Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research RFA
FAU # 0912180242

QUESTIONS AND ANSWERS
August 31 – November 14, 2011
Including an applicant conference

Letter of Intent and Pre-application

1. When is the Letter of Intent due?

   A. The Letter of Intent form (Attachment 4) is not mandatory but is **strongly recommended** and will assist in developing the peer review panels. Letters of Intent should be received by the due date (November 9, 2011 by 6pm). See Section IV.C. of the RFA.

2. Do we need to include any information (e.g., the title of the proposed project) in addition to the Letter of Intent form?

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

3. Who should we list on the Letter of Intent form?

   A. Identify all participants involved in the proposed project, 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. Sections may be added, if necessary, to list all participants.

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

   A. Yes.

5. 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; applicants are not held to this mechanism.

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

   A. Letters of Intent are not mandatory, but are strongly encouraged even for a revised application.

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

    A. The application number will be assigned via e-mail to the PI after the application deadline has passed.

8. Is there a fillable version of the Letter of Intent form (Attachment 4 to the RFA)?

    A. A Word document file was posted to the internet on October 25, 2011 at: http://www.health.ny.gov/funding/rfa/0912180242/ .

9. What is the purpose of the applicant conference? Do I have to attend if I plan to submit an application?

    A. The applicant conference is described in Section IV.D of the RFA. It is an opportunity to receive an overview of the RFA and ask specific questions that might facilitate completion of the application forms or the competitiveness of the application itself. There are no scientific presentations; the first part is a presentation about the RFA and the program, and the remainder is an opportunity to ask questions and listen to the answers given to the questions of others. Generally, members of the NYSTEM scientific staff and the Extramural Grants Administration staff are both present. Attendees can learn a lot about the program that will help with application and management of contract awards. Prospective applicants do not have to attend in order to apply but it is recommended.

Eligibility

10. Can I apply for both an IDEA and an IIRP award?

    A. Yes, as long as they are separate projects.

11. Can I be a PI on one application and a Co-PI on a different application?

    A. Yes, as long as they are separate projects.

12. I am a small business owner. Can my company apply for funding under this RFA?

    A. No, not directly. Eligible institutions are not-for-profit or governmental organizations in New York States and the PI is employed by the applicant institution. A for-profit organization may be a subcontractor in collaboration with an eligible organization. The NYSTEM website provides information about New York State stem cell researchers with whom collaborations might be forged.

13. I am a postdoctoral fellow. Am I eligible to apply or do I have to be tenured?

    A. Postdoctoral fellows are not eligible to apply, although there is no requirement regarding tenure. The RFA states, “staff whose positions are dependent upon the status of another researcher are not eligible to apply.” In other words, if the individual does not have independent status granted by their own institution, which gives them the ability to seek external funding, commits designated laboratory space and access to shared/core facilities to that individual for studies that are separate from and in addition to those of the PI’s whose grants on which they are paid by,

then they are considered “dependent” for purposes of this RFA and are not eligible to apply.

14. Is NYSTEM research done in other states or only in New York State?

    A. Applicants for funding to the NYSTEM program must be New York State institutions. However, those institutions are permitted to subcontract with collaborators world-wide.

15. What is the difference between the Investigator Initiated Research Projects and the Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research?

    A. Available Funds (Paragraph I.C.) and General Expectations (Paragraph III.A.) address the major differences between these two funding mechanisms. The four major differences are: length of time; annual direct cost limits; requirements for preliminary data; and absolute requirement for a hypothesis-driven application for IDEA awards. See also Questions 34-35.

16. Are projects that study cancer stem cells eligible for funding?

    A. Yes.

PIs, Co-PIs, Co-Investigators and Collaborators

17. 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.

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

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

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

    A. No. See Section VI.D. 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 separately. 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 14) 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.

20. Do I get bonus points for collaborations?

    A. No. See Section VI.D. 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 14) 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.

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

    A. A Co-PI is designated by the PI as an individual who has equal responsibility and authority for ensuring the completion of the entire project. A co-investigator may be responsible for a specific component of the research project.

22. 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-S), including original signatures.

23. Is joint Co-PI leadership from the same institution allowed?

    A. No. One individual from the applicant institution must be designated as the PI. If one or more Co-PIs are also designated, those individuals may or may not be from the applicant institution. For definitions of the terms "PI, Co-PI and Co-I" please see instructions for the completion of the Applicant Face Page (Form 1).

24. 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. There is no minimum percentage of professional effort required of Co-PIs or Co-Is.

