Telephone: 518-292-5220
Fax: 518-292-5884
<http://www.empire.state.ny.us>

A directory of certified minority and women-owned business enterprises is available from:

NYS Department of Economic Development
Division of Minority and Women's Business Development
30 South Pearl St -- 2nd Floor
Albany, New York 12245
Telephone: 518-292-5250
Fax: 518-292-5803
<http://www.empire.state.ny.us>

The Omnibus Procurement Act of 1992 requires that by signing this bid proposal or contract, as applicable, Contractors certify that whenever the total bid amount is greater than \$1 million:

(a) The Contractor has made reasonable efforts to encourage the participation of New York State Business Enterprises as suppliers and subcontractors, including certified minority and women-owned business enterprises, on this project, and has retained the documentation of these efforts to be provided upon request to the State;

(b) The Contractor has complied with the Federal Equal Opportunity Act of 1972 (P.L. 92-261), as amended;

(c) The Contractor agrees to make reasonable efforts to provide notification to New York State residents of employment opportunities on this project through listing any such positions with the Job Service Division of the New York State Department of Labor, or providing such notification in such manner as is consistent with existing collective bargaining contracts or agreements. The Contractor agrees to document these efforts and to provide said documentation to the State upon request; and

(d) The Contractor acknowledges notice that the State may seek to obtain offset credits from foreign countries as a result of this contract and agrees to cooperate with the State in these efforts.

21. RECIPROCITY AND SANCTIONS PROVISIONS. Bidders are hereby notified that if their principal place of business is located in a country, nation, province, state or political subdivision that penalizes New York State vendors, and if the goods or services they offer will be substantially produced or performed outside New York State, the Omnibus Procurement Act 1994 and 2000 amendments (Chapter 684 and Chapter 383, respectively) require that they be denied contracts which they would otherwise obtain. NOTE: As of May 15, 2002, the list of discriminatory jurisdictions subject to this provision includes the states of South Carolina, Alaska, West Virginia, Wyoming, Louisiana and Hawaii. Contact NYS Department of Economic Development for a current list of jurisdictions subject to this provision.

22. PURCHASES OF APPAREL. In accordance with State Finance Law 162 (4-a), the State shall not purchase any apparel from any vendor unable or unwilling to certify that: (i) such apparel was manufactured in compliance with all applicable labor and occupational safety laws, including, but not limited to, child labor laws, wage and hours laws and workplace safety laws, and (ii) vendor will supply, with its bid (or, if not a bid situation, prior to or at the time of signing a contract with the State), if known, the names and addresses of each subcontractor and a list of all manufacturing plants to be utilized by the bidder.

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APPENDIX A-2

STANDARD CLAUSES FOR ALL AIDS INSTITUTE CONTRACTS

1. Any materials, articles, papers, etc. developed by the CONTRACTOR under or in the course of performing this AGREEMENT shall contain the following, or similar acknowledgment, when deemed appropriate by the AIDS Institute: "Funded by a grant from the New York State Department of Health AIDS Institute". Any such materials must be reviewed and approved by the STATE for conformity with the policies and guidelines for the New York State Department of Health prior to dissemination and/or publication. It is agreed that such review will be conducted in an expeditious manner. Should the review result in any unresolved disagreements regarding the content, the CONTRACTOR shall be free to publish in scholarly journals along with a disclaimer that the views within the Article or the policies reflected are not necessarily those of the New York State Department of Health. The Department reserves the right to disallow funding for any educational materials not approved through its review process.
2. Any publishable or otherwise reproducible material developed under or in the course of performing this AGREEMENT, dealing with any aspect of performance under this AGREEMENT, or of the results and accomplishments attained in such performance, shall be the sole and exclusive property of the STATE, and shall not be published or otherwise disseminated by the CONTRACTOR to any other party unless prior written approval is secured by the STATE or under circumstances as indicated in paragraph 1 above. Any and all net proceeds obtained by the CONTRACTOR resulting from any such publication shall belong to and be paid over to the STATE. The STATE shall have a perpetual royalty-free, non-exclusive and irrevocable right to reproduce, publish or otherwise use, and to authorize others to use, any such material for governmental purposes.
3. No report, document or other data produced in whole or in part with the funds provided under this AGREEMENT may be copyrighted by the CONTRACTOR or any of its employees, nor shall any notice of copyright be registered by the CONTRACTOR or any of its employees in connection with any report, document or other data developed pursuant to this AGREEMENT.
4. All reports, data sheets, documents, etc. generated under this contract shall be the sole and exclusive property of the Department of Health. Upon completion or termination of this AGREEMENT the CONTRACTOR shall deliver to the Department of Health upon its demand all copies of materials relating or pertaining to this AGREEMENT. The CONTRACTOR shall have no right to disclose or use any of such material and documentation for any purpose whatsoever, without the prior written approval of the Department of Health or its authorized agents.
5. In the performance of a complete and accurate audit of the program, by the STATE, it may become necessary to extend the process to include foundations or other closely allied corporations which have as a primary goal the benefit and/or promotion of the CONTRACTOR. This extended audit would be pursued only to the extent of identifying funds received from or to be used for operation of the program, the purposes of such funds and is not intended as a monitoring device of the foundation or closely allied corporations as such.
6. The CONTRACTOR agrees to maximize third-party reimbursement available for HIV counseling, testing, medical care, case management, and other funded services, including Medicaid reimbursement for HIV primary care available through participation in the New York State Department of Health's HIV Primary Care Medicaid Program. If eligible, CONTRACTOR agrees to enroll in the HIV Primary Care Medicaid Program by signing the Provider Agreement contained in the Department of Health Memorandum 93-26 within 60 days of the execution date of this Agreement (if otherwise eligible to provide some or all of the primary care services reimbursable thereunder). The CONTRACTOR further certifies that any and all revenue earned during the term of the Agreement as a result of the services and related activities performed pursuant to this Agreement, including HIV counseling and testing, comprehensive HIV medical examinations, CD4 monitoring and associated medical treatment and case management, will be made available to the program within the health facility generating those revenues and shall be used either to expand those program services or to offset expenditures submitted by the CONTRACTOR for reimbursement. The CONTRACTOR shall request approval in writing of its proposed uses of these funds. No such revenue shall be allocated without the written endorsement of the State.
7. The CONTRACTOR, its officers, agents and employees and subcontractors shall treat all information, which is obtained by it through its performance under this AGREEMENT, as confidential information to the extent required by the laws and regulations of the United States and laws and regulations of the State of New York, including Chapter 584 of the Laws of 1988 (the New York State HIV Confidentiality Law) and the appropriate portions of the New York State Department of Health Regulation Part 63 (AIDS Testing and Confidentiality of HIV Related Information).

8. The CONTRACTOR, subcontractors or other agents must comply with New York State Department of Health AIDS Institute policy regarding access to and disclosure of personal health related information, attached to this AGREEMENT as Appendix F and made a part hereof.

9. Neither party shall be held responsible for any delay in performance hereunder arising out of causes beyond its control and without its fault or negligence. Such causes may include, but are not limited to fire, strikes, acts of God, inability to secure transportation or materials, natural disasters, or other causes beyond the control of either party.

10. The CONTRACTOR agrees not to enter into any agreements with third party organizations for the performance of its obligations, in whole or in part, under this AGREEMENT without the STATE's prior written approval of such third parties and the scope of work to be performed by them. The subcontract itself does not require the STATE's approval. The STATE's approval of the scope of work and the subcontractor does not relieve the CONTRACTOR of its obligation to perform fully under this contract.

11. All such subcontracts shall contain provisions specifying:

(1) that the work performed by the subcontractor must be in accordance with the terms of this AGREEMENT, and

(2) that the subcontractor specifically agrees to be bound by the confidentiality provisions set forth in the AGREEMENT between the STATE and the CONTRACTOR.

12. The CONTRACTOR agrees that it shall coordinate the activities being funded pursuant to this workplan with other organizations providing HIV-related services within its service area including, but not limited to, community service providers, community based organizations, HIV Special Needs Plans and other agencies providing primary health care - to assure the non-duplication of effort being conducted, and shall develop linkages with these providers in order to effectively coordinate and deliver services to the targeted population. As part of its reporting requirements, the contractor will in accordance with the workplan Appendix D advise the AIDS Institute as to the coordination efforts being conducted and the linkage arrangements agreed to.

13. The CONTRACTOR also agrees to assist the STATE in providing information regarding other initiatives that either party may be involved with during the term of this AGREEMENT. The CONTRACTOR in accordance with the payment and reporting schedule Appendix C is required to participate in the collection of data to evaluate the effectiveness of this initiative. The Data Collection forms will be provided to the CONTRACTOR in order to be able to measure numbers of population serviced and the impact of activities.

14. CONTRACTORS funded under the "Multiple Service Agency" and "Community Service Program" initiatives are supported, in part, for expenses relating to the maintenance of general infrastructure to sustain organizational viability. To ensure organizational viability, general infrastructure and administrative costs, as deemed appropriate by the Department of Health, may be supported subject to the review of the Commissioner of Health. Allowable expenses related to infrastructure will be explicitly outlined as a work plan objective in accordance with Appendix D and specified in Appendix B, the contract budget.

APPENDIX F

AIDS INSTITUTE POLICY

Access to and Disclosure of Personal Health Related Information

1. Statement of Purpose

The purpose of this policy is to set forth methods and controls to restrict dissemination and maintain control of confidential personal health related information by contractors, subcontractors and other agents of the Department of Health AIDS Institute.

2. Definition

For the purpose of this policy, personal health related information means any information concerning the health of a person which identifies or could reasonably be used to identify a person.

3. Access

(a) Contractors, subcontractors or other agents of the Department of Health AIDS Institute are not to have access to personal health related information except as part of their official duties;

(b) Access to personal health related information by contractors, subcontracts or other agents of the Department of Health AIDS Institute is to be authorized only after employees have been trained in the responsibilities associated with access to the information;

(c) Contractors, subcontractors, or other agents of the Department of Health AIDS Institute may be authorized to have access to specific personal health related information only when reasonably necessary to perform the specific activities for which they have been designated.

4. Disclosure

All entities, organizations and community agencies who contract with the AIDS Institute shall utilize a Department of Health-approved "Authorization For Release of Confidential HIV Related Information" form (Form DOH-2557 or DOH-2557S), copies of which are included in this Appendix F, when receiving or requesting HIV-related information. No contractor, subcontractor or other agent of the Department of Health AIDS Institute who has knowledge of personal health related information in the course of employment, shall disclose such information to any other person unless such disclosure is in accordance with law, DOH regulations and policy, and the information is required to perform an officially designated function.

5. Disposition

Documents containing personal health related information shall be disposed of in a manner in which the confidentiality will not be compromised.

6. Confidentiality Protocols

(a) Each contractor, subcontractor or other agent of the Department of Health AIDS Institute will develop confidentiality protocols which meet the requirements of this section. The protocols shall include as necessary:

(1) measures to ensure that letters, memoranda and other documents containing personal health related information are accessible only by authorized personnel;

(2) measures to ensure that personal health related information stored electronically is protected from access by unauthorized persons;

(3) measures to ensure that only personal health related information necessary to fulfill authorized functions is maintained;

- (4) measures to ensure that staff working with personal health related information secure such information from casual observance or loss and that such documents or files are returned to confidential storage on termination of use;
- (5) measures to ensure that personal health related information is not inappropriately copied or removed from control;
- (6) measures to provide safeguards to prevent discrimination, abuse or other adverse actions directed toward persons to whom personal health related information applies;
- (7) measures to ensure that personal health related information is adequately secured after working hours;
- (8) measures to ensure that transmittal of personal health related information outside of the contractor, subcontractor or other agent of the Department of Health AIDS Institute is in accordance with law, Department of Health regulation and policy;
- (9) measures to protect the confidentiality of personal health related information being transferred to other units within the contractor, subcontractor or other agent's operation; and
- (10) measures to ensure that documents or files that contain personal health related information that are obsolete or no longer needed are promptly disposed of in such a manner so as to not compromise the confidentiality of the documents.

(b) Protocols for ensuring confidentiality of personal health related information are to be updated whenever a program activity change renders the established protocol obsolete or inadequate.

7. Employee Training

(a) Employees of contractors, subcontractors of other agents of the Department of Health AIDS Institute are to be trained with respect to responsibilities and authorization to access personal health related information.

(b) Employees authorized to access personal health related information are to be advised in writing that they shall not:

- (1) examine documents or computer data containing personal health related information unless required in the course of official duties and responsibilities;
- (2) remove from the unit or copy such documents or computer data unless acting within the scope of assigned duties;
- (3) discuss the content of such documents or computer data with any person unless that person had authorized access and the need to know the information discussed; and,
- (4) illegally discriminate, abuse or harass a person to whom personal health related information applies.

8. Employee Attestation.

Each employee, upon receiving training, shall sign a statement acknowledging that violation of confidentiality statutes and rules may lead to disciplinary action, including suspension or dismissal from employment and criminal prosecution. Each employee's signed attestation is to be centrally maintained in the employee's personal history file.

HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV* Related Information

New York State Department of Health

This form authorizes release of medical information including HIV-related information. You may choose to release just your non-HIV medical information, just your HIV-related information, or both. Your information may be protected from disclosure by federal privacy law and state law. Confidential HIV-related information is any information indicating that a person has had an HIV-related test, or has HIV infection, HIV-related illness or AIDS, or any information that could indicate a person has been potentially exposed to HIV.

Under New York State Law HIV-related information can only be given to people you allow to have it by signing a written release. This information may also be released to the following: health providers caring for you or your exposed child; health officials when required by law; insurers to permit payment; persons involved in foster care or adoption; official correctional, probation and parole staff; emergency or health care staff who are accidentally exposed to your blood, or by special court order. Under State law, anyone who illegally discloses HIV-related information may be punished by a fine of up to \$5,000 and a jail term of up to one year. However, some re-disclosures of medical and/or HIV-related information are not protected under federal law. For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019.

By checking the boxes below and signing this form, medical information and/or HIV-related information can be given to the people listed on page two (or additional sheets if necessary) of the form, for the reason(s) listed. Upon your request, the facility or person disclosing your medical information must provide you with a copy of this form.

- I consent to disclosure of (please check all that apply):
- My HIV-related information
 - Both (non-HIV medical and HIV-related information)
 - My non-HIV medical information **

Information in the box below must be completed.

Name and address of facility/person disclosing HIV-related and/or medical information: _____ _____
Name of person whose information will be released: _____
Name and address of person signing this form (if other than above): _____ _____
Relationship to person whose information will be released: _____ _____
Describe information to be released: _____
Reason for release of information: _____
Time Period During Which Release of Information is Authorized From: _____ To: _____
Disclosures cannot be revoked, once made. Additional exceptions to the right to revoke consent, if any: _____ _____
Description of the consequences, if any, of failing to consent to disclosure upon treatment, payment, enrollment or eligibility for benefits (Note: Federal privacy regulations may restrict some consequences): _____ _____

All facilities/persons listed on pages 1,2 (and 3 if used) of this form may share information among and between themselves for the purpose of providing medical care and services. Please sign below to authorize.

Signature _____ Date _____

*Human Immunodeficiency Virus that causes AIDS

** If releasing only non-HIV medical information, you may use this form or another HIPAA-compliant general medical release form.

**HIPAA Compliant Authorization for Release of Medical Information
and Confidential HIV* Related Information**

**Complete information for each facility/person to be given general medical information and/or HIV-related information.
Attach additional sheets as necessary. It is recommended that blank lines be crossed out prior to signing.**

Name and address of facility/person to be given general medical and/or HIV-related information:

Reason for release, if other than stated on page 1:

If information to be disclosed to this facility/person is limited, please specify:

Name and address of facility/person to be given general medical and/or HIV-related information:

Reason for release, if other than stated on page 1:

If information to be disclosed to this facility/person is limited, please specify:

The law protects you from HIV related discrimination in housing, employment, health care and other services. For more information call the New York State Division of Human Rights Office of AIDS Discrimination Issues at **1-800-523-2437** or (212) 480-2522 or the New York City Commission on Human Rights at **(212) 306-7500**. These agencies are responsible for protecting your rights.

My questions about this form have been answered. I know that I do not have to allow release of my medical and/or HIV-related information, and that I can change my mind at any time and revoke my authorization by writing the facility/person obtaining this release. I authorize the facility/person noted on page one to release medical and/or HIV-related information of the person named on page one to the organizations/persons listed.

Signature _____ Date _____
(Subject of information or legally authorized representative)

If legal representative, indicate relationship to subject: _____

Print Name _____

Client/Patient Number _____

**HIPAA Compliant Authorization for Release of Medical Information
and Confidential HIV* Related Information**

**Complete information for each facility/person to be given general medical information and/or HIV-related information.
Attach additional sheets as necessary. Blank lines may be crossed out prior to signing.**

Name and address of facility/person to be given general medical and/or HIV-related information:

Reason for release, if other than stated on page 1:

If information to be disclosed to this facility/person is limited, please specify:

Name and address of facility/person to be given general medical and/or HIV-related information:

Reason for release, if other than stated on page 1:

If information to be disclosed to this facility/person is limited, please specify:

Name and address of facility/person to be given general medical and/or HIV-related information:

Reason for release, if other than stated on page 1:

If information to be disclosed to this facility/person is limited, please specify:

If any/all of this page is completed, please sign below:

Signature _____ Date _____
Client/Patient Number _____

Autorización para divulgar información médica e información confidencial relativa al VIH* conforme a la ley de Responsabilidad y Transferibilidad de Seguros Médicos (HIPAA)

Departamento de Salud del Estado de Nueva York

Mediante este formulario se autoriza la divulgación de información médica, incluso de datos relativos al VIH. Usted puede optar por permitir la divulgación de información relacionada con el VIH únicamente, información ajena al VIH únicamente o ambos tipos. La divulgación de tal información puede estar protegida por leyes de confidencialidad federales y estatales. Se considera "información confidencial relativa al VIH" toda información que indique que una persona se ha hecho una prueba relativa al VIH, está infectada con el VIH o tiene SIDA u otra enfermedad relacionada con el VIH, y toda otra información que podría indicar que una persona ha estado potencialmente expuesta al VIH.

