Targeted Projects in Human Embryonic Stem Cell Research RFA
FAU # 0903091046

QUESTIONS AND ANSWERS and MODIFICATIONS
7/8/09 – 7/27/09
Including two applicant conferences

Letter of Intent and Pre-application Materials

1. Must applicants attend the Applicant Conference?

   A. No, but if you do plan to attend, please register so that we can notify security that you are coming and ensure that we have enough space to accommodate everyone.

2. When is the Letter of Intent due?

   A. The Letter of Intent form (Attachment 4) is mandatory and must be received by the due date (August 5, 2009 by 2pm). See Section IV.C. of the RFA.

3. Do we need to include any information in addition to the Letter of Intent form?

   A. Submit only the information requested on the form. No additional information will be considered.

4. On the Letter of Intent form, do we need to include all internal collaborators (faculty at our institution that will help to design and/or deliver the program) or is this for primary contacts at our collaborating institutions?

   A. Identify all participants involved in the program, both internal and external to your organization. It is understood that these names may change; they are used as a preliminary screening for conflict of interest among possible peer reviewers. Remember that Letters of Intent cannot be transferred to another institution.

5. Can the PI change after the Letter of Intent is submitted?

   A. Yes, as long as the listed PI and the actual PI are from the same institution.

6. If there are Co-PIs and we're not sure who will be the lead PI, do we submit two Letters of Intent?

   A. The applicant number is assigned to the institution, and is not transferrable between institutions. So, to cover the possibility that the lead PI might change, each possible submitting institution should submit a Letter of Intent. If the Co-PIs are from the same institution only one Letter of Intent is needed; it should include all Co-PIs and collaborators. If the Co-PIs are from different institutions, a separate Letter of Intent should be submitted by the Co-PI at each institution.

7. My list of collaborators is longer than the form allows. May I add sections to list them all?

   A. Yes, add as many sections as you need to list your collaborators.

8. I have appointments at two institutions and will be submitting applications through both of them. Do I need separate letters of intent?

   A. Yes. Letters of Intent are submitted by the institution and the subsequently assigned application numbers are assigned to the institution. The application numbers are not transferrable between institutions. See Section IV.C. of the RFA.

9. Can a PI submit additional or fewer IDEA and IIRP applications than indicated on my Letter of Intent?

   A. Yes, as long as there are enough application numbers assigned to the institution.

10. What should I put on my Letter of Intent if I know I will submit one application but haven't yet decided whether to submit an IDEA or an IIRP application?

    A. Indicate the mechanism that is most likely (IDEA or IIRP) on the Letter of Intent form. This can change at time of application; it is collected so we can plan ahead for peer review.

11. If I am submitting a revised application, do I need to submit a new Letter of Intent?

    A. Yes, and a new application number will be assigned for use with the revised submission.

12. If I submit a Letter of Intent under this RFA and then decide to submit the application under the targeted RFA (# 0903091046) is that OK?

A. No. The Letter of Intent is specific to the RFA. If you are unsure, submit a separate Letter of Intent for each RFA.

13. When will my application number be sent to me?

    A. If the Letter of Intent form is accepted, an application number will be sent to the Principal Investigator during the week following August 5, 2009. That number must appear on application Form 1 for the applicant and each subcontractor.

Eligibility

1. I am a research scientist, not yet tenured, but have permission to write my own animal protocols and grant applications. Am I eligible to apply as a PI or would it be better to have someone in a faculty position be the PI on the application?

    A. As long as you meet the eligibility criteria in Section II of the RFA, you are eligible to apply. Consider the review criteria (found in Section V.C.) and put forth the best research team to accomplish the aims for your application.

2. I am a postdoctoral fellow. Am I eligible to apply?

    A. Yes, as long as your institution allows you to serve as the PI and you meet the other eligibility criteria in Section II of the RFA.

3. Can I put senior people on as consultants or should they put some percentage of effort toward the work?

    A. Be sure to designate participants correctly and attribute any time commitments in accordance with the role each will be playing in your ability to accomplish the specific aims of the research project. This will be considered by the peer review panel (see RFA Section V.D., Review Criteria). Also see Application Contents and Forms, below.