25. The required effort for the Investigator Initiated proposal is 20% and the IDEA 10%. Can this be shared effort between Co-PI's (e.g., 10% and 10%; 5% and 5%, respectively)?

    A. No. The single designated PI must maintain the required minimum percent effort throughout the contract term.

26. In an application that includes Co-PIs, is a leadership plan required?

    A. No. However, a Time Line and Collaboration Strategy (Form 14) is required as part of each application regardless of PI and Co-PI designations.

Submitting the Application

27. What is the application due date and time?

    A. The application must be received by 6pm on December 1, 2011.

28. 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 or DVD with the required forms and any appendix material, and should contain a complete paper copy. The paper copy should include original signatures on all Face Pages (Form 1 and 1-S). Forms can be downloaded from: http://www.nyhealth.gov/funding/rfa/0912180242.

    Also see Attachment 2 of the RFA.

Subcontractors in the Application

29. 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 limit is specifically imposed by the RFA.

30. Are subcontractors limited to the 20% indirect cost rate?

    A. Yes. The RFA states "Sub-applicant F&A costs are likewise limited and are included in the primary applicant's direct costs."

31. Are we required to provide a copy of the subcontract, or the subcontract indirect cost rate, as part of our application or at any time after award?

    A. The application is not required to contain a copy of a subcontract or documentation of the subcontract indirect cost rate. After award, contractors will be required to enter into subcontracts that meet the conditions of the contract and to monitor those subcontractors for compliance.

Scope and Content of the Proposed Research

32. Our laboratory was previously awarded an IDEA contract. Is it permissible to use that data to explore a different angle of that research via an IIRP application?

    A. Yes. If it is a continuation of the same research, it would be considered a Continuation Application. If it is a new direction, it would be considered a new application (see instructions for completing the Applicant Face Page – Form 1, in Section V of the RFA). However, a previously funded IDEA award cannot be continued as an IDEA award.

33. 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 VI.D., Review Criteria).

34. 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.

35. Is preliminary data required for an IIRP application? Does it have to be hypothesis-driven?

    A. Preliminary data is required for an IIRP application but the application does not need to be hypothesis-driven.

36. 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 VI.D., Review Criteria, for specifics regarding each award mechanism.

37. 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 overlap in aims and similar work.

38. Do I get bonus points, or is there a preference, for human embryonic stem cell research, a certain use of stem cells, clinical work, etc.?

    A. No. The unique thing about this RFA is that all of types of projects are eligible. Historically, the emphasis of the Funding Committee has been on funding the best science. However, Section VI.E. they are able to "consider 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."

<u>Application Content and Forms</u>

39. Can an investigator request a later contract start date to avoid a time commitment conflict?

    A. No. The estimated contract start date is predetermined by NYSTEM.

40. There are several 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 listed underneath it on the website?

    A. The forms for each RFA are different. Failure to use the correct application forms and instructions for the RFA will result in a scoring penalty. Please note that the forms listed below the RFA on the website are fillable and should be used rather than the forms included as part of the RFA PDF file.

41. My application will include unpublished data that may be patentable. Will the NYSTEM application constitute public disclosure for purposes of patent filings and if so, at what point?

    A. You should consult with your institutional officials regarding the interpretation of patent law and what constitutes public disclosure. However, it may be useful to note that the entire application is held confidential and cannot be requested under the Freedom of Information Law (FOIL) until such time as the contracts are executed.

42. How do I exempt my application from disclosure under the Freedom of Information Law (FOIL)?

    A. Marking the whole application submission as "confidential" or "proprietary" is not sufficient because there are several forms that contain publicly-available data. However, it may be acceptable to mark specific sections of the Workplan (Form 13) where unpublished data are present. Note, however, that the entire application package is considered confidential and proprietary and is not able to be requested under FOIL until such time as the contract is executed. So, if the contracts are executed on time, you might project that you have until shortly before December 1, 2012 (the expected start date of the contract) before the content of your application might be released.

    A cover letter to explain the rationale for protecting specifically identified text (e.g., paragraph 2 on page 7 of Form 13) is advisable in addition to marking the actual text in some way. It is important that the electronic version be marked as well as the paper copy. Applicants should use their best judgment about how to mark the text in a way that won't distract the reviewers from understanding the proposed project.