Según las leyes del Estado de Nueva York, sólo se puede divulgar información relativa al VIH a aquellas personas a quien usted autorice mediante la firma de un permiso escrito. También puede divulgarse a las siguientes personas y organizaciones: profesionales de la salud a cargo de su atención o la de su hijo expuesto; funcionarios de salud cuando lo exija la ley; aseguradores (para poder efectuar pagos); personas que participen en el proceso de adopción o colocación en hogares sustitutos; personal oficial correccional o afectado al proceso de libertad condicional; personal de salud o atención de emergencias que haya estado expuesto accidentalmente a su sangre; o a personas autorizadas mediante una orden judicial especial. Según lo estipulado por las leyes estatales, cualquier persona que ilegalmente revele información relacionada con el VIH puede ser sancionada con una multa de hasta \$5,000 o encarcelada por un período de hasta un año. No obstante, las leyes estatales no protegen las divulgaciones repetidas de cierta información médica o relacionada con el VIH. Para obtener más información acerca de la confidencialidad de la información relativa al VIH, llame a la línea directa de confidencialidad sobre el VIH del Departamento de Salud del Estado de Nueva York al 1 800 962 5065. Si desea obtener información acerca de la protección federal de la privacidad, llame a la Oficina de Derechos Civiles al 1 800 368 1019.

Al marcar las casillas que se encuentran a continuación y firmar este formulario, se autoriza la divulgación de información médica o relativa al VIH a las personas que figuran en la página dos de este formulario (o en páginas adicionales según corresponda), por las razones enumeradas. Cuando usted lo solicite, el establecimiento o la persona que reveló su información médica le deberá proporcionar una copia del formulario.

Autorizo la divulgación de (marque todas las opciones que correspondan):

Mi información relativa al VIH

Ambas (información médica tanto ajena como relativa al VIH)

Mi información médica ajena al VIH**

Complete la información en el siguiente cuadro.

El establecimiento o la persona que divulgue la información debe completar el recuadro que se encuentra a continuación:

Nombre y dirección del establecimiento o profesional que divulga la información médica o relativa al VIH:

Nombre de la persona cuya información será divulgada: _____

Nombre y dirección de la persona que firma este formulario (si difiere de la persona mencionada anteriormente):

Relación con la persona cuya información será divulgada: _____

Describa la información que se ha de divulgar: _____

Motivo de la divulgación: _____

Período durante el cual se autoriza la divulgación de la información Desde: _____ Hasta: _____

Una vez que la información ha sido divulgada, la autorización no podrá ser revocada. Excepciones adicionales al derecho de revocar una autorización, de existirlas: _____

Descripción de las consecuencias que la prohibición de la divulgación puede traer al momento del tratamiento, el pago, la inscripción o la elegibilidad para beneficios (Observaciones: Las reglamentaciones federales sobre privacidad pueden restringir algunas consecuencias):

Todas las instalaciones o personas incluidas en las páginas 1, 2 (y 3 si se la utiliza) de este formulario podrán compartir información entre sí con el propósito de prestar atención y servicios médicos. Firme a continuación para autorizar.

Firma _____ Fecha _____

*Virus de la inmunodeficiencia humana que causa el SIDA

** Si sólo se divulga información médica no relacionada con el VIH, puede utilizar este formulario u otro formulario de divulgación médica conforme a la HIPAA.

Autorización para divulgar información médica e información confidencial relativa al VIH* conforme a la ley de Responsabilidad y Transferibilidad de Seguros Médicos (HIPAA)

Complete la información para cada establecimiento o persona que recibirá información médica general o relativa al VIH. Adjunte hojas adicionales según sea necesario. Se recomienda tachar las líneas dejadas en blanco antes de firmar.

Nombre y dirección del establecimiento o la persona a quien se le brindará la información médica general o relativa al VIH:

Motivo de la divulgación, si difiere de lo indicado en la página 1:

Si se debe limitar la información que se ha de develar a este establecimiento o persona, especifique las restricciones.

Nombre y dirección del establecimiento o la persona a quien se le brindará la información médica general o relativa al VIH:

Motivo de la divulgación, si difiere de lo indicado en la página 1:

Si se debe limitar la información que se ha de develar a este establecimiento o persona, especifique las restricciones.

Las leyes lo protegen de la discriminación relativa al VIH en lo referente a servicios de vivienda, trabajo, atención médica, etc. Para obtener más información, llame a la División de Derechos Humanos del Estado de Nueva York, Oficina para Asuntos de Discriminación a Pacientes con SIDA al **1 800 523 2437** o al (212) 480-2493, o bien comuníquese con la Comisión de Derechos Humanos de la Ciudad de Nueva York al **(212) 306 5070**. Estas agencias son las encargadas de proteger sus derechos.

He recibido respuestas a mis preguntas referidas a este formulario. Sé que no tengo la obligación de autorizar la divulgación de mi información médica o relativa al VIH y que puedo cambiar de parecer en cualquier momento y revocar mi autorización enviando una solicitud por escrito al establecimiento o profesional que corresponda. Autorizo al establecimiento o a la persona indicada en la página uno a divulgar información médica o relativa al VIH de la persona también mencionada en la página uno a las organizaciones o personas enumeradas.

Firma _____ Fecha _____
(Persona a la que se le hará la prueba o representante legal autorizado)

Si es un representante legal, indique la relación con el paciente:

Nombre (en letra de imprenta) _____

Número de paciente o cliente _____

Autorización para divulgar información médica e información confidencial relativa al VIH* conforme a la ley de Responsabilidad y Transferibilidad de Seguros Médicos (HIPAA)

Complete la información para cada establecimiento o persona que recibirá información médica general o relativa al VIH. Adjunte hojas adicionales según sea necesario. Se recomienda tachar las líneas dejadas en blanco antes de firmar.

Nombre y dirección del establecimiento o la persona a quien se le brindará la información médica general o relativa al VIH:

Motivo de la divulgación, si difiere de lo indicado en la página 1:

Si se debe limitar la información que se ha de develar a este establecimiento o a esta persona, especifique las restricciones.

Nombre y dirección del establecimiento o la persona a quien se le brindará la información médica general o relativa al VIH:

Motivo de la divulgación, si difiere de lo indicado en la página 1:

Si se debe limitar la información que se ha de develar a este establecimiento o a esta persona, especifique las restricciones.

Nombre y dirección del establecimiento o la persona a quien se le brindará la información médica general o relativa al VIH:

Motivo de la divulgación, si difiere de lo indicado en la página 1:

Si se debe limitar la información que se ha de develar a este establecimiento o a esta persona, especifique las restricciones.

Si completó esta página en forma total o parcial, sírvase firmar a continuación:

Firma _____ Fecha _____

Número de paciente o cliente _____

Appendix G

NOTICES

All notices permitted or required hereunder shall be in writing and shall be transmitted either:

- (a) via certified or registered United States mail, return receipt requested;
- (b) by facsimile transmission;
- (c) by personal delivery;
- (d) by expedited delivery service; or
- (e) by e-mail.

Such notices shall be addressed as follows or to such different addresses as the parties may from time to time designate:

State of New York Department of Health

Name:

Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

[Insert Contractor Name]

Name:

Title:

Address:

Telephone Number:

Facsimile Number:

E-Mail Address:

Any such notice shall be deemed to have been given either at the time of personal delivery or, in the case of expedited delivery service or certified or registered United States mail, as of the date of first attempted delivery at the address and in the manner provided herein, or in the case of facsimile transmission or email, upon receipt.

The parties may, from time to time, specify any new or different address in the United States as their address for purpose of receiving notice under this AGREEMENT by giving fifteen (15) days written notice to the other party sent in accordance herewith. The parties agree to mutually designate individuals as their respective representative for the purposes of receiving notices under this AGREEMENT. Additional individuals may be designated in writing by the parties for purposes of implementation and administration/billing, resolving issues and problems, and/or for dispute resolution.

ATTACHMENT 2

Sample Letter of Interest

**RFA#09-0005
HIV Provider Education Guidelines Program**

Date

Valerie J. White
Deputy Director
Administration & Data Systems
New York State Department of Health, AIDS Institute
ESP, Corning Tower, Room 478
Albany, NY 12237

Dear Ms. White:

This letter is to indicate our interest in the above referenced Request for Applications (RFA) and to request that our organization be placed on the mailing list for any updates, written response to questions, or amendments to the RFA.

Sincerely,

Name
Title
Applicant Agency
Address
Email

Attachment 3

APPLICATION CHECKLIST RFA #09-0005

HIV Provider Education Guidelines Program

Please submit one original and eight (8) copies of your application.

Please be sure that your application adheres to the following submission requirements and indicate compliance with these requirements by placing a check in the applicable box below.

FORMAT

- The portion of the application to which page limits apply does not exceed 21 **double-spaced pages**;
- The application uses a **12-font type**;
- The application has **one-inch margins** on all sides;
- All copies are **legible**;
- All pages are **numbered**; and
- All appendices are **clearly marked**.

BUDGET

- Budget does not exceed the maximum budget amount of \$598,803

Please arrange your application in the following order and note inclusion of applicable elements by placing a check mark in the adjacent box.

- Application Checklist (Attachment 3)
- Application Cover Page (Attachment 4)
- Letter of Commitment (Attachment 5)
- Application Narrative

- Budget Forms and Narrative (Attachment 7)
- Vendor Responsibility Questionnaire (Attachment 8) (if you choose not to submit on line)
- Vendor Responsibility Attestation (Attachment 9)
- Copy of your most recent Yearly Independent Audit
- Curriculum Vitae for all program staff
- Agency Capacity Information (Attachment 6)
- Examples of recent printed program materials and any guidelines

**Attachment 4
Application Cover Sheet**

**RFA #09-0005
HIV Provider Education Guidelines Program**

Agency Name*: _____

Agency's Federal ID Number: _____

Contact Person (please type or print): _____

Contact Person's Signature: _____

Title: _____

Address: _____

Phone Number: _____

Fax Number: _____

Email Address: _____

Total Amount of Funding Requested: _____

* If applicant name is different from contracting agency, please briefly explain relationship:

Attachment 5

Sample Letter of Commitment from Board of Directors or Equivalent Official

**HIV Provider Education Guidelines Program
RFA #09-0005**

Date

Tracy Hatton
Office of the Medical Director
NYSDOH/AIDS Institute
90 Church Street, 13th Floor
New York, NY 10037

Dear Ms. Hatton:

The Board of Directors (*or Equivalent Official*) of (*Applicant Organization*) has reviewed and approved the enclosed application to the New York State Department of Health AIDS Institute for funding under the solicitation “HIV Provider Education Guidelines Program.”

The Board (*or Equivalent Official*) is committed to providing the related services and certifies that program staff are qualified, appropriately trained and have sufficient agency resources to effectively implement the program.

The Board (*or Equivalent Official*) attests that the organization meets the following eligibility requirement (please check the box):

- The organization is a not-for-profit 501c(3) organization or academic institution

Sincerely,

Board Chairperson (*or Equivalent Official*)

RFA #09-0005
HIV Provider Education Guidelines Program

Agency Capacity Information

Identify and describe the staff responsible for Program Oversight, Administrative/Fiscal Oversight, Information Systems, and HIV Medical/Scientific Content.

Area of Responsibility	Staff Person(s) Responsible	Indicate if position will be supported in-kind or through this funding	Qualifications Licenses Held /Certifications	Description of Duties Related to this Contract
Program Oversight				
Fiscal/Administrative Oversight				
Information Systems (Include Data Entry and IT Support Staff)				
HIV Medical/Scientific Content				

On an average, how long does it take for your organization to recruit and hire for vacant positions (provide information as it pertains to program, administrative and information systems positions)?

Attachment 7

INSTRUCTIONS FOR COMPLETION OF BUDGET FORMS FOR SOLICITATIONS

Page 1 - Summary Budget

- A. Please list the amount requested for each of the major budget categories. These include:
1. Salaries
 2. Fringe Benefits
 3. Supplies
 4. Travel
 5. Equipment
 6. Miscellaneous Other (includes Space, Phones and Other)
 7. Subcontracts/Consultants
 8. Administrative Costs
- B. The column labeled Third Party Revenue should only be used if a grant-funded position on this contract generates revenue. This could be either Medicaid or ADAP Plus. Please indicate how the revenue generated by this grant will be used in support of the proposed project. For example, if you have a case manager generating \$10,000 in revenue and the revenue will be used to cover supplies, the \$10,000 should be listed in the supplies line in the Third Party Revenue column.

Page 2- Personal Services

Please include all positions for which you are requesting reimbursement on this page. If you wish to show in-kind positions, they may also be included on this page.

Please refer to the instructions regarding the information required in each column. These instructions are provided at the top of each column. Following is a description of each column in the personal services category:

Column 1: For each position, indicate the title along with the incumbent's name. If a position is vacant, please indicate "TBD" (to be determined).

Column 2: For each position, indicate the number of hours worked per week regardless of funding source.

Column 3: For each position, indicate the total annual salary regardless of funding source.

Columns 4, 5, and 6 request information specific to the proposed program/project.

Column 4: Indicate the number of months or pay periods each position will be budgeted.

Column 5: For each position, indicate the percent effort devoted to the proposed program/project.

Column 6: Indicate the amount of funding requested from the AIDS Institute for each position.

Column 7: If a position is partially supported by third party revenue, the amount of the third-party revenue should be shown in Column 7.

The totals at the bottom of Columns 6 and 7 should be carried forward to page 1 (the Summary Budget).

Page 3 - Fringe Benefits and Position Descriptions

On the top of page 3, please fill in the requested information on fringe benefits based on your latest audited financial statements. Also, please indicate the amount and rate you are requesting for fringe benefits in this proposed budget. If the rate requested in this proposal exceeds the rate in the financial statements, a brief justification must be attached.

The bottom of the page is for position descriptions. For each position, please indicate the title (consistent with the title shown on page 2, personal services) and a brief description of the duties of the position related to the proposed program/project. Additional pages may be attached if necessary.

Page 4 -Subcontracts

Please indicate any services for which a subcontract or consultant will be used. Include an estimated cost for these services.

Page 5- Grant Funding From All Other Sources

Please indicate all funding your agency receives for HIV-related services. Research grants do not need to be included.

Page 6 - Budget Justification

Please provide a narrative justification for each item for which you are requesting reimbursement. (Do not include justification for personal services/positions, as the position descriptions on page 3 serve as this justification.) The justification should describe the requested item, the rationale for requesting the item, and how the item will benefit the proposed program/project. Additional sheets can be attached if necessary.

Those agencies selected for funding will be required to complete a more detailed budget and additional budget forms as part of the contract process.

**New York State Department Of Health
AIDS Institute
Summary Budget Form**

(To be used for Solicitations)

Contractor: _____

Contract Period: _____

Federal ID #: _____

Budget Items		Amount Requested from AIDS Institute	Third Party Revenue* <small>Show anticipated use of revenue generated by this contract. (Medicaid and ADAP Plus)</small>
(A)	PERSONAL SERVICES		
(B)	FRINGE BENEFITS		
(C)	SUPPLIES		
(D)	TRAVEL		
(E)	EQUIPMENT		
(F)	MISCELLANEOUS		
(G)	SUBCONTRACTS/CONSULTANTS		
(H)	ADMINISTRATIVE COSTS		
TOTAL (Sum of lines A through H)			
Personal Services Total			
Sum of A & B			
OTPS Total			
Sum of C through H			

** If applicable to RFA*

Fringe Benefits and Position Descriptions

Contractor:
Contract Period:
Federal ID #:

FRINGE BENEFITS

1. Does your agency have a federally approved fringe benefit rate?

YES

Approved Rate (%) : _____

Contractor must attach a copy of federally approved rate agreement.

Amount Requested (\$) : _____

NO

Complete 2-6 below.

2. Total salary expense based on most recent audited financial statements: _____

3. Total fringe benefits expense based on most recent audited financial statements: _____

4. Agency Fringe Benefit Rate: *(amount from #3 divided by amount from #2)* _____

5. Date of most recently audited financial statements: _____

Attach a copy of financial pages supporting amounts listed in #2 and #3.

6. Requested rate and amount for fringe benefits:

Rate Requested (%) : _____

If the rate being requested on this contract exceeds the rate supported by latest audited financials, attach justification.

Amount Requested (\$) : _____

POSITION DESCRIPTIONS

For each position listed on the summary budget page, provide a brief description of the duties supported by this contract. Contractors with consolidated contracts should indicate the initiative affiliated with the position. All contractors must have full job descriptions on file and available upon request. If additional space is needed, attach page 3a.

Title:

Contract Duties :

Title:

Contract Duties :

Title:

Contract Duties :

Position Descriptions (cont.)