4. What's the difference between a co-investigator and a Co-PI?

    A. A Co-PI has equal responsibility and authority for ensuring the completion of the entire project. A co-investigator is a partner in the work and is necessary to complete the work.

5. What if my Co-PI is from a different institution?

A. That is fine. Just be sure that each subcontracted institution has its own face page (Form 1), including original signatures.

6. Is it beneficial to have a collaborator from a different institution?

   A. The RFA (Section III.A.) states that collaborations are strongly encouraged. This is viewed as a benefit to advancement of the science. The location of the collaborator is not, by itself, a deciding factor (see Section V.D., Review Criteria).

7. The RFA requires that a minimum of 10% effort is required for the PI on an IDEA application and 20% for the IIRP application. Does this also apply to Co-PIs?

   A. No, only the PI has a minimum effort requirement.

8. Section II of the RFA refers to "an entity with demonstrated capability to conduct externally-funded research." What type of organization would that be and does this mean that for-profit organizations can apply?

   A. For-profit organizations are not eligible to apply under this RFA but may be subcontractors of an eligible organization. The RFA states: "The applicant must be a New York State not-for-profit organization or a governmental organization within New York State. The applicant must **also** [emphasis added] be one of the following: an academic institution; a research organization; a medical center; or an entity with demonstrated ability to conduct externally-funded research."

   "An entity with demonstrated capability to conduct externally-funded research" is meant to be a "catch-all" phrase but one such organization might be a hospital that is not a medical center.

<u>Submitting the Application</u>

1. What is the application due date and time?

   A. The application must be received by 2pm on September 10, 2009.

2. Which address listed in Section IV.E. is best to be used when submitting the application?

   A. For any mail being sent via the US Postal Service, including their Express Mail option, use the "Regular Mail Services" address. For all other carriers (FedEx, UPS, etc.) use the "Express Mail Services" address. The application **must be received** at one of the addresses

listed in Section IV.E. no later than 2pm on September 10, 2009. If sending the application on September 9, be sure to choose "morning delivery" to ensure that it arrives before 2pm.

3. What is to be submitted by the application due date?

   A. Refer to RFA Section V.A., Application Content and Format. An application package in response to this RFA must contain a CD-ROM with the required forms and any appendix material and a complete paper copy. The paper copy should include original signatures on all Face Pages (Form 1). The electronic files to be completed and included on the CD-ROM are:
      - Contractor Forms 1-5 in a single Microsoft Word (.doc) file. This version of Form 1 will not be signed. The contents will be extracted and used in various ways by NYSTEM and the peer review contractor.
      - Contractor Forms 1-5 in a single Portable Document Format (.pdf) file. This .pdf should be created from the electronic Word file of the contractor (not the subcontractors). This file will be sent to the peer reviewers.
      - Signed Forms 1 (Face Pages) for the contractor and all subcontractors in a single .pdf. These forms will be scanned into .pdf after original signatures are obtained. This file will be sent to the peer reviewers.
      - Forms 6-16 and all appendix material in a single .pdf not greater than 12MB. This file will be sent to the peer reviewers.

      Forms can be downloaded from: http://www.nyhealth.gov/funding/rfa/0903091046.

      Also see Attachment 2 of the RFA.

4. How is proprietary confidential information handled by New York State?

   A. RFA Section V.A., Application Content and Format, addresses this topic. Such information in the application must be marked by the applicant. Freedom of Information requests are generally not able to be fulfilled until after the contract is executed. All such requests are coordinated and processed by the Department in compliance with the law. In addition, staff, peer reviewers and Funding Committee members are all held to strict confidentiality requirements.

Subcontractors in the Application

1. If an application has subcontractors or collaborators that are out-of-state will that be looked at unfavorably?

   A. No, all collaborations are encouraged. Note, however, that any other institution that is getting funding needs a separate Face Page (Form 1), with original signatures.

2. Is there a limit to the percentage of work or the amount of funding that can be subcontracted to out-of-state collaborators?

   A. No such limit is specifically imposed by the RFA.

Scope and Content of the Proposed Research

1. Does this RFA support the generation of genetically modified human embryonic stem cell lines derived from an existing hES cell line?