43. On Form 1, what is the New York State Vendor ID Number and where do I get one?

    A. Effective January 1, 2012, in order to do business with New York State, you must have a vendor identification number. As part of the Statewide Financial System (SFS), the Office of the State Comptroller's Bureau of State Expenditures has created a centralized vendor repository called the New York State Vendor File. In the event of an award and in order to initiate a contract with the New York State Department of Health, vendors must be registered in the New York State Vendor File and have a valid New York State Vendor ID.

    If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State

Comptroller Substitute Form W-9, which can be found on-line at: http://www.osc.state.ny.us/vendors/substitute_formw9.pdf .

Additional information concerning the New York State Vendor File can be obtained on-line at: http://www.osc.state.ny.us/vendor_management/index.htm, by contacting the SFS Help Desk at 855-233-8363 or 518-475-7717 or by emailing at helpdesk@sfs.ny.gov.

44. On Form 1, how can I be sure whether I should check "Yes" or "No" for use of human pluripotent stem cells?

    A. Based on the specifics of your experimental design and methods, if an ESCRO review will be required, check "Yes" on Form 1. Also see instructions for the completion of Form 17. Note: NYSTEM contracts require ESCRO review of research involving all human totipotent and pluripotent cells, including hESCs, hiPSCs, and human neural and gonadal progenitor cells. Refer to Appendix A-2, Section E, page 74 for further information.

45. When using Form 1-S for an out-of-state sub-applicant, does the sub-applicant need a Charities Registration number?

    A. On Form 1-S, this field may be left blank only if the sub-applicant is from out-of-state.

46. On Form 2, how do I classify the stem cell expert who has agreed to collaborate on my project at no salary (i.e., consultant, collaborator, advisor)?

    A. Classification is often based on the functions of the individual, not on the salary. Consult with your grants office as to how they would classify such an individual based on the specific activities that expert will be relied upon to provide during the contract term.

47. How much detail should we include in the Scientific and Lay Abstracts?

    A. The Lay Abstract (Form 4) is limited to 300 words, should not contain any confidential data, and should follow the instructions on the form itself and within the RFA (see Section V). The Scientific Abstract (form 5) is limited to one page, and should follow the instructions on the form itself and within the RFA (see Section V).

48. What is the maximum number of words allowed for the Scientific Abstract (Form 5)?

    A. The Scientific Abstract combined with the information requested on the form about the source of any human pluripotent stem cell lines cannot exceed one page.

49. Form 3 (Acronyms and Abbreviations) is not long enough to enter all the abbreviations we use in our application. What do you recommend?

    A. The audiences for this list include: (1) the peer review panel whose members are generally knowledgeable in the fields addressed by the panel to which your application is assigned, and (2) the scientist editors who are not necessarily well-versed in your particular field and are responsible for making sure the critiques don't include typographical and other errors. It is recommended that the PI use best

judgment in creating the list given these audiences. In addition, it is customary upon its first use to state the full meaning of the acronym or full word of the abbreviation in the text, with the acronym or abbreviation included in parentheses after it, and then to revert to use of the acronym or abbreviation thereafter.

50. Are the fonts and margins the same limits used by the NIH?

    A. Applicants should use the Microsoft Word forms posted to the website along with the RFA. The fonts and margins are preset.

51. What is included in the page limit for Form 13 - Workplan?

    A. The application instructions in the RFA stipulate that the page limits include Sections A-D (Specific Aims, Significance, Background and Preliminary Results, and Research Design and Methods). Section E, Literature Cited, is not included in the page limits.

52. 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 and must be in place, for any activities that are expected to take place in Year One, at time of award. Delays in submitting protocol approvals to NYSTEM will cause additional delay in contract execution (also see Award and Contracting Process, below).

53. If Institutional Review Board (IRB) review is not required for my research, can I skip Form 15?

    A. No. You must check the box at the top of Form 15 and include Form 15 as part of the application. Similarly, check the box at the top of Forms 16 and 17, 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 scoring penalty. Subcontractors must also complete these forms.

54. If my human subject research has been approved by the IRB, I don't have to answer those eight questions at the bottom of Form 15, 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." The same is true for research that requires review of the institutional human stem cell (ESCRO) committee. Also, if your research requires review by the institutional animal care and use committee (IACUC), complete the four questions at the bottom of that form. Failure to complete any one or more of these forms will result in a 0.2 point penalty.

55. Form 17 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 with NYSTEM funds must have such a committee, in compliance with Appendix A-2 of the contract (a sample of which can be found in Attachment 5 to the RFA).