Contractor:
Contract Period:
Federal ID #:

For each position listed on the summary budget page, provide a brief description of the duties supported by this contract. Contractors with consolidated contracts should indicate the initiative affiliated with the position. All contractors must have full job descriptions on file and available upon request.

<p><u>Title:</u> <u>Contract Duties :</u></p>

Subcontracts/Consultants

Contractor:

Contract Period:

Federal ID #:

SUBCONTRACTS/CONSULTANTS :

Provide a listing of all subcontracts, including consultant contracts, a description of the services to be provided and an estimate of the hours worked and rate per hour, if applicable. If the subcontractor/consultant has not been selected, please indicate "TBA" in Agency/Name. Contractors are required to use a structured selection process consistent with agency policy and maintain copies of all subcontracts and documentation of the selection process. Line item budgets and workscopes must be submitted for each subcontractor/consultant budget over \$10,000.

Agency/Name

Description of Services

Amount

Total : _____

Grant Funding from All Other Sources

Contractor:

Contract Period:

Federal ID #:

List all grant funding which supports HIV programs in your organization, excluding research grants. Program summaries should include the program activities and targeted groups as well as any other information needed to explain how the funding is being utilized.

Funding Source	Total Funding Amount	Funding Period	Program Summary

AIDS Institute
Solicitation Budget Justification

Contractor:
Contract Period:
Federal ID #:

Please provide a narrative justification of all requested line items. Attach this form to the budget forms.

Attachment 8

Vendor Responsibility Questionnaire

Instructions for Completing the Questionnaire

The New York State Department of Health (NYSDOH) is required to conduct a review of all prospective contractors to provide reasonable assurances that the vendor is responsible. The attached questionnaire is designed to provide information to assist the NYSDOH in assessing a vendor's responsibility prior to entering into a contract with the vendor. Vendor responsibility is determined by a review of each bidder or proposer's authorization to do business in New York, business integrity, financial and organizational capacity, and performance history.

Prospective contractors must answer every question contained in this questionnaire. Each "Yes" response requires additional information. The vendor must attach a written response that adequately details each affirmative response. The completed questionnaire and attached responses will become part of the procurement record.

It is imperative that the person completing the vendor responsibility questionnaire be knowledgeable about the proposing contractor's business and operations as the questionnaire information must be attested to by an owner or officer of the vendor.

Please read the certification requirement at the end of this questionnaire.

Please note: Certain entities are exempt from completing this questionnaire. These entities should submit only a copy of their organization's latest audited financial statements. Exempt organizations include the following: State Agencies, Counties, Cities, Towns, Villages, School Districts, Community Colleges, Boards of Cooperative Educational Services (BOCES), Vocational Education Extension Boards (VEEBs), Water, Fire, and Sewer Districts, Public Libraries, Water and Soil Districts, Public Benefit Corporations, Public Authorities, and Public Colleges.

**NEW YORK STATE
VENDOR RESPONSIBILITY QUESTIONNAIRE
NOT-FOR-PROFIT BUSINESS ENTITY**

BUSINESS ENTITY INFORMATION				
Legal Business Name			EIN	
Address of the Principal Place of Business/Executive Office			Phone Number	Fax Number
E-mail		Website		
Authorized Contact for this Questionnaire				
Name:			Phone Number	Fax Number
Title			Email	
List any other DBA, Trade Name, Other Identity, or EIN used in the last five (5) years, the state or county where filed, and the status (active or inactive): (if applicable)				
Type	Name	EIN	State or County where filed	Status

I. BUSINESS CHARACTERISTICS	
1.0 Business Entity Type – Please check appropriate box and provide additional information:	
a) <input type="checkbox"/> Corporation (including PC)	Date of Incorporation
b) <input type="checkbox"/> Limited Liability Co. (LLC or PLLC)	Date Organized
c) <input type="checkbox"/> Limited Liability Partnership	Date of Registration
d) <input type="checkbox"/> Limited Partnership	Date Established
e) <input type="checkbox"/> General Partnership	Date Established County (if formed in NYS)
f) <input type="checkbox"/> Sole Proprietor	How many years in business?
g) <input type="checkbox"/> Other	Date Established
If Other, explain:	
1.1 Was the Business Entity formed in New York State?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If 'No' indicate jurisdiction where Business Entity was formed:	
<input type="checkbox"/> United States State _____	
<input type="checkbox"/> Other Country _____	
1.2 Is the Business Entity currently registered to do business in New York State with the Department of State? <i>Note: Select 'not required' if the Business Entity is a General Partnership.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not required
If "No" explain why the Business Entity is not required to be registered in New York State.	
1.3 Is the Business Entity registered as a Sales Tax vendor with the New York State Department of Tax and Finance?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Explain and provide detail, such as 'not required', 'application in process', or other reasons for not being registered.	
1.4 Is the Business Entity a Joint Venture? <i>Note: If the submitting Business Entity is a Joint Venture, also submit a separate questionnaire for the Business Entity comprising the Joint Venture.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

**NEW YORK STATE
VENDOR RESPONSIBILITY QUESTIONNAIRE
NOT-FOR-PROFIT BUSINESS ENTITY**

I. BUSINESS CHARACTERISTICS

1.5 Does the Business Entity have an active Charities Registration Number?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Enter Number: _____ If Exempt/Explain: _____ If an application is pending, enter date of application: _____ Attach a copy of the application		
1.6 Does the Business Entity have a DUNS Number?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Enter DUNS Number _____		
1.7 Is the Business Entity's principal place of business/Executive Office in New York State?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If 'No', does the Business Entity maintain an office in New York State?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Provide the address and telephone number for one New York Office.		
1.8 Is the Business Entity's principal place of business/executive office:		
<input type="checkbox"/> Owned <input type="checkbox"/> Rented Landlord Name (if 'rented') _____ <input type="checkbox"/> Other Provide explanation (if 'other') _____		
Is space shared with another Business Entity?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Name of other Business Entity _____		
Address _____		
City _____ State _____ Zip Code _____ Country _____		
1.9 Is the Business Entity a Minority Community Based Organization (MCBO)?		<input type="checkbox"/> Yes <input type="checkbox"/> No
1.10 Identify current Key Employees of the Business Entity. Attach additional pages if necessary.		
Name	Title	
1.11 Identify current Trustees/Board Members of the Business Entity. Attach additional pages if necessary.		
Name	Title	

II. AFFILIATES AND JOINT VENTURE RELATIONSHIPS

2.0 Does the Business Entity have any Affiliates? Attach additional pages if necessary (If no proceed to section III)		<input type="checkbox"/> Yes <input type="checkbox"/> No
Affiliate Name	Affiliate EIN (If available)	Affiliate's Primary Business Activity
Explain relationship with the Affiliate and indicate percent ownership, if applicable (enter N/A, if not applicable):		
Are there any Business Entity Officials or Principal Owners that the Business Entity has in common with this Affiliate?		<input type="checkbox"/> Yes <input type="checkbox"/> No
Individual's Name	Position/Title with Affiliate	

**NEW YORK STATE
VENDOR RESPONSIBILITY QUESTIONNAIRE
NOT-FOR-PROFIT BUSINESS ENTITY**

III. CONTRACT HISTORY	
3.0 Has the Business Entity held any contracts with New York State government entities in the last three (3) years? ? If “Yes” attach a list including the Contract Number, Agency Name, Contract Amount, Contract Start Date, Contract End Date, and the Contract Description.	<input type="checkbox"/> Yes <input type="checkbox"/> No

IV. INTEGRITY – CONTRACT BIDDING	
Within the past five (5) years, has the Business Entity or any Affiliate	
4.0 been suspended or debarred from any government contracting process or been disqualified on any government procurement?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.1 been subject to a denial or revocation of a government prequalification?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.2 been denied a contract or had a bid rejected based upon a finding of non-responsibility by a government entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.3 agreed to a voluntary exclusion from bidding/contracting with a government entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.4 initiated a request to withdraw a bid submitted to a government entity or made any claim of an error on a bid submitted to a government entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
For each “Yes” answer provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

V. INTEGRITY – CONTRACT AWARD	
Within the past five (5) years, has the Business Entity or any Affiliate	
5.0 been suspended, cancelled or terminated for cause on any government contract?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.1 been subject to an administrative proceeding or civil action seeking specific performance or restitution in connection with any government contract?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.2 entered into a formal monitoring agreement as a condition of a contract award from a government entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
For each “Yes” answer provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

VI. CERTIFICATIONS/LICENSES	
6.0 Within the past five (5) years, has the Business Entity or any Affiliate had a revocation, suspension or disbarment of any business or professional permit and/or license?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If “Yes” provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

VII. LEGAL PROCEEDINGS	
Within the past five (5) years, has the Business Entity or any Affiliate	
7.0 been the subject of an investigation, whether open or closed, by any government entity for a civil or criminal violation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.1 been the subject of an indictment, grant of immunity, judgment or conviction (including entering into a plea bargain) for conduct constituting a crime?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.2 received any OSHA citation and Notification of Penalty containing a violation classified as serious or willful?	<input type="checkbox"/> Yes <input type="checkbox"/> No

**NEW YORK STATE
VENDOR RESPONSIBILITY QUESTIONNAIRE
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VII. LEGAL PROCEEDINGS	
Within the past five (5) years, has the Business Entity or any Affiliate	
7.3 had any New York State Labor Law violation deemed willful?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.4 entered into a consent order with the New York State Department of Environmental Conservation, or a federal, state or local government enforcement determination involving a violation of federal, state or local environmental laws?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.5 other than the previously disclosed: (i) Been subject to the imposition of a fine or penalty in excess of \$1,000, imposed by any government entity as a result of the issuance of citation, summons or notice of violation, or pursuant to any administrative, regulatory, or judicial determination; or (ii) Been charged or convicted of a criminal offense pursuant to any administrative and/or regulatory action taken by any government entity?	<input type="checkbox"/> Yes <input type="checkbox"/> No
For each "Yes" answer provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

VIII. LEADERSHIP INTEGRITY	
Note: If the Business Entity is a Joint Venture, answer 'N/A- Not Applicable' to questions 8.0 through 8.4.	
Within the past five (5) years has any individual previously identified, any other Key Employees not previously identified or any individual having the authority to sign execute or approve bids, proposals, contracts or supporting documentation with New York State been subject to	
8.0 a sanction imposed relative to any business or professional permit and/or license?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
8.1 an investigation, whether open or closed, by any government entity for a civil or criminal violation for any business related conduct?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
8.2 an indictment, grant of immunity, judgment, or conviction of any business related conduct constituting a crime including, but not limited to, fraud, extortion, bribery, racketeering, price fixing, bid collusion or any crime related to truthfulness?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
8.3 a misdemeanor or felony charge, indictment or conviction for: (i) any business-related activity including but not limited to fraud, coercion, extortion, bribe or bribe-receiving, giving or accepting unlawful gratuities, immigration or tax fraud, racketeering, mail fraud, wire fraud, price fixing or collusive bidding; or (ii) any crime, whether or not business related, the underlying conduct of which related to truthfulness, including but not limited to the filing of false documents or false sworn statements, perjury or larceny?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
8.4 a debarment from any government contracting process?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
For each "Yes" answer provide an explanation of the issue(s), the individual involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

**NEW YORK STATE
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IX. FINANCIAL AND ORGANIZATIONAL CAPACITY	
9.0 Within the past five (5) years, has the Business Entity or any Affiliates received any formal unsatisfactory performance assessment(s) from any government entity on any contract?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	
9.1 Within the past five (5) years, has the Business Entity or any Affiliates had any liquidated damages assessed over \$25,000?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the contracting party involved, the amount assessed and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	
9.2 Within the past five (5) years, has the Business Entity or any Affiliates had any liens, claims or judgments over \$15,000 filed against the Business Entity which remain undischarged or were unsatisfied for more than 120 days?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, relevant dates, the lien holder or claimant's name(s), the amount of the lien(s), claim(s), or judgments(s) and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	
9.3 Within the last seven (7) years, has the Business Entity or any Affiliate initiated or been the subject of any bankruptcy proceedings, whether or not closed, regardless of the date of filing, or is any bankruptcy proceeding pending?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide the Business Entity involved, the relationship to the submitting Business Entity, the Bankruptcy Chapter Number, the Court name, the Docket Number. Indicate the current status of the proceedings as "Initiated," "Pending" or "Closed". Provide answer below or attach additional sheets with numbered responses.	
9.4 During the past three (3) years, has the Business Entity and any Affiliates failed to file or pay any tax returns required by federal, state or local tax laws?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide the Business Entity involved, the relationship to the submitting Business Entity, the taxing jurisdiction (federal, state or other), the type of tax, the liability year(s), the Tax Liability amount the Business Entity failed to file/pay, and the current status of the Tax Liability. Provide answer below or attach additional sheets with numbered responses.	
9.5 During the past three (3) years, has the Business Entity and any Affiliates failed to file or pay any New York State unemployment insurance returns?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "Yes" provide the Business Entity involved, the relationship to the submitting Business Entity, the year(s) the Business Entity failed to file/pay the insurance, explain the situation, and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	
9.6 During the past three (3) years, has the Business Entity or any Affiliates had any government audits? If "Yes", did any audit reveal material weaknesses in the Business Entity's system of internal controls If "Yes", did any audit reveal non-compliance with contractual agreements or any material disallowance (if not previously disclosed in 9.6)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
For each "Yes" answer provide an explanation of the issue(s), the Business Entity involved, the relationship to the submitting Business Entity, the government entity involved, relevant dates and any remedial or corrective action(s) taken and the current status of the issue(s). Provide answer below or attach additional sheets with numbered responses.	

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X. FREEDOM OF INFORMATION LAW (FOIL)	
10.0 Indicate whether any information supplied herein is believed to be exempt from disclosure under the Freedom of Information Law (FOIL). Note: A determination of whether such information is exempt from FOIL will be made at the time of any request for disclosure under FOIL.	<input type="checkbox"/> Yes <input type="checkbox"/> No
Indicate the question number(s) and explain the basis for your claim.	

**NEW YORK STATE
VENDOR RESPONSIBILITY QUESTIONNAIRE
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Certification

The undersigned: recognizes that this questionnaire is submitted for the express purpose of assisting the State of New York or its agencies or political subdivisions in making a determination regarding an award of contract or approval of a subcontract; acknowledges that the State or its agencies or political subdivisions may in its discretion, by means which it may choose, verify the truth and accuracy of all statements made herein; and acknowledges that intentional submission of false or misleading information may constitute a felony under Penal Law Section 210.40 or a misdemeanor under Penal Law Section 210.35 or Section 210.45, and may also be punishable by a fine and/or imprisonment of up to five years under 18 USC Section 1001 and may result in contract termination.

The undersigned certifies that he/she:

- is knowledgeable about the submitting Business Entity’s business and operations;
- has read and understands all of the questions contained in the questionnaire;
- has not altered the content of the question set in any manner;
- has reviewed and/or supplied full and complete responses to each question;
- to the best of their knowledge, information and belief, confirms that the Business Entity’s responses are true, accurate and complete, including all attachments; if applicable;
- understands that New York State will rely on information disclosed in this questionnaire when entering into a contract with the Business Entity; and
- is under obligation to update the information provided herein to include any material changes to the Business Entity's responses at the time of bid/proposal submission through the contract award notification, and may be required to update the information at the request of the state's contracting entity or the Office of the State Comptroller prior to the award and/or approval of a contract, or during the term of the contract.

Signature of Owner/Officer _____

Printed Name of Signatory _____

Title _____

Name of Business _____

Address _____

City, State, Zip _____

Sworn to before me this _____ day of _____, 20____;

_____ Notary Public

Vendor Responsibility Attestation

To comply with the Vendor Responsibility Requirements outlined in Section IV, Administrative Requirements, H. Vendor Responsibility Questionnaire, I hereby certify:

Choose one:

- An on-line Vendor Responsibility Questionnaire has been updated or created at OSC's website: <https://portal.osc.state.ny.us> within the last six months.
- A hard copy Vendor Responsibility Questionnaire is included with this application and is dated within the last six months.
- A Vendor Responsibility Questionnaire is not required due to an exempt status. Exemptions include governmental entities, public authorities, public colleges and universities, public benefit corporations, and Indian Nations.