   A. No. Please apply to RFA #0812220315.

2. If we propose to use a human embryonic stem cell line that is genetically modified from an existing line and subcloned, does this project fall under this RFA #0903091046 or RFA #0812220315?

   A. Such a proposal would be responsive to the other RFA, #0812220315.

3. Does this RFA support the generation of hESC lines from iPS cells?

   A. If what is proposed is an attempt to use iPS cells as a source for somatic cell nuclear transfer (SCNT), such a proposal would be responsive to this RFA. Otherwise, please apply to RFA #0812220315.

4. The RFA states the need for studies that derive and characterize new hESC lines. Does this mean the derivation part is essential for this RFA? For example could support be requested under this RFA to characterize panels of existing lines that may include lines that were recently derived but that are already in existence (i.e. not propose to actually derive new lines during the grant period)?

   A. Derivation of **new** human embryonic stem cell lines is at the heart of this RFA, yes. A project to characterize existing lines would fall under RFA # 0812220315.

5. Section III.A. of the RFA states that awards "will only be made to support the research projects conducting the derivation and characterization of **new** [emphasis added] hESC lines." Will it be acceptable to propose studies using stem cells isolated from humanized transgenic mice (i.e., mice containing and expressing human genes) under this RFA?

   A. No. Please respond to RFA # 0812220315 instead.

6. Is there any big change in the IDEA awards in comparison to last year?

   A. Yes, among other changes to the RFA, there is a 10% minimum effort instead of the 20% effort previously required for the IDEA award (IIRP awards still require 20% effort). The dollar amounts for IDEA awards have also changed. This year the available funds are $275,000 in direct costs to be spent over the two year period, but no single year can exceed $150,000 (see Section I.C.).

7. Does this targeted RFA mean that there's more of a priority for hESC than for iPS studies?

   A. No. The Funding Committee continues to view iPS studies as very important and expects to see many iPS applications in response to the more general RFA (FAU# 0812220315). However, there were very few hESC applications in the previous round of funding, so the Committee has targeted funds through this RFA (#0903091046) to encourage a larger number of applications in hESC than were submitted in the previous round.

8. One sub-aim of my project is not hypothesis driven, it is hypothesis-generating (a screen). Other aims are not dependent upon its success. But we could identify potentially important targets with this screen. Should I include only hypothesis driven aims in my application?

   A. There is no prohibition against mechanistic studies or non-hypothesis-driven research for an Investigator Initiated Research Project (IIRP). Relevance to the field and a conceptual framework with a coherent plan to achieve the goals are important (see Section V.D., Review Criteria).

9. The RFA states that preliminary data is not required for an IDEA application, but if I have some, is it a good idea to show it?

   A. Yes. IDEA applications do not require preliminary data, and they are not intended to fund smaller components of an IIRP project or to compress a larger project into a smaller time frame. They should be

hypothesis-driven and innovative, exploratory or developmental in nature.

10. How do I decide whether to apply for an IDEA or an IIRP award? I do have some preliminary data but little expertise in the stem cell area.

    A. See Section III.A. of the RFA (General Expectations) and apply for the type of award that best suits the project you envision. Assemble a research team that provides the expertise to accomplish the aims. See also Section V.D., Review Criteria, for specifics regarding each award mechanism.

11. How can I convince the reviewer that my application does not duplicate other work being done in my lab?

    A. Form 11 of the application identifies Other Research Support. The information from this page is used in many ways, administratively and by the peer reviewers, including an assessment of similar work.

Application Contents and Forms

1. There are two RFAs out right now; are the forms interchangeable? And what's the difference between the forms included with the RFA in the .pdf file versus those attached underneath it on the website?

   A. The forms for each RFA are different. In addition, the forms underneath the RFA on the website are fillable and should be used rather than the forms included as part of the RFA .pdf file.

2. How is an Early Stage Investigator defined?

   A. Section V.A. of the RFA defines an early stage investigator as a Principal Investigator within ten years of completing a terminal (doctoral) degree or within ten years of completing a medical residency.