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

    A. Possibly. ESCRO approval is required for all work involving human pluripotent stem cells, neuronal and gonadal progenitor stem cells. Refer to Appendix A-2, Section E, page 74 for types or research requiring ESCRO review.

57. If my application is not a resubmission, or does not include human subjects, for example, can I omit those forms from my application submission?

    A. No. The application instructions require that each form be submitted. Form 12 – Revisions and Comments would be marked "not applicable" and Forms 15-17 require completion of the first "box" on each page. In addition, each applicant and sub-applicant must submit Forms 15-17.

58. What is a NYS DOH Animal Care and Use Certificate Number (referenced on Form 16)?

    A. Your Institutional Animal Care and Use Committee or Veterinary staff should have this number on file. Each laboratory animal facility in New York State is required to have one. An out-of-state sub-applicant could leave this field blank or insert "N/A."

59. Can I submit the same aims to another funder? And if so, how do I indicate the potential overlap in my application?

    A. Yes. Form 11 – Other Support is where you would report this information for active and pending applications.

60. Can I split-fund a project, where NYSTEM would fund part of the project and NIH another part?

    A. No. It is not possible to "split-fund" a grant project with a NYSTEM contract. The NYSTEM application is reviewed as one complete project.

<u>Revised Applications</u>

61. I submitted an application two years ago in response to an RFA with the same title as this one. Can I submit a revised application in response to this new RFA?

    A. Yes. A revised application is defined in Section V of the RFA as one that includes research aims that were submitted by the same PI in response to a NYSTEM RFA and reviewed during a previous cycle, but not funded. Instructions and requirements for submitting a revised application are found in Section V of the RFA, instructions for Form 12.

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

    A. Instructions for submitting a revised application are found in Section V. Revised applications **must** have the same PI. Also see instructions for Forms 1 and 12, as well as Attachment 2 to the RFA.

63. How much detail can be relegated to the response to the past critique?

    A. Form 12, Revisions and Comments, is limited to two pages.

64. Will my revised application be reviewed by the same people who reviewed my first submission?

    A. Not necessarily. Independent peer review panel members are selected separately for each round of funding and may not be the same as in prior reviews. Also see "Peer Reviewers," below.

65. Will I get bonus points for submitting a revised application?

    A. No.

Continuation Applications

66. I am just finishing up an IDEA application. Can I apply for a continuation of that project as an IIRP?

    A. Yes. A previously funded IDEA award can be continued through an IIRP application and an IIRP award can be continued through a subsequent IIRP application. However, a previously funded IDEA award cannot be continued as an IDEA award. Also see question and answer #32, above.

67. Will I get bonus points for submitting a continuation application?

    A. No.

Budgeting

68. 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).

69. Can we pay for graduate students and others on the project budget?

    A. Yes. Staff your project appropriate to what you will need to complete the proposed project.

70. Are there salary limits for PIs, postdocs or graduate students?

    A. No such limits are required by the RFA. Consistent application of institutional policy regarding payment is required (see instructions for Budget – Form 7).

71. How do I list/classify a stem cell expert who has agreed to collaborate with me at no cost?

    A. Consult with your grants office as to how they would classify such an individual based on the specific activities that expert will be relied upon to provide during the contract term. Classification is often based on the functions of the individual, not on the salary.

72. How much budget justification is necessary? And is it required only for the Year One budget?

    A. Justify the budget lines for each year. The instructions for completion of the Personal Effort and Budget Justification – Form 8 state "For each budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered…"

73. Is foreign travel permitted in the budget?

    A. Yes. Be sure to justify each trip fully.

74. The RFA stipulates that patient care is not an allowable expense. If we were, for example, to do a bone marrow punch on a series of patients as part of our research aims, is that considered patient care or would it be allowable?

    A. The bone marrow punches would be allowable because they are part of the research aims. The RFA limitation on patient care pertains to the following type of circumstance: during the course of working with a patient as part of the research project, that patient is diagnosed with a condition or disease; NYSTEM funds cannot be used to treat it.

75. 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 the subcontractor's 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.

76. The indirect costs are 20% of the modified total direct costs. Does this mean that indirect costs do not apply (i.e., are 0%) for budget allocated to equipment over $5,000?

    A. No. The RFA defines F&A costs as follows: "F&A support is limited to a maximum of 20 percent of modified total direct costs. Modified total direct costs consist of all salaries and wages, fringe benefits, materials and supplies, services, travel, and subgrants and subcontracts up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships and fellowships, as well as the portion of each subgrant and

subcontract in excess of $25,000 shall be excluded from modified total direct costs…"

Generally, equipment is defined as "having a useful life of more than one year and costing more than $5,000." But each institution may have a different definition that needs to be followed. It is recommended that you consult with your office of sponsored programs on the budget.