Signature of Organization Official: _____

Print/type Name: _____

Title: _____

Organization: _____

Date Signed: _____

Attachment 10

HIV CLINICAL GUIDELINES *September 1, 2009*

POST EXPOSURE PROPHYLAXIS

- HIV Prophylaxis Following Occupational Exposure
- HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault
- HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period

ADULT GUIDELINES

- Primary Care Approach to the HIV-Infected Patient
- Identification and Ambulatory Care of HIV-Exposed and -Infected Adolescents
- Diagnostic, Monitoring, and Resistance Tests for HIV
- New Antiretroviral Drugs: Maraviroc, Raltegravir, and Etravirine
- Antiretroviral Therapy
- Immune Reconstitution Inflammatory Syndrome (IRIS) in HIV-Infected Patients
- Long-Term Complications of Antiretroviral Therapy
- HIV Drug-Drug Interactions
- HIV Prophylaxis Following Occupational Exposure
- HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault
- Management of STIs in HIV-Infected Patients
- Syphilis
- Human Papillomavirus (HPV)
- Genital Herpes Simplex Virus (HSV)
- Gonococcal and Chlamydial Infections
- Lymphogranuloma Venereum (LGV)
- Bacterial Vaginosis (BV)
- Hepatitis A Virus
- Hepatitis B Virus
- Hepatitis C Virus
- Infectious Complications Associated With HIV Infection
- Parasitic Infections
- Mycobacterial Infections
- General Nutrition, Weight Loss, and Wasting Syndrome
- Gastrointestinal Complications of HIV
- Oral Health Complications in the HIV-Infected Patient
- Neoplastic Complications of HIV Infection
- Neurologic Complications of HIV Infection
- Ophthalmologic Complications of HIV Infection
- Smoking Cessation in HIV-Infected Patients

CHILDREN AND ADOLESCENTS

- HIV Testing and Diagnosis in Infants and Children
- Identification and Ambulatory Care of HIV-Exposed and -Infected Adolescents
- Supportive Care Issues for Children With HIV Infection
- Pediatric Antiretroviral Therapy
- HIV Post-Exposure Prophylaxis for Children Beyond the Perinatal Period

Attachment 10

HIV CLINICAL GUIDELINES *September 1, 2009*

- Immunologic Considerations in HIV-Infected Children
- Growth, Body Composition, and Metabolism
- Neurologic Complications in HIV-Infected Children and Adolescents
- Oral Health Care
- Dermatologic Manifestations
- Pediatric Malignancies
- HIV-Related Hematologic Manifestations in Pediatrics

WOMEN WITH HIV INFECTION

- Gynecological Care
- Bacterial Vaginosis (BV)
- Medical Care for Menopausal and Older Women With HIV Infection
- Care for the HIV-Infected Female Adolescent

PREVENTION

- How to Integrate Prevention Into Primary Care
- Prevention of HIV Transmission
- Health Promotion and Maintenance
- Smoking Cessation in HIV-Infected Patients
- Prevention of Secondary Disease: Preventive Medicine
- Immunizations
- Viral Hepatitis
- Opportunistic Infections
- Diabetes
- Lipid Screening and Cardiovascular Risk
- Gynecological Care

MENTAL HEALTH CARE

- Mental Health Screening: A Quick Reference Guide for HIV Primary Care Clinicians
- Somatic Symptoms: Mental Health Approach and Differential Diagnosis
- Depression and Mania in Patients With HIV/AIDS
- Suicidality and Violence in Patients With HIV/AIDS
- Cognitive Disorders And HIV/AIDS: Minor Cognitive Disorder, HIV-Associated Dementia, and Delirium
- Trauma and Post-Traumatic Stress Disorder in Patients With HIV/AIDS
- Personality Disorders in Patients With HIV/AIDS
- Anxiety Disorders in Patients With HIV/AIDS
- Severe and Persistent Mental Illness in HIV-Infected Patients
- Adherence to Antiretroviral Therapy Among HIV-Infected Patients With Mental Health Disorders
- Family Issues for Patients With HIV/AIDS
- The Role of the Primary Care Practitioner in Assessing and Treating Mental Health in Persons With HIV
- Appendix I: Mental Health Screening Tools

Attachment 10

HIV CLINICAL GUIDELINES *September 1, 2009*

- Appendix II: Interactions Between HIV-Related Medications and Psychotropic Medications
- Appendix III: Mental Health Care Resources in New York State

SUBSTANCE USE

- Alcohol Use and Abuse
- Mental Health and Substance Use
- Screening and Ongoing Assessment for Substance Use
- Working With the Active User
- Substance Use Treatment Modalities for HIV-Infected Patients
- Smoking Cessation in HIV-Infected Patients
- Aspects of Primary Care for the HIV-Infected Substance User
- Adherence to Antiretroviral Therapy Among Substance Users
 - Drug-Drug Interactions Between HAART, Medications Used in Substance Use Treatment, and Recreational Drugs
- Pain in the HIV-Infected Substance User
- Medical Care of HIV-Infected Substance-Using Women
- Care of the Hospitalized HIV-Infected Substance User
- Substance Use in Adolescents
- Buprenorphine appendix

ORAL HEALTH CARE

- General Principles
- Diagnosis and Management of Soft-Tissue Lesions
- Clinical Manifestations and Management of HIV-Related Periodontal Disease
- Oral and Maxillofacial Surgery
- Oral Health Management in Children and Adolescents With HIV Infection
- Infection Control
- Ethical and Legal Considerations

PHARMACY

- Pharmacists: Partners in Health Care for HIV-Infected Patients

Attachment 10

HIV CLINICAL GUIDELINES *September 1, 2009*

Chapter 14

Substance Use and Dependence Among HIV-Infected Adolescents and Young Adults

I. Introduction

Recommendations:

Clinicians treating HIV-infected adolescents should know how to screen adolescents for substance use and, if substance misuse is present, to develop a treatment plan and make referrals as appropriate.

Clinicians should be familiar with the stages of substance use progression and patterns of adolescent drug and alcohol use.

The American Academy of Pediatrics defines adolescence as 13 to 21 years. However, many pediatric and adolescent clinicians follow patients from 13 to 24 years of age before they transition to adult HIV care. For the purpose of these guidelines, the term *adolescents* refers to both adolescents and young adults, 13 to 24 years of age.

The use and abuse of alcohol and other mood-altering substances can be particularly problematic for both adult and adolescent HIV-infected patients. However, substance use patterns are different between adolescents and adults.¹ Screening, assessment, and treatment of substance use in adolescents require unique considerations, including the following:

- Social factors, particularly strong peer influences, have a significant impact on adolescent substance use.^{1,2}
- Experimentation with substances, especially with alcohol, is common among adolescents and is often considered normative behavior.³
- HIV-infected adolescents presenting for treatment typically demonstrate a high degree of co-occurring mental health symptoms or prior mental health diagnoses,⁴ which frequently precede the onset of problem substance use.

Marijuana and alcohol are used frequently by HIV-infected adolescents. Use of heroin, methamphetamine, and cocaine is less commonly reported^{5,6}; however, males and those with asymptomatic HIV infection may be more likely to use these substances.^{5,7} In the general adolescent population, the misuse of prescription opioids is increasing.⁸ Methamphetamine use is increasing among young adults (aged 18 to 26), particularly among

men who have sex with men.⁹ Awareness of factors that influence the use of other types of substances among adolescents is also important. Adolescents in school may be at risk for misusing stimulants, such as methylphenidate, for enhancing academic performance.¹⁰ Adolescents involved in sports or concerned with body image may be at risk for using anabolic steroids to enhance their athletic performance and appearance.¹¹

This chapter provides guidance on how to:

- Identify HIV-infected adolescents at risk for substance use
- Communicate with adolescents about substance use
- Screen and assess for substance use in HIV-infected adolescents
- Implement appropriate substance use interventions and make necessary referrals

II. Risk Factors for Substance Use in HIV-Infected Adolescents

Recommendation:

Clinicians should be able to recognize adolescents who are at high risk for substance use (see Table 1).

The developmental changes that occur during adolescence, coupled with HIV infection, can increase the use of alcohol and other substances. These patients may feel a sense of vulnerability, which may further place them at risk for substance use. Understanding adolescent development is critical to helping adolescents mature into well-adjusted adults (see *Ambulatory Care of HIV-Infected Adolescents* at: www.hivguidelines.org).

Assessment of the emotional support available to HIV-infected adolescents is essential, including whether an adult role model is present. Homeless and transient adolescents, as well as adolescents in foster care, are particularly vulnerable to social isolation and often require intensive case management. Because support networks may include family, friends, sexual partners, healthcare providers, teachers, counselors, clergy, and adult role models, clinicians should be inclusive when inquiring about who is significant in adolescents' lives (see *Ambulatory Care of HIV-Infected Adolescents*, as well as *Screening and Ongoing Assessment for Mental Health Disorders*, at: www.hivguidelines.org).

Many of the individual, family, and social factors associated with increased risk for substance use in adolescents are prevalent in HIV-infected adolescents (see Table 1). Clinicians can use this information to help identify HIV-infected adolescents who may be at particular risk for substance use.

Table 1
Potential Risk Factors for Substance Use
in HIV-Infected Adolescents

Risk Factor	Comment
Mental health diagnoses	Adolescents with diagnoses of depression, anxiety, post-traumatic stress disorder, attention-deficit/hyperactivity disorder, and conduct disorder are more likely to use substances than adolescents with no mental health diagnosis. ¹²⁻¹⁴
Sexual, emotional and physical abuse	Abuse and neglect in childhood is consistently associated with a high likelihood of substance use during adolescence in both males and females. ¹⁵⁻¹⁷ Violence associated with dating is also linked to high levels of alcohol and marijuana use in adolescents. ¹⁸ One study found that one in seven young men who have sex with men (YMSM) experienced childhood sexual abuse and that adolescents with a history of being sexually abused by adults were more likely to use substances than their peers. ¹⁹
Homelessness or street involvement	Early experiences of homelessness may predict substance use in adolescents and young adults. ²⁰ Homelessness is associated with the use of a variety of substances, including alcohol, methamphetamine, and injection drug use. ¹⁶ Two studies of YMSM found that homelessness and running away from home were associated with substance use. ^{21,22}
Lesbian, gay, bisexual, and transgendered (LGBT)	LGBT adolescents, especially lesbian and bisexual adolescents, have higher rates of substance use than heterosexual adolescents, but little information on the moderating or mediating factors is available. ²³ LGBT adolescents with other risk factors for substance use, including homelessness, residential instability, mental health diagnoses, peer substance use, and childhood abuse, have high rates of substance use. ^{19,21,22,24,25} Among YMSM, HIV-infected individuals may be more likely to use substances, especially methamphetamine, compared to their non-infected peers. ²⁶ Transgender adolescents are at risk for illicit feminizing hormone use (see <i>Care of the HIV-Infected Transgender Adolescent</i> at: www.hivguidelines.org).

Table 1 continues...

Table 1
Potential Risk Factors for Substance Use
in HIV-Infected Adolescents (Cont'd.)

Risk Factor	Comment
HIV-infected parents and family functioning	Family functioning plays a major role in predicting substance use in children of HIV-infected parents. ²⁷ In one large study, family functioning was disrupted frequently by substance use. Over one-half of children of HIV-infected parents were not in the parents' custody; the most common reason for non-parental custody was parental substance use. ²⁸ Children of HIV-infected parents have high rates of mental health diagnoses, placing them at additional risk for substance use. ²⁹
Parental substance use	Parental substance use predicts early and increased levels of alcohol and substance use in children and adolescents. ³⁰⁻³² Protective factors for adolescent substance use in families with parental substance use include close sibling relationships and parental disapproval of children's substance use. ^{32,33}
Incarceration	Adolescent incarceration is associated with increased substance use. ^{12,13}
Foster care	Evidence in this area is limited due to restrictions on research involving adolescents in the foster care system. However, available research shows that adolescents in foster care have higher rates of substance use than adolescents not in foster care. ³⁴ Substance use among those in foster care is especially common in adolescents who have mental health diagnoses. ^{35,36}
Early puberty	Early puberty is associated with both increased substance use and adolescent pregnancy. ³⁷
Adolescent pregnancy	Adolescent mothers use substances more often than their peers, and this difference persists into young adulthood. ³⁸
Peers who use substances	Peer influence is important in predicting substance use in adolescents, and adolescents who use substances are likely to have friends who also use substances. ^{2,39}
<i>Table 1 continues...</i>	

Table 1 Potential Risk Factors for Substance Use in HIV-Infected Adolescents (Cont'd.)	
Risk Factor	Comment
Educational experience	Lack of educational attainment or school attendance is a marker for substance use in adolescents. ⁴⁰ Inversely, some adolescents may experience pressure to increase their academic performance, which can place them at risk for using cognitive-enhancing substances, such as methylphenidate. ¹⁰
Body image and athletics	Some adolescents may experience pressure to alter their appearance through body-building or increase their athletic performance, both of which can place them at risk for using performance-enhancing substances, such as steroids. ¹¹
Tobacco use	Tobacco use has been consistently reported in adolescents receiving treatment for alcohol and substance dependence, ^{41,42} and adolescent smoking has been suggested as an indicator for both alcohol use and dependence. ^{43,44}

III. Communicating With Adolescents About Substance Use

Recommendations:

Clinicians should convey a nonjudgmental attitude toward adolescents when discussing substance use and should use words and concepts appropriate to the patient's cultural background and cognitive, linguistic, and emotional development.

Clinicians should reassure adolescent patients that discussions regarding substance use are confidential.

Trust between the patient and clinician is essential for an honest discussion that differentiates among experimentation, use, and abuse. To establish rapport and facilitate engagement, clinicians need to have a nonjudgmental attitude and use words and concepts appropriate to the patient's cultural background and cognitive, linguistic, and emotional development. Effective communication with adolescents about substance use includes the following:

- *Assurances of confidentiality.* Adolescent patients are often concerned about confidentiality and about the consequences of providing honest answers to questions about substance use.

- *Rationale for screening.* An explanation of why the screening questions are important. This can help establish trust and enable clinicians to educate patients about the effects of substance use on the course of their HIV illness.
- *Common terminology.* Asking the patient what terms he/she uses, such as, *What do you call heroin? Do you have a name for being on ecstasy?*, can teach the healthcare provider what the adolescent knows about the drug scene and can help the clinician obtain information about the patient's experiences with and understanding about substance use. However, providers should avoid using slang terms unless they are very adept at working with this population; otherwise, this can seem patronizing, particularly because adolescents have been shown to understand conventional medical terminology.

● **Key Point:**

Patients who are not ready to discuss substance use may develop trust in a clinician who demonstrates competence in addressing other challenges, such as housing instability or other case management needs. Once such trust is established, the patient may become comfortable with discussing substance use.

IV. Baseline History and Substance Use Screening

Recommendations:

Clinicians should obtain a comprehensive history from adolescent patients that includes substance use and mental health screening and psychosocial assessment. Screening should include all levels of alcohol and substance use.

Clinicians should screen HIV-infected adolescents for substance use at baseline and every 3 months thereafter. If the HIV-infected adolescent's initial drug screening result is positive, or if the patient has a history of substance use, the clinician should re-evaluate the patient's drug use more frequently as needed.

As part of the history-taking process, clinicians should incorporate selected brief screening instruments and discuss the confidentiality of screening with HIV-infected adolescents. The chosen screening instruments should be individually tailored for optimal use at baseline and follow-up visits and adjusted for the patient's substance use history.

A comprehensive history is essential for identifying substance use, guiding management of patients with psychosocial stressors, and accurately establishing mental health diagnoses in HIV-infected adolescents. A non-judgmental and caring approach to history-taking may elicit more accurate responses regarding sensitive issues, including substance use.

● **Key Point:**

Screening for all levels of alcohol and other substance use in HIV-infected adolescents is important because:

- Both alcohol and substance use are risk factors for HIV transmission and STI acquisition
- Even intermittent use can interfere with adherence to medications,⁴ raise the risk of drug-drug interactions, and reduce the patient's ability to practice safer sex

Substance use screening tools can be integrated easily into the primary care of adolescents. Some programs have their own screening tools with questions tailored to their clinic setting. A patient's answers to the questions listed in Table 2 can provide useful information about his/her attitudes about and frequency of substance use and can help clinicians determine whether further substance use assessment is necessary.

Table 2
Questions to Assess Attitudes About and
Frequency of Substance Use*

- Ask about current and past substance use in a nonjudgmental way
 - *Do you drink alcohol?*
 - *Have you experimented with or used other drugs?*
- Ask about specific substances (e.g., marijuana, alcohol, stimulants, opiates, and sedatives). Questions that target specific substances can elicit more accurate responses. For example:
 - *Did you smoke marijuana today, yesterday, recently?*
 - *How many times do you smoke during the week?*
 - *What do you like about it?*
 - *What do you dislike about it?*
- It is also important to include a question that specifically addresses over-the-counter and prescription medications, such as cough syrup (i.e., dextromethorphan), ephedrine, cognitive stimulants (e.g., methylphenidate and other “study drugs”), anabolic steroids, prescription opiates, and benzodiazepines, as well as family members’ prescriptions that he/she may be able to access.
- Patients who use multiple drugs may succeed at discontinuing the use of one drug while continuing to use others. Clinicians should phrase questions to inquire into the use of other substances as well.

* For information about specific substances, refer to Chapter 1: *What Are These Drugs?*

Some clinicians may prefer validated tools. The SAMHSA Center for Substance Abuse Treatment (CSAT) TIP 31 guidelines *Screening and Assessing Adolescents for Substance Use Disorders* provide a list of recommended tools that are appropriate for adolescent substance use screening (available at: www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.54841). Although screening tools with greater numbers of items have also been validated, brief screening instruments are preferable in the clinic setting because large-item screening tools may not be practical when time is limited. Additional information about substance use screening is also available in Chapter 2: *Screening and Ongoing Assessment for Substance Use*, as well as the *Quick Reference Substance Use Screening Card* at: www.hivguidelines.org

The selected tool should be tailored for optimal use at initial and follow-up visits and adjusted according to the patient's substance use history.

● **Key Points:**

- Ongoing assessment is important. However, adolescent patients who express a lack of readiness to address the issue of substance use may not provide honest answers and may become alienated if they feel ongoing pressure to continually discuss the topic.
- Signs of social withdrawal or a sudden change in behavior or peer influences may be an indicator of substance use and require further assessment.

Unless there is a life-threatening medical emergency, drug testing should only be conducted with the knowledge and consent of the adolescent. The patient should be told that it is a part of the treatment plan and may provide useful information to the provider as well as a means for the patient to avoid use. However, laboratory tests yield a narrow range of information; severity of use and the consequences of that use cannot be obtained from testing for the presence of drugs in urine and blood.⁴⁵ Drug monitoring cannot substitute for an ongoing therapeutic alliance with the adolescent.