3. Do I get bonus points for being an Early Stage Investigator?

   A. No, however, the applications will be grouped for peer review whenever possible. Also, the Funding Committee is interested in knowing what level of expertise exists in New York State and may use such information to assess the benefit of offering future funding/career development opportunities.

4. Does my application stand a better chance of funding if the PI is more senior?

    A. No. See Section V.C. for the review criteria for the type of funding mechanism you plan to submit. For the Investigator Initiated Research Program (IIRP), the team of investigators is scored. For the Innovative, Developmental or Exploratory Activities (IDEAs), the background and experience of the investigative team is part of the score for feasibility. Also note, the Time Line and Collaboration Strategy (Form 13) asks you to describe how the collaboration will function. This is also informative to the peer reviewers with regard to the strength of the collaboration and the operation of the team.

5. How much minutia should we get into for the Acronyms list (Form 3)?

    A. Please be as thorough as possible so that there is no misunderstanding by the peer reviewers or the critique editors with regard to an acronym or abbreviation used in the application. Some "common" acronyms are not common to all and others have different meanings in different fields and/or contexts.

6. Must we submit a biosketch for everyone we list on Form 2?

    A. A biographical sketch (Form 9) must be provided for all key personnel listed on Form 8. Form 2 is a list of all staff, collaborators, consultants and contributors that is used to identify potential members of the Independent Scientific Merit Peer Review Panel and should include mentors as well as other personnel, collaborators, etc.

7. Is the administrative assistant, clearly important to the implementation of the project, considered Key Personnel?

    A. No. Include such persons as support personnel on Form 8.

8. When assembling the section of the application that includes Form(s) 9, should we group the PI, Co-PI and then all key personnel from the same institution or should we group the PI, Co-PI and then the PIs and Co-PIs from each of the subcontractors next?

    A. See the instructions at the bottom of Form 9. Beyond these, the general grantsmanship principle is usually "which order would make most sense for the reviewers?"

9. Can we insert an NIH biosketch form instead of using Form 9?

    A. To do so would cause a penalty of .01 point (see Section V.A., Application Content).

10. Do I need to provide proof of my vertebrate animal (IACUC) protocol approval as part of the application?

    A. No. Proof of all necessary protocol approvals will be required at time of notification of award. Following receipt of those approvals, there is approximately a six month process before the contract is fully executed (also see Award and Contracting Process, below).

11. If Institutional Review Board (IRB) review is not required for my research, can I skip Form 14?

    A. No. You must check the box at the top of Form 14 and include Form 14 as part of the application. Similarly, check the box at the top of Forms 15 and 16, respectively, if vertebrate animal approvals and human stem cell approvals are not needed. Failure to complete any one or more of these forms will result in a 0.2 point penalty.

12. If my human subject research has been approved by the IRB, I don't have to answer those eight questions at the bottom, do I?

    A. Yes, you do need to answer each of those questions if IRB review is required for your research project, unless the IRB has already reviewed your project and deemed it to be "Exempt." Do similarly for research that requires review of the institutional human stem cell committee, and if your research requires institutional animal care and use committee review, complete those four questions as well. Failure to complete any one or more of these forms will result in a 0.2 point penalty.

13. In Section V.A., the instructions for Form 14 (Human Subjects) question #7 references the Food and Drug Administration (FDA). Does Investigational New Drug (IND) approval need to be obtained before the application is submitted and are these expenditures then reimbursable under the contract? And, is award of the contract contingent upon obtaining IND approval?

    A. No, IND approval does not need to be obtained prior to application submission, and no expenses related to obtaining such approval that are incurred prior to the start date of the contract will be reimbursed. The contract would be conditional upon IND approval only if the specific aims of the application require that the IND be approved prior

to the start of the work. The application should clearly address related issues in response to Form 14.

14. Form 16 references an ESCRO. What is that?

    A. The acronym stands for Embryonic Stem Cell Review and Oversight. An ESCRO committee is the institutional committee charged with the review and oversight of all human pluripotent stem cell related work. Each institution where human pluripotent stem cell work is being conducted must have one, in compliance with Appendix A-2 of the contract (a sample of which can be found in Attachment 5 to the RFA).