77. 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.

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

    A. Yes, with sufficient justification. Also note that contractors are required to travel to and participate in any ESSCB-sponsored annual or other meeting during the contract period (see Section III.C., Reporting Obligations). Such meetings will be held in New York State.

<u>Peer Reviewers</u>

79. How will the peer reviewers be selected?

    A. Section V.C.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).

80. 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 very strict conflict of interest, bias and confidentiality standards by the peer review contractor.

81. Are peer reviewers from New York State excluded from serving, as in past RFAs?

    A. Yes.

Awards and Contracting Process

82. Section VI.A. 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 mandatory elements listed on Attachment 2. If any one or more of those criteria are not met, the application will not pass this administrative review and will not be forwarded for peer review. The applicant will be notified of this determination. NOTE: For Revised applications, there is an additional mandatory element that must be met in order for the application to be forwarded to peer review (see Attachment 2 to the RFA).

83. How is the budget scored?

    A. The peer reviewers are required to score each criterion listed in Section VI.D. They will determine the score for this criterion (weighted at 20% of the overall score of the application). Section VI.D. also states "The Review Panel will also consider the appropriateness of the requested project duration and percent effort, and identify potential overlap with other resources."

84. 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 May 2012. 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.

85. Please explain the Funding Committee vote and notification process. Do they have full latitude or does everything that scores 2.5 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 VI.E. 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 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 worse 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.

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

    A. Critiques, without scores, will be sent to applicants following the Funding Committee meeting where recommendations for award are made. Several administrative approvals are needed before formal communications and critiques with scores can be sent from the Extramural Grants Administration office. These approvals generally take six to eight weeks. Upon receipt of those approvals, 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.

87. 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.

88. Can a PI submit essentially the same application to NYSTEM that it has submitted to the NIH (or the New York State Breast Cancer Research and Education program) 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.

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

    A. A determination about when to re-issue the RFA has not been made. The future RFA will indicate whether resubmissions will be accepted.

90. What can we do to facilitate contract execution?

    A. Upon receipt of the letter of award, PIs should gather documentation including any required IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) and ESCRO (human pluripotent stem cell) approvals. At the same time, 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.) ready for submission/return with the signed contract. Then, the institution can sign and expeditiously return all necessary documents to the Department of Health.

91. 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 December 1, 2012. Expenses incurred prior to the contract start date are ineligible and will not be reimbursed. Eligible expenses incurred after the contract start date and prior to contract execution are made at the applicant's risk. If the contract is not executed, no funds will be reimbursed.

92. 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.

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

    A. Funding is always dependent upon budget process. We expect appropriations to be sufficient but if that is not the case, the Department will notify the contractor to renegotiate the contract.

94. 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 in advance of the need 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>

95. What is the expected success rate for IDEA and IIRP applications submitted in response to this RFA?

    A. Historic data shows that in the two earlier times this RFA was offered, roughly 25% of the applications for both funding mechanisms received recommendations for funding. However, the total dollar amount of funds set aside for each round has been reduced substantially (from $53.4 million to $35 million to $25 million in the current round).

96. Are there data on success rates by panels/areas of research from those previous rounds of funding?

    A. Not at this time. The emphasis of the Funding Committee has historically been to fund the most meritorious research.

Post-Award

97. 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. If the PI is transferring to another New York State institution, and if the awarded institution, the new institution and NYSTEM 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.

98. What kind of progress reporting is required?

    A. Written progress reports are required. NYSTEM has attempted to reduce the reporting burden. See Appendix C of the sample contract provided as Attachment 5 to the RFA for the reporting schedule. Progress report forms and instructions are available on the website.

99. If I have explained in my application workplan that I anticipate a problem and that if it occurs, I will have to pursue an alternative way of accomplishing the aim, will I need to request that change in advance?

    A. No. The progress report should reflect this alternative approach. However, if that change also requires a budget modification, it must be requested in advance.

100. Can I take off in a new direction on the same topic if things don't go as I planned?

    A. No. A change in aims that have not yet been peer reviewed and approved cannot be approved. A divergence based on the scientific progress may be allowed but must be reviewed and approved by NYSTEM in advance.

There are no modifications to this RFA.