V. Intervention Strategies

For HIV-infected adolescents, substance use is often just one problem among many psychosocial problems that need to be addressed.⁴⁶ For some adolescents, substance use may be a transient reaction to learning that they are HIV-infected or may be a result of parental substance use. Substance use may also be a result of an untreated or undertreated mental health diagnosis (see Chapter 11: *Mental Health Disorders Among Substance-Using HIV-Infected Patients*). Information about mental health screening and treatment is available in the Mental Health Guidelines at: www.hivguidelines.org

Determination of the most appropriate intervention for an individual recognizes the context of the HIV-infected adolescent's chronicity of use and degree of dependence. The American Society of Addiction Medicine criteria can help clinicians determine which patients have serious problems that require a higher level of substance use intervention.⁴⁷ Substance use treatment and related services are also available (see Section X: *Resources for Adolescent Substance Use Treatment*).

The strategies outlined below have been used primarily as interventions for alcohol, marijuana, and opioid use in adolescents. Unfortunately, the efficacy of such interventions for addressing adolescent methamphetamine use has not been determined. Because methamphetamine dependence often requires psychotherapeutic intervention, methamphetamine programs for adolescents are needed. Cognitive-behavioral approaches that have demonstrated promising results in adults, such as the Matrix Model,⁴⁸ have not yet been adapted for adolescents, and pharmacotherapy for methamphetamine has not been established for either adults or adolescents. At the present time, standard youth intervention programs, such as those discussed below, are likely to be more appropriate for adolescents than methamphetamine programs for older adults.

A. Harm-Reduction Approach

Recommendation:

Clinicians should use harm-reduction principles for adolescents who are not ready, or not willing, to make abstinence a goal. Such harm-reduction strategies include counseling adolescents to reduce harmful use, such as binge drinking, heavy or daily marijuana use, and polydrug use, as well as referring injection drug-using adolescents and young adults to syringe exchange programs.

The American Academy of Child and Adolescent Psychiatry (1997) defines harm reduction as a decrease in the use and adverse effects of substances, a reduction in the severity and frequency of relapses, and improvement in one or more areas of the adolescent's functioning, including academic achievement or family functioning. Harm reduction is intended to engage the patient in health care through the clinician's nonjudgmental stance toward the patient's current substance use. Adolescents who are not ready or who are unwilling to abstain from alcohol or other substances may be receptive to education and encouragement from a clinician who focuses on reducing harmful use instead of insisting on abstinence. Such education can include:

- Caution against binge drinking, heavy or daily marijuana use, and polydrug use, with a focus on educating patients about the risk of drug-drug interactions, both between substances and between substances and HIV medications, and the health effects of heavy substance use

- Encouragement of behaviors that reduce HIV transmission risk, such as not sharing equipment used for administering substances, including straws for snorting and equipment for injecting substances, and referral to syringe access exchange programs as available

Harm reduction is developmentally appropriate for adolescents who consider some level of substance use normative in their peer group, because the approach emphasizes safety if the patient is using, rather than lifetime abstinence.⁴⁹

Refer to Chapter 3: *Working With the Active User* for more information regarding harm-reduction strategies.

B. Brief Interventions

Recommendation:

Clinicians should implement brief interventions for HIV-infected adolescents when a problem with substance use is identified.

Brief interventions are short-term, less intensive alternatives to traditional substance use treatment modalities. These interventions share a common goal of enhancing a person's motivation and ability to change. Information about risks of substance use, means to reduce problems related to use, benefits to reducing use, and referrals to more extensive services are usually included in brief interventions. Because brief interventions have been shown to be effective in reducing substance use and substance-related harms in adolescents, including use of alcohol,⁵⁰ marijuana,^{51,52} and other drugs,^{53,54} clinicians should implement brief interventions when a problem with substance use is identified.

Time limitations and limited provider training have been identified as barriers to effective use of brief interventions.⁵⁵ It has been suggested that all healthcare providers, including nurses, may effectively implement brief interventions.

Preliminary research indicates brief interventions may not be as effective for reducing cigarette smoking as for reducing alcohol, marijuana, and other substance use.⁵¹ Mixed results with some populations at high risk for problem substance use, including homeless adolescents, indicate that there is a need for further research and alternative interventions for reduction of substance use and its harms during adolescence.

Refer to Chapter 3: *Working With the Active User* for more information regarding brief interventions.

1. Motivational Interviewing

Motivational interviewing is a brief psychotherapeutic intervention to increase the likelihood of a patient's consideration, initiation, and maintenance of specific change strategies to reduce harmful behavior. Motivational interviewing is one type of brief intervention shown to be effective with adolescents.⁵² Table 3 shows the four components of a motivational interview. More information on motivational interviewing, training, and a video on motivational interviewing for adolescents who use marijuana are available at: www.motivationalinterview.org

Component	Involves
Expressing empathy	Understanding and being aware of and sensitive to the feelings, thoughts, and experiences of another. Accomplished through reflective listening.
Supporting self-efficacy	Supporting the patient with the sense that an individual can identify and meet one's needs and goals.
Avoiding argumentation and rolling with resistance	Listening to the patient's resistance to change. Working collaboratively with the patient to develop his/her input regarding the treatment plan.
Discovering discrepancies	Helping patients identify discrepancies between their current behavior and desired future behavior.

2. Motivational Enhancement Therapy

Motivational *enhancement* therapy is a brief intervention that combines motivational interviewing with cognitive-behavioral techniques, such as problem-solving. A four-session motivational enhancement therapy intervention for HIV-infected adolescents and young adults aged 16 to 25 was shown to be effective in reducing alcohol use. It was also associated with improved health outcomes, such as a reduction in HIV viral load.^{56,57}

C. Group Interventions

Adolescents may prefer group treatment over other options for substance use treatment. Group interventions using a cognitive-behavioral approach have been shown to be effective in lowering rates of substance use among HIV-infected adolescent participants.⁵⁸ These cognitive-behavioral strategies emphasize how contextual and environmental factors can influence adolescents' response to stressful situations, including problem-solving and social-negotiating strategies. Group interventions for substance use have been developed for HIV-infected adolescents and provide risk education and social-negotiating and problem-solving training (for more information, refer to: www.effectiveinterventions.org/go/interventions/together-learning-choices).

In most studies, group interventions were not associated with negative outcomes.^{59,60} Group interventions may be challenging to implement in some areas, due to scheduling and confidentiality concerns. Telephone and internet-based groups have been suggested as alternatives to the traditional group format.⁶¹

D. Pharmacotherapy

With the exception of opioid agonist therapy and smoking cessation, the efficacy of pharmacotherapy for substance use has not been well established in adolescents.

Pharmacotherapy for Opioid Dependence

Recommendation:

Clinicians should refer injection drug-using adolescents for opioid-dependence treatment or more intensive levels of care as appropriate, such as extended counseling and case management.

Among adults, methadone maintenance has been shown to be highly efficacious in reducing heroin use, reducing HIV risk behaviors, and supporting ARV treatment adherence.^{62,63} A review of existing studies of adolescents found that methadone had the highest retention rate over other modalities and may be more effective in reducing illicit drug use.⁶⁴ However, many methadone maintenance programs lack resources for addressing co-occurring psychosocial and mental health concerns in adolescents. For patients who stay in treatment for at least 6 months, other modalities, including therapeutic communities and abstinence-based treatment with and without naltrexone, have the best long-term outcomes, with greater reductions in the use of opiates and other substances, as well as increased rates of employment.⁶⁴ Although therapeutic communities and abstinence-based treatment may have greater success in helping patients with

long-term adjustment, these programs have a lower initial retention rate in comparison with methadone maintenance.

Many opioid dependence treatment facilities, including methadone maintenance programs, do not accept individuals who are younger than 18 years of age. For facilities that do treat individuals younger than 18, Federal law requires two documented failures of drug-free detoxification and verification of 2 years of opioid dependence before admission.

Buprenorphine prescribed by an ambulatory care clinician may be a suitable alternative to illicit opioid use for many adolescents.

Buprenorphine may also be used both for maintenance and for detoxification and appears to have similar benefits to methadone with several advantages, including:

- It can be prescribed by any physician who has taken an 8-hour course, rather than only in specialized clinics
- As a partial agonist, it has a higher safety profile
- One formulation, Suboxone, includes naloxone to reduce the misuse of buprenorphine

For more information regarding treatment with buprenorphine, refer to Appendix VI.

Pharmacotherapy for Smoking Cessation

Cessation of smoking among adolescents may reduce their risk for future substance dependence, particularly alcohol dependence.⁴³ For information regarding pharmacotherapy for smoking cessation, see Chapter 6: *Smoking Cessation in HIV-Infected Patients*.

VI. Mental Health Treatment

Recommendation:

HIV-infected adolescents with co-occurring substance use and mental health diagnoses should be carefully assessed for psychotropic management of their mental health diagnosis.

Effective psychotropic management of co-occurring mental health diagnoses can often aid in reducing substance use, including alcohol and marijuana. Adolescents with comorbid mental health diagnoses, especially depression and bipolar disorder, generally decrease their use of substances, including alcohol and marijuana, when they received psychotropic management for their mental health diagnosis.⁶⁵ Accordingly, adolescents with co-occurring mental health diagnoses should be assessed for psychotropic management.

For additional information regarding mental health considerations for substance users, refer to Chapter 11: *Mental Health Disorders Among Substance-Using HIV-Infected Patients*.

VII. Referral for Substance Use Treatment

Recommendations:

Clinicians should have access to experienced case managers who can address the multiple disciplines involved in working with HIV-infected substance-using adolescents.

Clinicians should recognize that many adolescents do not know about substance use intervention services or how to access them.

With the patient's consent, substance use programs should make every effort to involve the adolescent's family and supportive adults in their care when appropriate.

Substance use programs and HIV care providers should collaborate in the development of treatment plans for adolescents who are engaged in both types of care.

Adolescents often do not know where they can obtain mental health and substance use services in their community and are seldom motivated to self-refer to substance use treatment. Typically, they are referred by a parent, clinician, juvenile justice, school, child welfare, or other government/community agency.

Linking HIV-infected adolescents to appropriate adolescent-specific drug treatment is difficult because few programs specialize in the needs of adolescents, and adult programs that do accept young adults 18 years of age and older may not be sensitive to the numerous other needs of an HIV-infected adolescent. Barriers to care include lack of financial resources and/or insurance and mistrust of healthcare professionals. Some HIV-infected adolescents who are addicted to substances may not require rehabilitative strategies as much as they require strategies that enable them to develop life skills.

The SAMHSA Center for Substance Abuse Treatment (CSAT) TIP 32 guidelines, *Treatment of Adolescents with Substance Use Disorders*,⁶⁶ emphasize the differences between treating adults and adolescents and discuss treatment options that emphasize adolescents' special needs, including attention to their cognitive, emotional, and social development. CSAT has also published a comprehensive description of the continuum of adolescent treatment options based on multiple client assessment criteria.⁶⁶

Familiarity with the following treatment levels can enable clinicians to individualize the appropriate level of treatment for each patient:

- Outpatient
- Intensive outpatient options
- Long-term residential psychosocial care (therapeutic communities)
- Half-way houses
- Group home living arrangements for adolescents who have experienced significant drug abuse

Some adolescents, especially those in the earlier stages of dependence who have supportive families and less severe coexisting problems, respond better in outpatient environments, where they can maintain their academic and family lives. Hospitalization may be indicated in some cases (see Table 4).

A list of community resources should be easily accessible to HIV-infected adolescents visiting the clinic setting. One resource for locating substance use treatment programs for adolescents is the SAMHSA Substance Abuse Treatment Facility Locator at: <http://dasis3.samhsa.gov/Default.aspx>

Table 4
Indicators for Hospitalization of
HIV-Infected Substance-Using Adolescents

- Overdose that cannot be safely treated in the outpatient or emergency room setting (e.g., severe respiratory depression, coma)
- Risk for a severe or complicated withdrawal syndrome, including dependence on multiple drugs, history of delirium tremens
- Acute or chronic medical conditions that make detoxification in a residential or ambulatory setting unsafe
- A documented history of not engaging in, or benefiting from, treatment in a less intensive setting
- Marked psychiatric comorbidity with an acute danger to self or others
- No response to less intensive treatment efforts
- Substance use poses an ongoing threat to own physical and mental health

VIII. Maintaining the Substance-Using Adolescent in Care

Recommendations:

Clinicians should ensure that HIV-infected adolescents are engaged in medical care regardless of whether or not they are actively using drugs.

Clinicians should include substance-using HIV-infected adolescents in the medical treatment planning process as early as possible.

Patients with comorbid substance use and HIV infection are more likely to leave medical treatment when they are given treatment goals that they are not ready to accept. The inclusion of patients early in the planning process of medical treatment may lead to more successful outcomes. Medical treatment goals will vary according to the adolescent's needs, which will depend on his/her level of family support and pattern of use of alcohol and other substances. However, if a patient does not fully understand his/her HIV diagnosis and management, he/she may not be able to achieve the desired clinical outcome. In such cases, clinicians may need to address the patient's substance use before engaging him/her in medical care.

For additional information about maintaining substance-using patients in care, refer to Chapter 3: *Working With the Active User*.

IX. Relapse Prevention

Recommendations:

Clinicians should coordinate with relapse prevention programs and mental health care providers when caring for HIV-infected adolescents with a history of substance or alcohol dependence.

Clinicians should ask HIV-infected adolescents in early recovery at each visit about the date of last use of substances, alcohol, and tobacco.

By definition, recovery from substance use behavior can be interrupted by periods of relapse. Relapse is defined by the American Society of Addiction Medicine as the “recurrence of psychoactive substance-dependent behavior in an individual who has previously achieved and maintained abstinence for a significant period of time beyond withdrawal.”⁴⁷

Patients with a known history of substance/alcohol dependence are at high risk for relapse, particularly when stressed by a new diagnosis of HIV or its complications. Clinicians should collaborate with relapse prevention programs and mental health providers as part of the overall care of patients with a history of substance or alcohol dependence. Relapse in patients who are in early recovery can be better identified when patients are asked at each visit about the date of last use of substances, alcohol, and tobacco.

Relapse is not a failure but an opportunity to learn from what happened and to change tactics to more effectively prevent future relapse.

When a patient relapses, the clinician should:

- Be nonjudgmental and voice continued optimism
- Ask what the specific circumstances were that led to the relapse
- Encourage a return to treatment
- Discuss difficulties and stresses
- Reassess the need to initiate pharmacotherapy or adjust doses
- Refer to or include other providers, such as social workers, in the patient's care
- Schedule more frequent visits

For additional information regarding relapse prevention, refer to Chapter 3: *Working With the Active User*.

X. Resources for Adolescent Substance Use Treatment

- **Daytop:** Adolescent treatment programs based on therapeutic community concept. Residential and daycare programs are offered. Refer to: www.daytop.org/adolescent.html
- **New Directions:** A substance use residential program that offers individual, group, and family services. A division of the Brooklyn Center for Psychotherapy, Inc. Refer to: www.newdirectionsbrooklyn.com
- **Odyssey House, Inc:** Enhanced therapeutic community providing residential and other substance use treatment services for individuals and families. Refer to: www.odysseyhouseinc.org
- **Phoenix House:** Offers residential and outpatient substance use treatment services to adolescents and adults. Refer to: www.phoenixhouse.org/NewYork/index.html
- **Promesa, Inc:** Provides residential and outpatient substance use treatment services, as well as medical and educational services. A subsidiary of Promesa Systems. Refer to: www.promesa.org
- **Safe Horizon's Streetwork Project:** Provides a range of services to street-involved youth, including case management, referral services, legal, medical, mental health, and substance use services. Refer to: www.safehorizon.org/page.php?page=homelesseyouth
- **SAMSHA Substance Abuse Facility Treatment Locator:** Search tool for locating substance use treatment services. Refer to: <http://dasis3.samhsa.gov>
- **Vertex Outpatient:** Program that provides outpatient counseling and other substance use treatment and other services. Refer to: www.vertexoutpatient.com

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HEPATITIS B VIRUS

	Key to Abbreviated Terms
AFP	α -Fetoprotein
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
HBcAb	Hepatitis B core antibody
HBeAb	Hepatitis B envelope antibody
HBeAg	Hepatitis B envelope antigen
HBsAb	Hepatitis B surface antibody
HBsAg	Hepatitis B surface antigen
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCC	Hepatocellular carcinoma
HCV	Hepatitis C virus
HDV	Hepatitis delta virus
IFN	Interferon
PegIFN	Pegylated IFN
PT/INR	Prothrombin time international normalized ratio

What's New — June 2008 Update

The committee recommends:

- Administering the HBV vaccination series to HIV-infected patients who are negative for HBsAb, unless they are chronically infected (see Figure 3).
- Testing for HBsAb between 4 and 12 weeks after vaccination. Nonresponders (HBsAb <10 IU/L) should be revaccinated with another three-dose hepatitis B vaccine series (see Figure 3). If a patient's CD4 count is <200 cells/mm³ or the patient has symptomatic HIV disease, revaccination may be deferred until several months after initiation of ARV therapy in an attempt to maximize the antibody response to the vaccine. However, revaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count (see Figure 3).
- Initiating treatment active against HBV when HBV DNA levels are >2000 IU/mL.
- Initiating ARV therapy when initiating treatment against HBV in HIV/HBV co-infected patients.