15. If the study involves only adult stem cells, then is there need for ESCRO approval?

    A. ESCRO approval is required for all work involving human pluripotent stem cells.

16. One sub-aim of my project is not hypothesis driven, it is hypothesis-generating (a screen). Other aims are not dependent upon its success. But we could identify potentially important targets with this screen. Should I include only hypothesis driven aims in my application?

    B. There is no prohibition against mechanistic studies or non-hypothesis-driven research for an Investigator Initiated Research Project (IIRP). Relevance to the field and a conceptual framework with a coherent plan to achieve the goals are important (see Section V.D., Review Criteria).

Revised Applications

1. How do I submit a revised iPS application in response to this RFA?

    A. You don't. You submit a revised iPS application in response to RFA #0812220315 instead. This RFA (#0903091046) is only for a very specific set of targeted projects in human embryonic stem cell research (see Section I., Introduction). No revised applications will be accepted in response to this RFA.

Budgeting

1. What are the budget caps for IDEA and IIRP applications?

A. IDEA applications are capped at $275,000 to be spent over a period of up to two years, and with no more than $150,000 being spent in any one year. IIRP applications are capped at $300,000 per year to be spent over a period of up to three years. These are direct cost figures. Additional funding for Facilities and Administrative Costs (indirect costs) is allowable (see Section V.A.).

2. Do we report percent effort or calendar months on the budget forms?

   A. Percent of Total Professional Effort is to be reported (see Form 8).

3. How much budget justification is necessary?

   A. Form 8 requires that you describe and justify all elements of the budget. Also see the instructions for completion of the form in Section V.C., Application Content and Forms.

4. What are the rules regarding equipment purchases?

   A. See Section V.A., Application Content, where instructions regarding completion of the budget (Form 7) state:
   "Requests for purchase of equipment may be granted if strongly justified as essential to the proposed project; a current price quote should be included in the application appendix. During the course of the contract term, prior approval will be required for all equipment purchases that were not detailed in the application and its appendix."

5. Would a PI with an academic year appointment be able to use 1.2 summer months (40% summer effort – equivalent to 10% of a 12 month appointment) or would they need to be 10% throughout the 12 month period (10% academic months and 10% summer months)?

   A. The percentage of professional effort is attributed across the project time period as is necessary to complete it. If the project can take place only within summer months, that would be fine. However, that is most often not the case.

6. How is the Facilities and Administrative (F&A) rate for a subcontractor calculated into the budget?

   A. The subcontractor is also held to the Modified Total Direct Cost rate established by the RFA (see instructions for Budget – Form 7 in Section V.A.). A separate Form 7 is completed for each subcontractor and the contractor. The F&A for each subcontractor is included in the Grand Total Costs on line 14 of Form 7. That figure on line 14 of the subcontractor budgets is carried over to line 11 of the contractor

budget. Thus, the F&A costs of the subcontractors are considered to be "part of" the direct costs of the contractor.

7. Section E.5. of Appendix A-2 of the sample contract provides that the compensation of oocyte donors is an allowable expense under the contract. Are their any restrictions on the amount of compensation that can be made?

   A. Yes. Payments made to oocyte donors are only an allowable expense when a woman is donating solely for research purposes (payments for the transfer of pre-existing embryos for research purposes are not permitted), the payment is limited to what is allowed by the guidelines issued by the American Society for Reproductive Medicine, and an ESCRO Committee and IRB have conducted a detailed and rigorous review of the compensation amount and procedures and determined the payments would not constitute an undue inducement to donate. The amount of compensation must not be dependent upon the number or quality of the oocytes provided for research. Researchers must also comply with all of the other requirements for informed consent and the compensation of donors set out in Appendix A-2.

8. Can we budget for travel to meetings in the budget?

   A. Yes. In fact, contractors are required to travel to and participate in at least one ESSCB-sponsored meeting or symposium during the contract period (see Section III.C., Reporting Obligations). Such meetings will be held in New York State.

9. What is the allowable fringe benefit cost rate?

   A. The fringe benefit costs are determined by the institutional insurance coverage and are not capped by New York State. However, the indirect cost rates (Facilities and Administrative costs) are capped at 20 percent.

10. What is the allowable Facilities and Administrative (F&A) rate?

    A. These costs are capped at 20% for this RFA.

<u>Peer Reviewers</u>

1. How will the peer reviewers be selected?

   A. Section V.B.1. states: "The Panel members will be selected from among non-New York State experts in the appropriate fields based on

the nature of the applications received." Peer reviewers are also screened for conflict of interest with applicant participants (see Form 2 of the application).

2. Will the peer reviewers have experience in all types of stem cell research or is there a preference toward certain areas? If we proposed cancer stem cell studies, for instance, would there be cancer stem cell scientists on the review panel?

   A. The NYSTEM program supports all kinds of stem cell related research except for activities related to human reproductive cloning. Peer reviewers will be "experts in the appropriate fields based on the nature of the applications received." See also Section I.B., Purpose of the Funds.

3. Can we provide a list of reviewers that we do not want to be assigned to review our application?

   A. No. With hundreds of applications, this would be an extremely difficult process to manage without adding considerable time to the review process. Our peer reviewers are held to a strict conflict of interest policy and the peer review contractor is very cognizant of the need to have robust and fair discussions.

4. How many applications are reviewed by each panel?

   Panels vary in size and number based upon the number of applications received and the commonalities and differences among them. For example, there were 10 panels of nine or more reviewers for the last round of peer review (roughly 420 applications).

<u>Awards and Contracting Process</u>

1. Section V.B. references a set of Pass/Fail requirements and refers to Attachment 2. How is this done?

   A. After applications are received, they are inspected for the six mandatory elements listed on Attachment 2. If any one or more of those criteria are not met, the application will not pass the preliminary review and will not be forwarded for peer review. The applicant will be notified of this determination. NOTE: For Revised applications, there are three additional mandatory elements that must be met in order for the application to be forwarded to peer review.

2. Section V.B. suggests that if we don't get a score of 3.0 or better, we have no chance of funding. Is that correct?

A. Yes. The Funding Committee has decided that it will not consider applications that score in the range of 3.1 to 5.0.

3. How is the budget scored?

   A. The peer reviewers are required to score each criterion listed in Section V.C. They will determine the score for this criterion (weighted at 20% of the overall score of the application) based upon "the appropriateness of the budget allocations to the accomplishment of the proposed internship program, including an assessment of cost reasonableness and percentage of effort." In other words, is the budget reasonable for implementation of the program as described in the application? Section V.B.1. also states "The Panel will also consider the appropriateness of the requested project duration, effort and overlap with other resources. Additionally, the Panel will evaluate and comment on the application with regard to the Contract Policy Statements and Conditions (Contract Appendix A-2)."

4. When should we expect the Funding Committee to vote on the awards?

   A. This will depend on the number of applications and the length of time it takes to complete peer review but is expected in Spring 2010. Meeting notices are sent to those who sign up for e-Alerts at http://stemcell.ny.gov/sign_up_ealerts.php and elect to receive Event Announcements. The meeting agendas are posted on the website at http://stemcell.ny.gov/events.html.

5. Please explain the Funding Committee vote and notification process. Do they have full latitude or does everything that scores 3.0 or better get funded as long as there is funding available?

   A. Following the peer review scoring process, the resulting critiques, recommendations, comments and scores are distributed to the members of the Funding Committee for consideration at an upcoming meeting. During that meeting, as described in Section V.B. of the RFA, the members will discuss the applications and make recommendations for funding to the Commissioner of Health based on "responsiveness to the mission of the ESSCB, responsiveness to the RFA, programmatic balance, availability of funds and compliance with Public Health Law Article 2, Title 5-A, Section 265." The primary factor for consideration is the peer review score. There may be many reasons for deciding not to recommend an application for funding, including but not limited to, geographic diversity of the applicants and diversity of the subject matter covered by the applicants. If the Committee does not fund an application in order to fund another with a

lower score, or stops before the designated funding runs out, it must explain the rationale to the Office of the State Comptroller. The Funding Committee recommendations are voted on during the public portion of the meeting, which can be viewed by webcast live and for approximately 30 days thereafter. Also note that they can move funds between this targeted RFA and RFA # 0812220315 if they deem it appropriate (see Section I.C., Available Funds).