I. INTRODUCTION

Hepatitis B virus (HBV) is a double-stranded DNA, enveloped virus that replicates in hepatocytes. Its primary routes of transmission are vertical (mother-to-child), blood exposure, and sexual exposure. It is significantly more transmissible than HIV via blood-borne exposure, and some fluids that do not normally transmit HIV, such as saliva and sweat, contain infectious

HBV but at much lower levels than blood. In many cases, a patient's route of infection is not identified.

Approximately 1 to 1.25 million people are HBV carriers in the United States,¹ and four to five thousand deaths due to HBV-related cirrhosis or hepatocellular carcinoma (HCC) occur annually in the US. HBV infection resolves spontaneously in 90% to 95% of immunocompetent adults who are infected²; however, 5% to 10% develop chronic HBV infection that is characterized by persistence of circulating hepatitis B surface antigen (HBsAg) in the blood. Individuals with chronic hepatitis B are at risk for progression to cirrhosis or HCC. The similar routes of transmission for HIV and HBV place patients with either infection at greater risk for HIV/HBV co-infection. The rate of HBV infection in HIV-infected patients varies widely depending on the population. The highest rates of HIV/HBV co-infection (5% to 10% in the United States) are generally in men who have sex with men and injection drug users.^{3,4} HIV-infected women in the US have co-infection rates of 3% to 4%.⁵ HIV-infected patients in the EuroSIDA cohort had a co-infection rate of 9%.⁶

HIV-infected patients have lower rates than non-HIV-infected patients of hepatitis B envelope antibody (HBeAb) and hepatitis B surface antibody (HBsAb) seroconversion, resulting in higher rates of chronic HBV. HIV-infected individuals also have increased rates of HBV replication and accelerated disease progression, with increased incidence of liver fibrosis, cirrhosis, end-stage liver disease, HCC, and liver-related deaths compared with HBV mono-infected patients.⁷ In the MACS cohort, HIV/HBV co-infected patients had a risk of liver-related mortality that was 13 times higher than HIV mono-infected patients.⁸

Assessment for HBV infection is part of the baseline evaluation of all HIV-infected patients (see [Primary Care Approach to the HIV-Infected Patient](#)), and treatment of HBV in HIV-infected patients requires consideration of both infections (see Section VI. Treatment of HBV Infection in the Setting of HIV).

II. CLINICAL SYNDROMES

A. Acute Hepatitis B Infection

The incubation period for HBV is 30 to 180 days (mean, 90 days), and acute infections may vary from asymptomatic or mild to severe jaundice and, rarely, fulminant hepatic failure. Fever, right upper-quadrant abdominal pain, headache, and malaise are common, as are elevated serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels. Up to 20% of patients may develop arthralgias or arthritis. Symptoms resolve in 4 to 6 weeks, and 90% to 95% of non-HIV-infected patients develop HBsAb and are considered HBV-immune.² However, the rate of HBsAb development in HIV-infected individuals is lower.⁹

During acute infection, hepatitis B core antibody (HBcAb) IgM (IgM anti-HBc) appears within 4 weeks of HBsAg and is sometimes used as a marker for acute infection (although it can sometimes reappear during a reactivation of chronic infection). The emergence of HBsAb (antiHBs) signals resolving infection (see Figure 1).

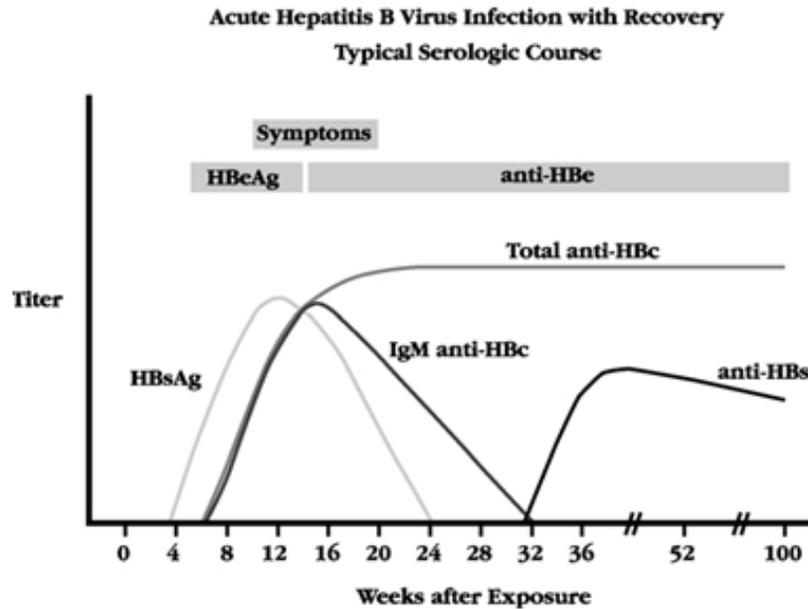


Figure 1. Reprinted from Centers for Disease Control and Prevention. Available at: www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_b/hep_b.pdf

B. Chronic Hepatitis B Infection

HIV/HBV co-infected patients are those who have HIV infection and chronic HBV, i.e., necroinflammatory disease of the liver caused by persistent infection with HBV. Chronic HBV infection can be subdivided into HBeAg-positive and HBeAg-negative HBV. Chronic hepatic inflammation, sometimes with elevated ALT, may progress to hepatic fibrosis and cirrhosis. In contrast to HCC in hepatitis C, HCC can develop in HBV infection without prior cirrhosis. Chronic HBV infection is often asymptomatic, although some patients experience periodic jaundice. In non-HIV-infected patients, HBsAg will clear in 2% of chronic carriers per year. HBeAg may often clear despite persistent HBsAg and is frequently associated with resolution of inflammation and hepatic recovery. This is attributable to continued expression of HBsAg from HBV DNA integrated into the hepatocyte genome with little viral replication.

Chronic HBV infection has been categorized into high and low replication:

- *High replication*—hepatitis B envelope antigen (HBeAg) positivity, high levels of HBsAg and HBV DNA, and elevated ALT
- *Low replication*—HBeAg negativity, low levels of HBsAg and HBV DNA, and low or normal ALT

This distinction is complicated by variants of HBeAg negativity in HBV infection, including the “precore” and “core promoter” mutants, which result in a state of high viral replication (i.e., >2000 IU/mL defined as significant). These mutations are present in up to 10% of HBeAg-negative patients. Identification of these cases is important because despite HBeAg negativity, liver disease progression is similar to that in patients who are positive for HBeAg (see Section IV. Evaluation of Patients with Chronic HBV). Figure 2 shows the serologic responses to chronic HBV infection.

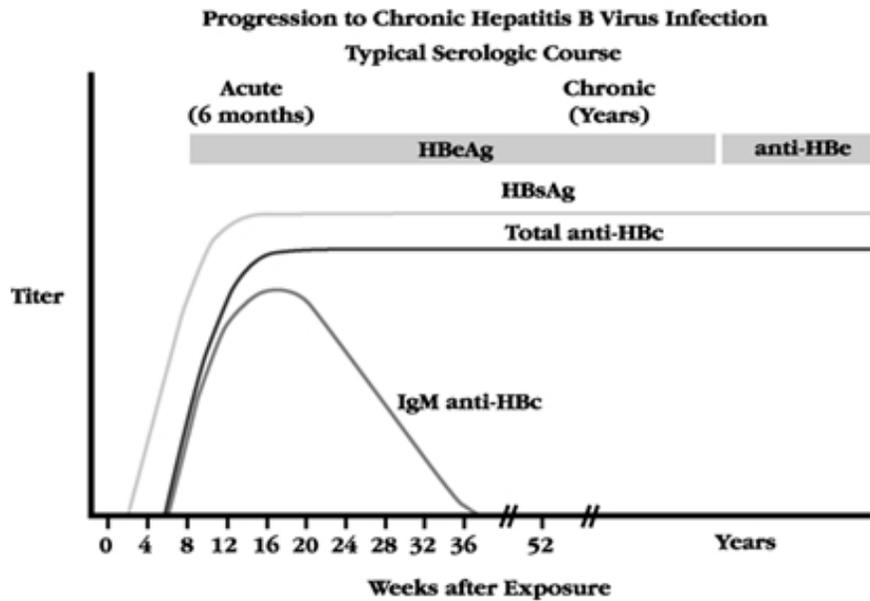


Figure 2. Reprinted from Centers for Disease Control and Prevention. Available at: www.cdc.gov/ncidod/diseases/hepatitis/slideset/hep_b/hep_b.pdf

C. Reactivation

Reactivation is defined as reappearance of active necroinflammatory disease of the liver in a person known to have the inactive HBsAg carrier state or resolved HBV (as defined in Table 1).¹⁰ This is rare and is usually associated with severe immunosuppression but may be more common in HIV-infected patients, including those who experience immune reconstitution after initiation of ARV therapy.¹¹ Reactivation may result in severe hepatitis and should be considered as a potential cause of hepatitis in patients who have had previously resolved hepatitis B. During reactivation, ALT will be elevated and patients who were previously HBeAg- and/or HBsAg-negative may become both HBeAg-positive and HBsAg-positive. This requires confirmation by one of the appropriate serologic tests: HBeAg, HBeAb, or HBV DNA levels.

D. Hepatitis Delta Virus (HDV)

HDV is a defective virus that requires active HBV infection for its replication and is associated with more severe liver disease, hepatic flares, and more rapid progression of liver disease when present in HBV-infected patients. Some clinicians assess for HDV with a serum total HDV IgM and IgG test in patients who are positive for HBsAg, particularly if the patient is from an HDV-endemic area. According to the Centers for Disease Control and Prevention, such areas include southern Italy, parts of Russia and Romania, and isolated regions of some South American countries in the Amazon River Basin.¹²

E. HIV/HBV/HCV Tri-Infection

Hepatitis C virus (HCV) in the presence of HBV is of particular concern for clinicians treating HIV-infected patients. Studies have indicated that patients with chronic HBV/HCV co-infection have a significantly higher degree of liver fibrosis,¹³⁻¹⁵ as well as hepatocellular apoptosis, bile duct damage, and ductular proliferation.¹⁴

These findings suggest more severe forms of HCV-related cirrhosis attributable to the presence of HBV.¹⁴ Furthermore, HBV/HCV co-infection may be associated with rapid progression to HCC.¹⁶

III. BASELINE EVALUATION, SCREENING, AND PREVENTION OF HIV/HBV CO-INFECTION

A. Baseline Hepatic Evaluation

RECOMMENDATION:

As part of the baseline assessment of HIV-infected patients, clinicians should evaluate liver function, including AST and ALT.

Liver function, including AST and ALT, should be assessed at baseline in all HIV-infected patients. If AST or ALT is elevated, the clinician should assess for causes of hepatic inflammation. Although the patient's platelet count may decrease as a result of many factors, low platelet count could be an indication of cirrhosis. Low albumin, high cholesterol, and elevated PT/INR (prothrombin time international normalized ratio) may indicate cirrhosis or end-stage liver disease, although they remain insensitive for liver dysfunction.

B. Hepatitis Screening

RECOMMENDATIONS:

As part of the baseline assessment, clinicians should ask HIV-infected patients about their HBV vaccination history and should obtain the following:

- ③ **HBV serologies: HBsAg, HBsAb, and HBcAb (IgG or total)** ③
- Hepatitis A IgG and hepatitis C IgG**

Clinicians should obtain an HBV DNA test for patients with negative HBsAb, negative HBsAg, and positive HBcAb to determine whether the patient has occult HBV infection (see Figure 3).

Screening for HBV should include obtaining HBsAb, HBsAg, and HBcAb. Patients with HBsAb levels of ≥ 10 IU/L are considered to be immune to HBV. Patients who are positive for HBcAb but are negative for HBsAb and HBsAg may have: 1) resolved HBV infection with < 10 IU/L HBsAb; 2) acute HBV infection; 3) occult HBV infection and thus will be positive for HBV DNA; or 4) a false-positive result. Table 1 shows the serologic and virologic responses to HBV, and Table 2 shows interpretation of HBV serologies.

TABLE 1 SEROLOGIC AND VIROLOGIC RESPONSES TO HBV							
Stage of Infection	HBsAg	HBsAb	HBcAb IgG	HBcAb IgM	HBeAg	HBeAb	HBV Viral Load
Incubation	+	-	-	-	+ or -	-	Low
Acute hepatitis B	+	-	+	+	+	-	High
HBsAg-negative acute hepatitis B	-	-	+	+	+/-	-	High
Inactive HBsAg carrier	+	-	+++	+ or -	-	+	Low
Precore mutant	+	-	+ or -	+ or -	-	+	High
Occult infection*	-	-	+	+ or -	-	-	High or low
Chronic hepatitis B	+	-	+++	+ or -	+ or -	-	High or low
Resolved HBV infection†	-	++	++	+ or -	-	+	Undetectable
HBV vaccination	-	++	-	-	-	-	Undetectable

* Studies have found occult HBV infection in approximately 10% of HBcAb-positive and HBsAg- and HBsAb-negative HIV-infected patients.^{17,18} Occult infection may be associated with greater immunosuppression (<200 cells/mm³) and higher HIV DNA levels.¹⁹

† Formerly known as convalescent.

TABLE 2 INTERPRETATION OF THE HEPATITIS B PANEL		
Tests	Results	Interpretation
HBsAg HBcAb* HBsAb	Negative Negative Negative	Susceptible to infection
HBsAg HBcAb HBsAb	Negative Negative or positive Positive	Immune
HBsAg HBcAb IgM HBcAb HBsAb	Positive Positive Positive Negative	Acutely infected
HBsAg HBcAb IgM HBcAb HBsAb	Positive Positive Negative Negative	Chronically infected
HBsAg HBcAb HBsAb	Negative Positive Negative	Four interpretations possible†

* Note about HBcAb: in the context of chronic infection, IgG is the applicable HBcAb marker. Therefore, references to HBcAb in these guidelines and elsewhere in the literature indicate IgG HBcAb, *not* IgM HBcAb, unless otherwise specified.

† 1) May be recovering from acute HBV infection; 2) may be distantly immune with test not sensitive enough to detect very low level of HBsAb in serum (<10 IU/L); 3) may be susceptible with a false-positive HBcAb; and 4) may be a carrier with an undetectable level of HBsAg, although HBV DNA may be detectable in this setting.

C. Prevention of HIV/HBV Co-Infection

RECOMMENDATIONS:

Clinicians should counsel patients about behavior modifications that decrease their risk of acquiring HBV infection through unprotected sexual activity and injection drug use.

Vaccination:

Clinicians should administer the HBV vaccination series to HIV-infected patients who are negative for HBsAb, unless they are chronically infected (see Figure 3).

Clinicians should test for HBsAb between 4 and 12 weeks after vaccination. Nonresponders (HBsAb <10 IU/L) should be revaccinated with another three-dose hepatitis B vaccine series (see Figure 3). If a patient's CD4 count is <200 cells/mm³ or the patient has symptomatic HIV disease, revaccination may be deferred until several months after initiation of ARV therapy in an attempt to maximize the antibody response to the vaccine. However, revaccination should not be deferred in pregnant patients or patients who are unlikely to achieve an increased CD4 count (see Figure 3).

Patients who are negative for HBsAb (who are not HBsAg-positive) should receive the HBV vaccination series and should be counseled to prevent HBV infection through avoidance of high-risk sexual behaviors and needle-sharing. Quantitative HBsAb levels should be obtained between 4 and 12 weeks after vaccination, and nonresponders (HBsAb <10 IU/L) should be revaccinated. *Revaccination* can be deferred for patients initiating ARV therapy until CD4 count is ≥ 200 cells/mm³ because response rates to HBV vaccination in immunocompromised patients is low, whereas vaccination may be more than 60% effective in patients with CD4 counts of ≥ 200 cells/mm³.²⁰ One study has shown efficacy of double-dose HBV revaccination in some patients²¹; however, these results were not reproduced in another study.²²

Key Point:

Patients who are unlikely to achieve CD4 counts of ≥ 200 cells/mm³ after ARV therapy (e.g., patients with HCV co-infection), as well as HIV-infected pregnant women, are at risk for severe complications resulting from HBV infection.