6. Many of the Funding Committee members seem to be from research institutions in New York State. How is that handled during the Committee's deliberations regarding applications?

   A. The conflicts of interest of Funding Committee members are assessed similarly to those of the peer reviewers. In addition, members of the ESSCB must comply with the Public Officers' Law, which has very strict conflict of interest and confidentiality provisions.

7. How long will it take to get feedback from peer reviewers? When will an official notice of award be sent?

   A. After the Funding Committee meeting recommendations are made, several administrative approvals to enter into a contract are needed before formal communications can be sent from the Extramural Grants Administration office. These approvals generally take six to eight weeks. Upon approval, letters of award or regret will be sent to the Principal Investigator and the Grants Official from the applicant institution. With that correspondence, the PI will also receive a copy of the reviewer critiques, scores, summary statement and review panel roster. The letter of award is not a guarantee of funding; a contract must first be executed before funding is provided.

8. What happens when the Funding Committee determines an application to be "approved but not funded?"

   A. The Funding Committee has attributed an approximate amount of funding to the RFA. When that funding level has been reached, they may decide to "award but not fund" a small number of applications in the event that one or more of the awards is not accepted or cannot be finalized. In such an instance, the designation of "approved but not funded" authorizes program staff to fund the next best scoring application without further action by the Committee. Applicants to whom this applies are notified of this status as part of the award/ regrets notification process and are given an estimated date by which a "funded" determination might be made.

9. Can a PI submit essentially the same application to NYSTEM that it has submitted to the NIH and then decide later which one to accept?

    A. Yes. If the NYSTEM award is declined, this would allow staff to fund an "approved not funded" application.

10. If our application is not funded, can we resubmit it?

    A. The Funding Committee has not made a determination about whether to re-issue the RFA. If it does, the RFA will indicate whether resubmissions will be accepted.

11. What is a Vendor Responsibility Questionnaire?

    A. This is a tool used by the Department and the Office of the State Comptroller to assess the risk of entering into contract with an organization. It can be completed and updated on-line. See Section IV.I. for details.

12. Does the Vendor Responsibility Questionnaire have to be completed for each application or is it completed once for each institution?

    A. The Vendor Responsibility Questionnaire must be complete for each institution. This could be done on-line but Attachment 3 to the RFA should be completed and included in each application.

13. What can we do to facilitate contract execution?

    A. Upon receipt of the letter of award, PIs should gather "just in time" information including any required IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) and ESCRO (human pluripotent stem cell) approvals; and Grants Offices should complete/update the Vendor Responsibility Questionnaire (see Section IV.I.) and get the Workers' Compensation and Disability Insurance forms (see Section IV.K. of the RFA) ready for submission/return with the signed contract. Then, when the contract is sent to the institution for signature, it can expeditiously return all necessary documents to the Department of Health with the signed contract.

14. When will we actually receive the funds?

    A. Funds under the contract are reimbursed in accordance with the payment and reporting schedule (See RFA Attachment 5, Appendix C to the contract for a sample). The contract must be executed (signed by all required parties and returned to the applicant institution) in order for allowable expenditures to be reimbursed. Contract execution

generally takes six months from the date of the notice of award. The contract start date will be noted on the letter of award; it is expected to be September 1, 2010. Eligible expenses incurred prior to contract execution are made at the applicant's risk. If the contract is not executed, no funds will be reimbursed.

15. If my institution provides funds to my lab before the contract start date and I have all my protocol approvals (vertebrate animals, etc.), can I start my project?

    A. Yes, if your institution allows – but the institution cannot be reimbursed for expenditures prior to the contract start date.

16. Can we count on receipt of the funds in this fiscal/economic environment? Under what circumstances might we not receive them?

    A. Once the contract is executed, eligible expenses will be reimbursed according to the terms of the contract. For purposes of program stability and demonstration of fiscal accountability, it is important that quarterly vouchers and semi-annual progress reports are submitted in a timely fashion. If the contract is terminated in accordance with Section III of the contract (See Attachment 5 for a sample contract), expenses incurred beyond the date of termination will not be reimbursed.