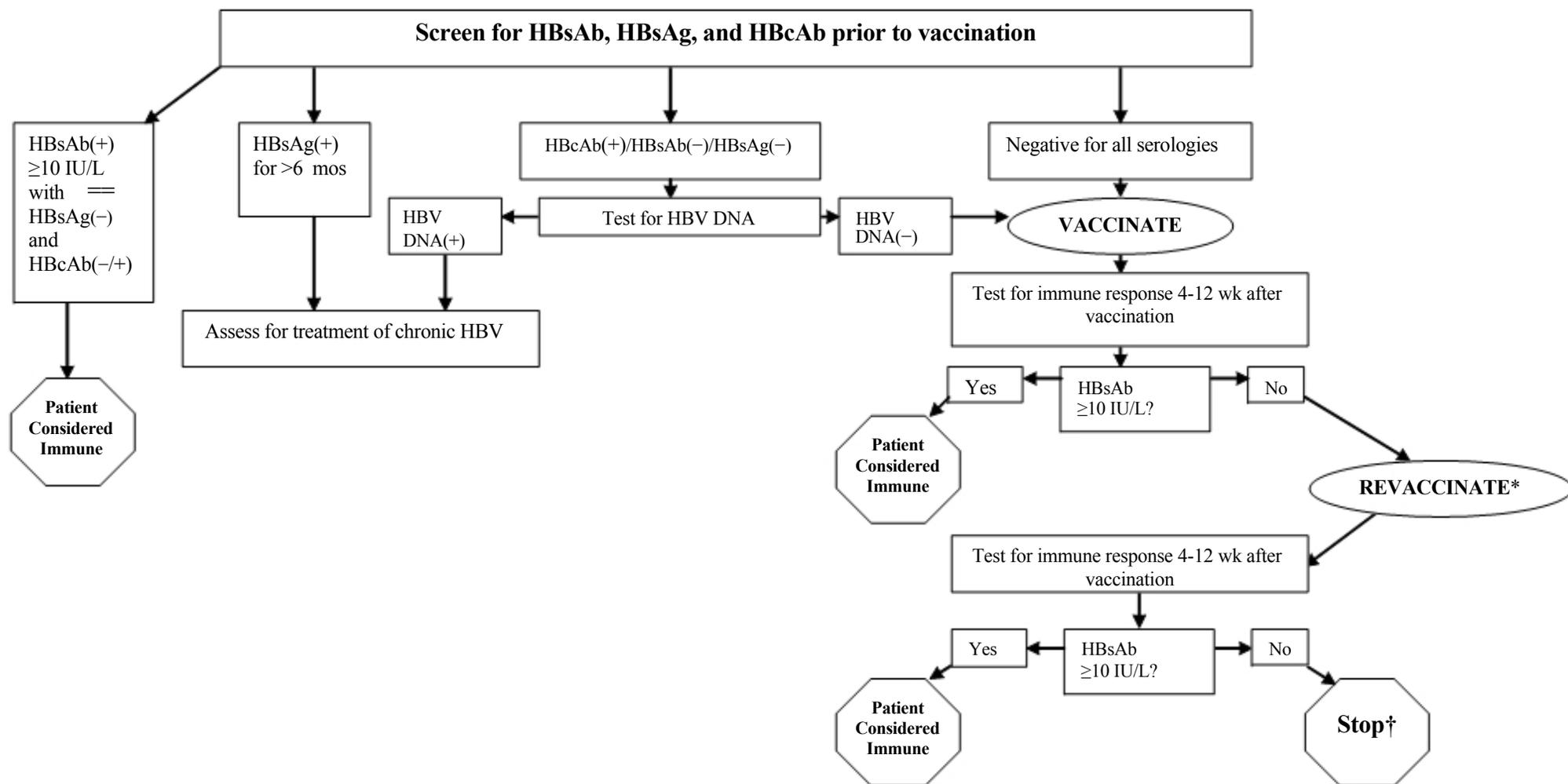
For information regarding perinatal HBV prophylaxis, see the Women's Health guidelines *Management of HIV-Infected Pregnant Women Including Prevention of Perinatal HIV Transmission*.

If HBsAb is not induced by primary vaccination and revaccination, then HBV DNA testing can be performed to determine whether the patient is a primary nonresponder or has chronic HBV infection (see Tables 1 and 2 and Figure 3). Primary nonresponders are individuals who are HBsAg-negative but are unable to develop immunity after receiving vaccinations that are administered according to standard protocols. Primary nonresponders are considered susceptible to HBV infection.²³

Key Point:

Patient education regarding HBV vaccination is important to ensure awareness of the continued risk for acquiring HBV until adequate surface antibody response is documented.

Figure 3. Algorithm for HBV prevaccination screening and vaccination in HIV-infected patients



* Revaccination can be deferred in patients initiating ARV therapy until CD4 count is ≥ 200 cells/mm³; revaccination should not be delayed in pregnant patients or those who are unlikely to experience immune reconstitution of ≥ 200 cells/mm³.

† A patient who is negative for all serologies and who does not respond to revaccination may be a primary nonresponder or have chronic infection. HBV DNA testing may be used to detect the presence of chronic HBV infection.

RECOMMENDATION:

Clinicians should administer the HAV vaccine to HIV-infected patients who are negative for HAV IgG to prevent concurrent HAV infection (see [Hepatitis A Virus](#)).

Hepatitis A virus (HAV) and HBV vaccines should be administered regardless of CD4 counts to patients who are all of the following: HAV IgG-, HBsAb-, and HBsAg-negative. A combined hepatitis A and B vaccine is available and can be used in persons susceptible to both HAV and HBV. Patients who do not require HBV vaccination may benefit from deferral of HAV vaccination until CD4 counts reach ≥ 200 cells/mm³ (see [Hepatitis A Virus](#)).²⁴ Such deferral is not advisable in pregnant women or in patients who are not likely to achieve CD4 counts of ≥ 200 cells/mm³.

For additional information regarding prevention of viral hepatitis, refer to the Prevention guidelines [Viral Hepatitis](#). For information regarding post-exposure prophylaxis to hepatitis infection, refer to [HIV Prophylaxis Following Occupational Exposure](#) and [HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault](#).

IV. EVALUATION OF PATIENTS WITH CHRONIC HBV**RECOMMENDATIONS:**

Clinicians should evaluate the extent of liver disease in patients with chronic hepatitis by:

- ③ **Obtaining an HBV-related history**
- ③ **Performing a physical examination for signs and symptoms of advanced liver disease**
- ③ **Measuring serial ALT levels, PT/INR, albumin, and platelet count**
- ③ **Assessing inflammation, fibrosis, HBV replication, and risk of HCC**
- ③ **Obtaining HBeAg, HBeAb, and HBV DNA quantification (nucleic acid amplification)**

If the baseline HBV DNA level is ≤ 2000 IU/mL in HBeAb-positive patients with elevated ALT, then clinicians should perform serial HBV DNA measurements at least annually.

Patients who are positive for HBsAg should be evaluated for signs and symptoms of advanced liver disease. Serial ALT measurements should be obtained because of the possibility of significant fluctuation. Higher ALT levels do not directly correlate with liver disease, but they do increase the likelihood of significant liver disease with increased disease progression.

All patients with chronic hepatitis should be tested for HBeAg and HBeAb. Patients who are positive for HBeAg usually have higher HBV DNA levels and more rapid progression of liver disease. One of the goals of treatment for patients who are positive for HBeAg is seroconversion to HBeAg negativity and HBeAb positivity. HBe seroconversion is associated with decreased levels of HBV DNA and halted or reversed progression of liver disease.

Key Point:

HBeAg negativity can be associated with greater HBV DNA replication and more rapid disease progression in patients carrying mutations in either the precore or the basic core promoter region of the HBV genome.²⁵

HBV DNA levels should be obtained at baseline in patients with chronic HBV. If the baseline HBV DNA level is ≤ 2000 IU/mL in HBeAb-positive patients with elevated ALT, then HBV DNA levels should be measured serially because wide fluctuation of ALT in these patients makes ALT an unreliable indicator. The laboratory that measures HBV DNA should participate in external quality control and use an assay with high sensitivity and a wide range (e.g., 80 to 10^{10} /mL).

Additional Evaluation

Liver biopsy is considered the gold standard to assess fibrosis and inflammation and to stage chronic disease; however, treatment of HIV/HBV co-infected patients is often guided by elevated ALT and HBV DNA levels. Because HIV-infected patients are at higher risk for fibrosis, liver biopsy may be prudent for HIV/HBV co-infected patients with normal ALT or low HBV DNA levels who are considering deferral of treatment or who are also infected with HCV (see [Hepatitis C Virus](#)). Ultrasound of the liver can sometimes detect cirrhosis, steatosis, and HCC. If cirrhosis is identified, then triple-phase CT scan can be used for detecting HCC. Liver stiffness measurements and calculations of a fibrosis score from noninvasive tests, such as ALT and platelet count, can be used but have not yet been validated in HIV/HBV co-infected patients. A method for calculating liver stiffness, known as the elastography technique (FibroScan), has demonstrated promising results²⁶; clinical trials in the US are ongoing.

V. COUNSELING FOR HIV/HBV CO-INFECTED PATIENTS**1. Alcohol Consumption****RECOMMENDATIONS:**

Clinicians should obtain a substance use and alcohol history for HIV/HBV co-infected patients and should refer patients with alcohol abuse or dependence for chemical dependency treatment.

Clinicians should educate HIV/HBV co-infected patients regarding the effects of alcohol on the course of HBV infection. Patients who have other underlying liver disease should be advised to abstain from alcohol.

Alcohol consumption accelerates liver fibrosis and decreases response to treatment. Psychological, social, and medical support to decrease alcohol intake is strongly recommended. Although more than 50 g of ETOH per day has been shown to be detrimental, no safe threshold for alcohol consumption has been established.

2. Transmission

RECOMMENDATIONS:

Clinicians should assess for HBV transmission risk behaviors and advise household contacts of HBV carriers to be vaccinated for HBV and to avoid sharing objects that may be contaminated with blood, such as razors or toothbrushes, until their immunity has been confirmed.

Clinicians should encourage all sexually active patients who are positive for HBsAg to use effective barrier protection consistently and correctly, including latex or polyurethane condoms and dental dams, to reduce the risk of transmission of HIV and HBV.

Clinicians should refer active injection drug users for substance use treatment, including opioid substitution therapy. Active injection users who are not ready for treatment should be referred to needle exchange programs.

HBV is significantly more transmissible through exposure to blood and body fluid than HIV and requires more frequent assessment for behaviors that increase risk of HIV/HBV transmission. Latex or, if one partner is allergic to latex, polyurethane condoms and dental dams should be recommended to decrease the risk of sexual transmission. Active drug users should be offered treatment programs, including opioid substitution. Needle exchange programs can decrease HBV and HIV transmission rates. New York State's two syringe access initiatives are the [Expanded Syringe Access Demonstration Program and Syringe Exchange Programs](#).

VI. TREATMENT OF HBV INFECTION IN THE SETTING OF HIV

Few studies address HBV treatment recommendations in the setting of HIV. The recommendations provided in this section are based on this panel's expert opinion.

In HIV/HBV co-infected patients, options for effective treatment of HBV are limited without concurrent treatment of HIV. However, effective treatments for HBV are significantly increased when an HIV-infected patient is treated concomitantly with ARV therapy. Importantly, once treatment is initiated, the interruption of therapy for either infection should be avoided whenever possible. Treatment interruption of anti-HIV/HBV agents can cause transaminase flares.

HIV/HBV co-infected patients develop lamivudine-resistant HBV more rapidly than HBV mono-infected patients. HIV/HBV co-infected patients also respond less well to interferon (IFN)alpha therapy than HBV mono-infected patients^{27,28}; however, limited data are available regarding pegylated IFN (PegIFN) or IFN-alfa in the era of ARV therapy.

A. Treatment of Acute HBV Infection

RECOMMENDATIONS:

Patients with acute HBV infection accompanied by fulminant liver disease should receive treatment with lamivudine. Initiation of ARV therapy is not recommended during fulminant hepatic liver disease.

Clinicians should not treat patients with fulminant hepatitis with adefovir or tenofovir.

Most cases of acute HBV infection resolve spontaneously without specific therapy, and there is no evidence that treatment in the acute phase improves the likelihood of development of HBsAb positivity.²⁹ In cases of fulminant liver disease resulting from acute HBV infection, lamivudine treatment has been shown to increase patient survival.³⁰ Therapy with lamivudine should be used in patients with fulminant hepatic failure despite the risk of developing lamivudine-resistant HIV. Patients with fulminant hepatitis should not be treated with adefovir or tenofovir because of the high concomitant rate of renal failure in fulminant hepatitis.

Key Point:

In an HIV-infected patient with fulminant hepatic failure induced by acute HBV infection, treatment with lamivudine therapy alone is indicated. In patients with less severe hepatic injury from acute HBV infection, and for whom ARV therapy may be indicated, ARV therapy should be deferred until resolution of the acute hepatic insult.

B. Treatment of Chronic HBV Infection

RECOMMENDATIONS:

Clinicians treating HIV/HBV co-infected patients should:

- **Initiate treatment active against HBV when HBV DNA levels are >2000 IU/mL**
- **Consider HBV treatment in patients with detectable HBV DNA ≤2000 IU/mL who also have elevated ALT levels above baseline or fibrosis or inflammation**
- **Consult with a specialist experienced in the treatment of hepatitis and HIV to discuss treatment decisions, including changes to a patient's existing ARV regimen when HBV treatment is indicated, and to establish a schedule for monitoring (see Table 3)**

When initiating treatment against HBV in HIV/HBV co-infected patients, clinicians should:

- **Initiate ARV therapy**
- **Use a standard ARV regimen that includes two drugs that are also active against HBV (see Figure 4)**

HBV

Clinicians should avoid discontinuing either HBV or HIV treatment whenever possible and should monitor ALT closely if discontinuation of HBV treatment is unavoidable.

HBV should be continued whenever possible to avoid risk of reactivation of HBV.

No large controlled trials have been conducted to define efficacy of combination therapies in HIV/HBV co-infected patients. These guidelines are therefore extrapolated from the treatment of HBV mono-infected patients, limited data from co-infected patients, and best practices for HIV treatment.^{15,31-34} Treatment goals and the agents used depend on the clinical status of the patient (see Figure 4). Initiation of ARV therapy is prudent when HBV treatment is indicated because resistance may result if an agent that is active against both viruses is used inadvertently to treat one or the other exclusively.

Timing of treatment initiation in patients with HBV mono-infection is based on HBV DNA level, liver disease (ALT, inflammation, fibrosis), and evaluation for cirrhosis. Patients at risk for HCC require additional monitoring (see Section VI. B. 5. Patients at Risk for Hepatocellular Carcinoma). Anti-HBV therapy is indicated for HIV/HBV co-infected patients with HBV DNA levels >2000 IU/mL because they have a greater risk of progression to HCC and cirrhosis.^{35,36} ALT levels are often lower in HIV/HBV co-infected patients in comparison with HBV mono-infected patients.³⁶ As such, ALT levels above baseline, regardless of whether or not the levels exceed the upper limit of normal, may also be predictive of HBV disease progression. Although HBV DNA is a more definitive indication for treatment, HBV DNA levels that are \leq 2000 IU/mL, but accompanied by elevated ALT levels above baseline or hepatic fibrosis or inflammation, may also warrant anti-HBV treatment. The primary goal of HBV treatment for HIV/HBV co-infected patients is HBsAg clearance with HBsAb seroconversion. However, because the rate of HBs seroconversion is low among HIV-infected patients,³⁷ and treatment should be considered chronic once it is initiated, the following secondary goals are reasonable:

- HBeAg to HBeAb seroconversion
- Suppression of HBV replication
- Reduction of liver inflammation
- Prevention or delay of progression of fibrosis, cirrhosis, and HCC

1. Patients Eligible for Both HBV and HIV Treatment

RECOMMENDATIONS:

Clinicians should treat patients who are eligible for both HBV and HIV treatment with an ARV regimen that contains tenofovir plus lamivudine or emtricitabine if such treatment is not contraindicated because of renal insufficiency or fulminant hepatic disease. If the ARV regimen needs to be changed because of HIV resistance to any of these agents, then these agents should still be continued as part of anti-HBV treatment (see Figure 4).

Patients with lamivudine or emtricitabine resistance to HBV should receive an alternative ARV regimen with optimal combined anti-HBV activity (see Figure 4).

Clinicians should monitor ALT during initiation of or changes to the ARV regimen, especially in patients with cirrhosis.

standard ARV regimen that includes two drugs that are also active against HBV should be used. Some experts would include dual anti-HIV/HBV agents in the ARV regimen regardless of HBV DNA levels.

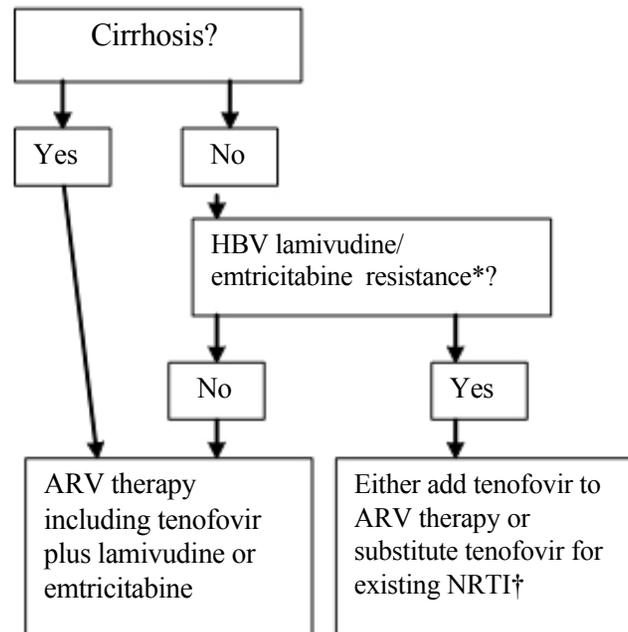
For patients already on successful ARV therapy, the benefits of adding anti-HBV agents to the existing ARV regimen are compared with the advantages of restructuring the ARV regimen to include medications that are active against both HIV and HBV. Currently, tenofovir plus lamivudine or emtricitabine provides a backbone active against both HIV and HBV for use with an NNRTI or boosted PI. For patients who have previously received lamivudine or emtricitabine, determination of lamivudine/emtricitabine HBV resistance, where available, can help guide the selection of an appropriate regimen (see Figure 4 and Appendix A). When assessment for HBV resistance is not an option, obtaining HBV DNA levels after 3 months can indicate treatment efficacy in these cases. Maintenance of suppression should be monitored every 3 to 6 months (see Section VII. Monitoring Treatment Response).

The anti-HBV activity of lamivudine, emtricitabine, and tenofovir warrants the continuation of their use when HIV resistance requires a change in the ARV regimen. In addition, these agents should be continued after HBV treatment response has been achieved, even when the ARV regimen needs to be changed.