17. Are "no cost extensions," "carry-forwards" and budget modifications allowed and are they treated in the same way as the NIH?

    A. They are allowable under the contract but are treated very differently from an NIH grant. Each must be formally requested and none are guaranteed. A formal contract amendment process, which is both lengthy and time-consuming, is generally necessary. Careful budgeting in the application should reduce the need for contract amendments.

<u>Learning from Previous Funding Decisions</u>

1. My last critique listed reviewers A through P, but not scores from each of them, and comments from two. Are the scores of the panel members equally weighted or are the primary and secondary reviewers scores weighted more heavily?

    A. The scores of all panel members are weighted equally and scoring is not done until after panel discussion. Although only the primary and secondary reviewers provide written critiques for each criterion, they

are generally reflective of the entire panel discussion. The Critique Summary is written to reflect the entire panel's views. Notably, Reviewer A and Reviewer B in the list of scores are not necessarily the primary and secondary reviewers for the application as identified in the subsequent text of the critique.

2. What was the funding success rate for the last targeted (iPS) and more general RFAs?

   A. For the targeted (iPS) RFA, the success rate was roughly 49% (20 funded of 41 applications received) and for the more general RFA, the rate was 24%. However, those were larger amounts of funding than are being offered in this round of RFAs.

3. How many awards were given in each area of research?

   A. That data is currently being assimilated for the annual report, which will be published on the website at http://stemcell.ny.gov. What is notable is that the Funding Committee did not select awards based on area of research but based on the quality of the applications as evidenced by peer review score.

4. What was the average size of each award?

   A. The average size of the IDEA awards was very close to the maximum, and the average size of the IIRP awards was slightly lower than maximum.

5. How many IDEA awards were given last year and is that an indication of the percentage that will be awarded in this round?

   A. More than 30 of the 78 were IDEA awards. This in no way suggests that a similar percentage will be awarded in this round. It is purely a function of the number of high quality IDEA and IIRP applications that were received relative to the amount of funding that was available.

Post-Award

1. If a contract is awarded but during the year, the PI is no longer at the institution, can an alternative PI from that institution take over the award?

   A. Most often, if the PI is transferring to another New York State institution, and if the awarded institution and the new institution agree, the contract can be assigned to the new institution. This process takes approximately six months to complete. If the PI is transferring out of

state or there is no agreement reached between the current and new institution regarding the assignment, the contract can be retained by the current institution under the direction of another PI designated by the institution, provided that NYSTEM agrees that the new PI has the proper experience, training and resources to complete the work as described in the contract work plan. Otherwise, the contract is terminated. NOTE: this is a much longer and more cumbersome process if the PI transfers to a new institution before the contract is executed.

2. What kind of reporting is required?

   A. Semi-annual progress reports are required. Progress report forms and instructions will be available on the website.

General

1. Based on your experience, what have been the major mistakes made by applicants?

   A. Common mistakes have included: failure to submit the Letter of Intent with both required signatures; submission of a DVD instead of CD-ROM; submission of a blank CD-ROM; failure to complete the forms as directed (especially human subjects, vertebrate animals and human embryonic stem cell forms); failure to appropriately justify the budget; failure to meet the minimum required percent of effort; and failure to check the final Questions, Answers and Modifications to the RFA that are posted to the Department website.

2. How many contracts does each contract manager oversee?

   A. The contract managers are currently working with approximately 150 stem cell contracts.

3. Is there a list of the funded projects?

   A. Information about funded projects is available at: http://stemcell.ny.gov/research_support_grants_awards.html. Following contract execution, the title and abstract of each award is expected to be posted there as well.

4. Regarding grantees conferences. How large are they, do only funded investigators get to attend, how will information about these be shared?

A. Each conference is likely to be a bit different in terms of scope, attendance and size and advertised on the website and through e-Alert notifications and direct communications with contractors.

MODIFICATIONS TO FAU # 0903091046

Section V.B.1. Review and Scoring Process

The table should read as follows:

Numerical	Adjectival
1.0 – 1.5	Outstanding
1.6 – 2.0	Excellent
2.1 – 2.5	Very Good
2.6 – 3.0	Good
3.1 – 5.0	Fair