Key Point:

Agents with dual activity against both HBV and HIV can simplify treatment regimens because a single agent can be used as part of a regimen to treat both viruses.

Figure 4. Initial Treatment for HIV/HBV Co-Infection



* When lamivudine and emtricitabine cease to be effective against HIV, but are still active against HBV, they should be continued as part of anti-HBV therapy.

2. Patients With Co-Infection Receiving HBV Treatment but Not HIV Treatment

RECOMMENDATION:

Clinicians should use pegylated interferon-alfa 2a for the treatment of HBV in HIV-infected patients who decline ARV treatment. No drug other than interferon should be used alone for the treatment of chronic HBV in patients with HIV.

If liver disease is active and the patient declines ARV treatment, then clinicians should initiate therapy with PegIFN alfa 2a (180 µg weekly for 48 weeks). The goal of IFN therapy is to achieve one of the following:

- A sustained seroconversion from HBsAg to HBsAb
- Seroconversion from HBeAg to HBeAb
- Normalization of ALT and sustained HBV DNA ≤ 2000 IU/mL

If patients are unable to tolerate IFN or do not respond, then concomitant treatment for HIV should be encouraged. No drug other than IFN should be used alone for the treatment of chronic HBV in patients with HIV. If used as monotherapy, tenofovir, lamivudine, emtricitabine, and telbivudine may select for HIV resistance. Entecavir can select for lamivudine/emtricitabine-resistant HIV.³⁸ Telbivudine and lamivudine are also likely cross-resistant.³⁹ Adefovir 10 mg daily is not active against HIV, but it is unclear whether it can induce HIV resistance to tenofovir or NRTIs. Although limited data do not show K65R mutations during treatment with adefovir 10 mg daily in HIV-infected patients,⁴⁰ the small but poorly defined rates of K65R mutation, as well as the manufacturer's warning against its use as monotherapy in HIV/HBV co-infected patients,⁴¹ suggest that monotherapy with adefovir should be avoided.⁴²

3. Patients With Co-Infection Eligible for HIV Treatment but Not HBV Treatment

RECOMMENDATION:

For patients who require HIV treatment and in whom HBV treatment is not indicated, lamivudine or emtricitabine should not be used without tenofovir.

For HIV/HBV co-infected patients who meet the medical criteria for initiation of ARV therapy but have HBV DNA levels ≤ 2000 IU/mL, clinicians should generally follow guidelines established for patients with HIV mono-infection (see [Antiretroviral Therapy](#)). However, lamivudine or emtricitabine should not be used without tenofovir to avoid selecting for lamivudine/emtricitabine-resistant HBV.

4. Patients With Cirrhosis

RECOMMENDATIONS:

Patients with hepatitis who develop symptomatic cirrhosis should be managed by a clinician experienced in the management of cirrhosis, preferably a hepatologist.

Clinicians should refer HIV/HBV co-infected patients with known cirrhosis for endoscopy

HIV/HBV co-infected patients with cirrhosis are at increased risk for a life-threatening hepatitis flare during immune reconstitution after initiation of ARV therapy, particularly when their baseline CD4 count is <200 cells/mm³. Reduction of HBV levels with adefovir, which does not inhibit HIV replication, prior to starting ARV therapy, may be beneficial but is controversial because most experts prefer initiating a full ARV regimen with monthly monitoring of transaminases. HBV-infected patients with known cirrhosis should be referred for endoscopy every 1 to 2 years to monitor for esophageal varices.

5. Patients at Risk for Hepatocellular Carcinoma

RECOMMENDATION:

In patients with chronic HBV who are at higher risk for HCC, clinicians should:

- **Screen serum α -fetoprotein every 3 to 6 months**
- **Perform annual imaging with either a triple-phase CT scan of the abdomen, MRI scan of the abdomen, or hepatic ultrasound, depending on the imaging protocol of the institution**
- **Perform imaging every 6 months if cirrhosis is present**

The decision to initiate treatment in patients at risk for HCC is established according to routine monitoring, including α -fetoprotein (AFP) measurements every 3 to 6 months and annual imaging with triple-phase CT scan of the abdomen, MRI scan of the abdomen, or hepatic ultrasound. The choice of imaging technique will depend on the imaging protocol of the institution. Because the sensitivity of hepatic ultrasound is more variable in detecting small tumors, some experts alternate between CT and MRI every year and perform ultrasound at the 6-month interval between the annual scan. If cirrhosis is present, then imaging should be performed every 6 months.

VII. MONITORING TREATMENT RESPONSE

RECOMMENDATION:

After initiation of HBV treatment, clinicians should obtain HBV DNA levels and should assess for HBeAg and HBsAg seroconversion every 3 to 6 months.

An initial response of at least 1 log decrease in HBV DNA in 3 months for nucleoside or nucleotide analog regimens is considered a response to therapy. Clinically relevant responses to HBV therapy are a sustained seroconversion from HBsAg to HBsAb, from HBeAg to HBeAb, or normalization of ALT and sustained HBV DNA ≤ 2000 IU/mL. If HBV DNA level increases by more than 1 log in adherent patients after a decrease in therapy, then resistance should be suspected. Although the appropriate interval for monitoring HBV DNA and seroconversion to HBeAb positivity has not been established, monitoring every 3 to 6 months is a reasonable approach because of the risk of future virologic resistance and a subsequent hepatic flare. Transaminase flares are also possible when initiating ARV therapy.^{11,43}

TABLE 3 ROUTINE LABORATORY ASSESSMENT AND THERAPEUTIC MONITORING OF HIV-INFECTED PATIENTS WITH HBV*	
Diagnostic Screen	Frequency
Laboratory Testing	
HBeAg and HBeAb	Baseline and every 3-6 months for patients receiving treatment who are HBeAg(+) and HBeAb(-)
ALT	Serial measurements every 3-6 months or more frequently if stopping HBV therapy
HBV DNA	Serial measurements if low (≤ 2000 IU/mL) in HBeAb(+) patients with elevated ALT; every 3-6 months to monitor therapy
PT/INR, AST, platelets	Baseline and 6 months
AFP	Baseline and every 3-6 months in patients at risk for HCC†
Imaging Studies	
MRI, triple-phase CT, or alternation between the two	Annual triple-phase CT scan of the abdomen, MRI scan of the abdomen, or hepatic ultrasound, depending on the imaging protocol of the institution; if cirrhosis is present, then every 6 months
Liver Biopsy‡	Consider at baseline for the following: <ul style="list-style-type: none"> • Patients who are considering deferring anti-HBV treatment <i>or</i> • Patients who are HIV/HBV/HCV tri-infected

* These routine assessment and monitoring procedures are performed in conjunction with those recommended for all HIV-infected adults (see [Primary Care Approach to the HIV-Infected Patient](#)).

† HBV-infected patients at risk for HCC are those with cirrhosis, those who are HBsAg(+), those with high HBV DNA, and those with a family history of HCC.

‡ If HCC is suspected, refer to a hepatologist or oncologist. Monitoring considerations are different for patients with HCC.

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CURRENTLY AVAILABLE ANTI-HBV MEDICATIONS

Tenofovir disoproxil fumarate	Nucleotide reverse transcriptase inhibitor that inhibits both HIV and HBV (wild-type and lamivudine-resistant). It has been effective at decreasing the viral loads of both HIV and HBV when used in combination with lamivudine. In a small trial of HIV/HBV co-infected patients, many of whom had been receiving lamivudine, addition of tenofovir decreased HBV DNA level 4 logs vs. 3.2 logs with adefovir. ⁴⁴ Tenofovir-resistant mutations have been described, but the rate of developing mutations is not defined.
Lamivudine	Nucleoside analog that is active against HIV and inhibits HBV replication in most HIV/HBV co-infected patients. It results in low (10%) seroconversion rates. It should always be used at its 300-mg daily or 150-mg twice-daily dose in HIV-infected patients. It should not be used as monotherapy for HBV in HIV-infected patients because HIV resistance will develop rapidly. Likewise, HBV resistance to lamivudine will develop in up to 30% of HIV-infected patients per year if used as the only active agent against HBV in a regimen. ⁴⁵ ALT levels frequently increase 1 to 2 months after lamivudine is started, and this should not prompt discontinuation of the drug. ALT may also increase during seroconversion from HBeAg to HBeAb positive.
Emtricitabine	Emtricitabine is a nucleoside analog, similar to lamivudine, that is active against both HIV and HBV. HBV resistance also develops rapidly (12% in 1 year) if used as monotherapy, and lamivudine-resistant isolates are also crossresistant to emtricitabine. ⁴⁶
Entecavir	Nucleoside analog that is active against both HIV and HBV. It is approved in the US for use against HBV. In a small study, 84% of HIV/HBV co-infected patients failing lamivudine therapy achieved significant decrease in HBV DNA levels (vs. 0% of placebo) with entecavir. ⁴⁷ However, it can select for lamivudine/emtricitabine-resistant HIV; therefore, it is not recommended for treatment of HBV in HIV-infected patients not receiving ARV therapy. ³⁸ It is active against both wild-type and lamivudine-resistant HBV but more so against wild type.
Adefovir dipivoxil*	Nucleoside analog reverse transcriptase inhibitor active against HBV, including lamivudine-resistant strains. At the 10-mg daily dose, it does not appear to affect HIV replication, and, in one study, there was a negligible rate of selection for K65R mutant HIV, although the true rate is yet to be determined. ⁴⁰ In a small trial of HIV/HBV co-infected patients, many of whom had lamivudine-resistant HBV, addition of adefovir decreased the HBV DNA level 3.2 log (vs. 4 log for tenofovir). ⁴⁸ However, the manufacturer warns against its use as monotherapy in HIV/HBV co-infected patients. ⁴¹

Telbivudine	<p>Telbivudine has not been studied in HIV/HBV co-infected patients. It is a nucleoside analog that, in contrast to other nucleoside analogs, has no antiviral activity against any known human viruses other than HBV.⁴⁴ Patients achieve normalization of transaminase levels at a higher rate with telbivudine than with lamivudine (86% vs. 63%).⁴⁹ Telbivudine and lamivudine share cross-resistance,³⁹ and combination of telbivudine and lamivudine is not more effective than telbivudine alone.⁴⁹ The rate of HBeAb seroconversion appears to be higher with telbivudine than with lamivudine (31% vs. 22%) but lower when telbivudine and lamivudine are combined (17%).⁴⁹ Rates of telbivudine resistance are high; therefore, it is not recommended as monotherapy.</p>
Interferon-alfa	<ul style="list-style-type: none"> ○ INF-alfa 2a or 2b or PegIFN alfa 2a are used as therapy for HBV mono-infected patients. PegIFN alfa 2a has been shown to be superior to the shortacting IFN. Some small studies suggest a lower response rate in HIV/HBV coinfectd patients (approximately 10%), but it may be useful if an agent that is not active against HIV is desired. It has a higher success rate in HBeAg(+) patients and those with elevated ALT levels (>200 IU/L) and with CD4 counts ≥ 200 cells/mm³.²⁸ Advantages include the following: <ul style="list-style-type: none"> ③ A finite treatment duration—6 months for HBeAg(+) and 12 months for HBeAg(-) ③ Higher likelihood of HBeAg seroconversion ③ No activity against HIV to promote HIV resistance ○ IFNs have numerous side effects and toxicities that should be managed by a clinician experienced with its use. IFN-alfa cannot be used in patients with decompensated cirrhosis.

* A dose of >10 mg daily increases the likelihood of HIV resistance when used as HBV monotherapy. However, monotherapy with any agent other than IFN-alfa, regardless of dose, is not recommended.

Attachment 12

Mental Health Guidelines Committee Bylaws

Revised: 9/12/2007

I. Objective

- To create state-of-the-art mental health care practice guidelines for New York State that reflect variations in clinical practice.
- To consult on related clinical matters for the AIDS Institute, including those that involve reimbursement for mental health services and/or medical care.
- To advise on HIV-related policy issues involving clinical and scientific aspects.

II. Committee Membership and Functions

- The Committee is composed of clinical health professionals with expertise in the mental health care needs of people affected by HIV in New York State.
 - The Committee comprises up to 15 members who reflect the diversity of clinical programs in New York State and to the extent possible, geographic, gender, ethnic, and racial diversity. A minimum of one, and up to two members, will be primary HIV care providers. Included among the membership are the Chair, a Vice-Chair, and a physician representative from the AIDS Institute.
 - In addition to the regular members, the Committee comprises liaison members. Liaisons to the Committee are considered in the geographic, gender, ethnic, and racial diversity distribution of membership. Liaisons to the Committee can include but are not be limited to the following:
 - Designated representative from the New York State Department of Corrections
 - Designated representative from the New York City Health and Hospitals Corporation
 - Designated representative from the Veterans Administration Hospital System
 - Designated representative from the New York State Office of Mental Health
 - Designated representative from the New York City Department of Mental Health, Alcoholism, and Substance Abuse Services
 - Chair, Part A Planning Council Mental Health Workgroup
 - Designated representative from OASAS.
 - Designated represented from the New York/New Jersey AIDS Education Training Center (AETC).
 - Persons infected or affected by HIV participate in Committee activities as representatives of the Consumer Advisory Committee. Representatives of the Consumer Advisory Committee are invited to attend meetings, review guidelines, and provide their expertise on specific subjects as necessary.
 - The term of membership for full Committee members is four years, with the exception of the Chair and Vice-Chair (the term limits for whom are described in Section III). In addition, when a replacement cannot be located by the end of a member's term, and that member is among an underrepresented group, he/she may be asked to extend his/her term beyond four years. New members are chosen each year to replace outgoing members. Outgoing members may rejoin the Committee after a one year's absence.
 - The term of membership for liaison members is determined by the organizations they represent.
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Attachment 12

Mental Health Guidelines Committee Bylaws

Revised: 9/12/2007

- All members, full and liaison, have voting power with respect to adoption of recommendations contained in the clinical guidelines.
- Elections are to be held yearly. Nominations for new members are solicited from the committee. The Chair, Vice-Chair, and Physician Representative screen the qualifications of candidates for membership and their willingness to serve on the Committee, with emphasis on recruiting members with specific expertise or geographic representation needed by the Committee. Nominations from Committee members for potential members are accepted throughout the year and are subject to the approval of the AIDS Institute.
- All Committee decisions require a quorum, defined as 50 percent of all members plus one and a majority vote. Any change in the bylaws will require two-thirds majority vote of the entire Committee membership.
- Members who are repeatedly unable to participate in conference calls, attend meetings, or contribute to tasks assigned to the Committee are subject to an evaluation by the Chair to determine their continued membership.
- All new guidelines drafted by the Committee undergo, whenever possible, peer review by two mental health professionals who are specialists in the subject matter at hand. In addition, the Committee makes every effort to have drafted guidelines reviewed by a representative from the Consumer Advisory Committee who is knowledgeable about the subject. All modifications suggested after Committee approval should be reviewed and approved by the Chair (or Vice-Chair) and the AIDS Institute Physician Representative.

III. Chair and Vice-Chair

- The Committee is headed by a Chair with a term of two years' duration. The Chair will rotate off the Committee at the end of his/her term but may remain in an advisory position for one additional year. In addition, it is expected that the former Chair will be available for consultation regarding any Committee projects that began during his/her tenure.
 - The individual having served as Vice-Chair for two years will automatically assume the position of Chair. If elected Vice-Chair at the end of the fourth year on the Committee, the Chair may serve a total of eight years on the Committee. The Vice-Chair position will be elected by a majority vote of the Committee membership. Nominations for the Vice-Chair will be solicited from members of the Committee biannually and are subject to the approval of the AIDS Institute. Any member is eligible to be nominated for Vice-Chair, and any member may nominate him/herself for the position of Vice-Chair.
 - The Chair, along with the AIDS Institute physician representative, supervises periodic updating of the guidelines for mental health care by committee members. AIDS Institute Staff coordinates this effort. All chapters are reviewed according to their individually assigned frequency, as determined by the Chair and Committee. Changes to any guidelines are posted on the HIV Clinical Resource website (www.hivguidelines.org).
 - The Vice-Chair assists the Chair as necessary in the review of guidelines, leading of meetings and sign-off on guidelines changes in the Chair's absence, and coordination of special projects as necessary.
-

Stipend Rate Guidance

Below are the current criteria used for stipends paid to committee members and consultants who write new guidelines chapters and update existing guidelines.

Newly written guidelines chapters

Stipends for new chapters are determined by the length and thoroughness of the draft.

\$200	8 or fewer pages
\$300	8-15 pages, all pertinent areas covered, reference list included
\$400	15+ pages, all pertinent areas covered, reference list included

Updates to existing guidelines (amount per guideline)

Stipends for updates are determined by the extent to which the guideline needs updating as listed below.

\$100	Section did not require major revision: author made minor updates to text, updated reference list
\$200	One or more sections required major revisions: author significantly updated or rewrote one or more sections of the guidelines; smaller updates to other sections; updated reference list
\$300	Majority of guideline in need of rewriting: author rewrote or significantly revised the majority of the guidelines sections, updated reference list

Peer Reviewer Rate:

\$200 per guideline

Guidelines Committee Member Reimbursement Rate

\$125/hr	Committee Chairs and Vice-Chairs for attendance at guidelines development meetings and for conference call reviews of guidelines chapters
\$85/hr	Guidelines committee member for attendance at guidelines development meetings and conference call reviews of guidelines chapters