**Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research RFA**
**RFA# 1206180230**

**QUESTIONS AND ANSWERS AND MODIFICATIONS**
**April 16 – June 13, 2013**
**Including an applicant conference**

Letter of Intent and Pre-application

1. I missed the due date for the Letter of Intent. Will my application be accepted? Should I still submit a Letter of Intent form?

   A. Yes the application will be accepted. It would be very helpful to submit a Letter of Intent form, even after the deadline.

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. 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.

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

   A. Yes please. Letters of Intent are not mandatory, but are strongly encouraged.

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

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

7. Is there a fillable version of the Letter of Intent form (Attachment 3 to the RFA)?

   A. Yes, a Word document file was posted to the internet on May 16, 2013 at: http://www.health.ny.gov/funding/rfa/1206180230. See "Attachment 3: Letter of Intent."

8. Can the title of the application and/or the list of collaborators that was submitted in the Letter of Intent be changed at time of application?

   A. Yes.

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 and improve the competitiveness of the planned application. The first part is a presentation about the RFA 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 and you do not submit more than one of each type. Section II of the RFA states: "If a PI submits more than one application for an IDEA award and/or more than one application for an IIRP award, all applications from the PI for that funding mechanism will be disqualified and will not be forwarded to peer review."

11. I am affiliated with two institutions. Can I submit an IDEA application from one institution and an IIRP from another?

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

12. Can I be a PI on one application and a Co-PI or collaborator on one or more different applications?

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

13. Can you please describe the rationale for the new requirement that limits the number of applications a PI can submit in response to each funding mechanism?

    A. The Funding Committee instituted this requirement as one means by which to enable the funds to be distributed widely among investigators in New York State. In addition, the Committee has significant latitude when making award recommendations. It can consider responsiveness to the mission of the Empire State Stem Cell Board, responsiveness to the RFA, programmatic balance (which can include such things as areas of scientific investigation or geographical distribution of funds), and availability of funds.

14. 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 State. 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.

15. 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) on whose grants they are paid, then they are considered "dependent" for purposes of this RFA and are not eligible to apply. Also see # 30 below.

16. 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.

17. 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 major differences are: length of time; annual direct cost limits; and requirements for preliminary data. See also # 42-50.

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

    A. Yes.

<u>PIs, Co-PIs, Co-Investigators and Collaborators</u>

19. How is an Early Stage Investigator defined?

    A. Section V 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.

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

    A. No, however, the applications from Early Stage Investigators 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. Historically, less experienced and early stage investigators have done as well as more senior investigators in terms of score, awards and funding. The Funding Committee does have the ability to consider early stage investigator status when making funding decisions, particularly in tie-breaker situations. Also see Evaluation Criteria in Section VI.D.

21. 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. The background and experience of the investigative team is part of the score for Approach and Feasibility. Also note, the Time Line and Collaboration Strategy (Form 15) asks you to describe how the collaboration will function. Form 15 is informative to the peer reviewers with regard to the strength of the collaboration and the operation of the team. In addition, the Budget Justification (Form 9) is used to evaluate the appropriateness of the roles of each member of the investigative team.

22. Do I get bonus points for collaborations?

    A. No.

23. What is the difference between a collaborator and a subcontractor?

    A. Often the words are used interchangeably, such as on our Letter of Intent form. In other cases, a collaborator is considered to be unpaid. A subcontractor is always paid.

24. 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.

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

    A. That is okay. Just be sure that each subcontracted institution has its own face page (Form 1-S), including original signatures, and its own Forms 16-18.

26. Can a Co-PI, paid collaborator or subcontractor be from out of state?

    A. Yes. There is no limitation on payment to an out of state subcontractor or collaborator. The limitation is that the PI and the applicant organization must be in New York State.

27. Does the lead on every subcontract have to be designated a Co-PI?

    A. No.

28. Can collaborators in my application already be holding NYSTEM awards?

    A. Yes.

29. Is joint Co-PI leadership allowed?

    A. No, not in the sense of the NIH-accepted multi-PI awards. For NYSTEM, 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 and Co-PI" please see instructions for the completion of the Applicant Face Page (Form 1).

30. Can a dependent staff member serve as Co-PI under the oversight of the independent PI, thereby allowing the Co-PI to manage the project?

    A. No. A Co-PI has equal responsibility and authority for ensuring completion of the entire project. If the Co-PI does not have independent status (her own laboratory, etc. as described in # 15 above), then by definition, s/he is not able to serve as PI or Co-PI. The applicant institution is responsible for assuring that this eligibility requirement is met prior to submission of the application.

31. The RFA stipulates 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, Co-Is or collaborators, but the peer review panel will take commitment of effort by all staff into consideration when reviewing the application.

32. 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.

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

    A. No. However, a Time Line and Collaboration Strategy (Form 15) is required as part of each application regardless of PI and Co-PI designations.

34. If several groups from my institution choose to use the same collaborator on multiple applications, will that hurt the applications' chances of getting funded?

    A. That should not impact the peer review score unless that person appears to be "spread too thin" to be effective. All participants must be well-justified as required for the successful completion of the project.

35. Will a collaborator that commits little or no effort to the project be seen as a strong collaborator or would it be better to have them contribute effort?

A. Percentage of effort and the level of participation of collaborators should be determined by their role/contributions to the project, and will be taken into consideration by the peer review panel.

Submitting the Application

36. What is the application due date and time?

    A. The application must be received by 5pm on July 30, 2013.

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

    A. Refer to RFA Sections IV.E and V. An application package in response to this RFA must contain a CD or DVD of the entire application and supporting documents using the required forms. It should also contain a complete paper copy. Forms can be downloaded from: http://www.health.ny.gov/funding/rfa/1206180230.

    Also see Attachment 1 of the RFA.

38. When we create the PDF, would you prefer that we scan in the paper copy or use conversion software?

    A. Please use the conversion software. This can result in a significant improvement in "readability" of the document when compared to a scanned copy.

Subcontractors in the Application

39. 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.

40. 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."

41. 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 provide copies of subcontracts for NYSTEM review and approval prior to execution and to monitor subcontractors for compliance.

Scope and Content of the Proposed Research

42. 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.

43. 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 non-hypothesis-driven research. Relevance to the field and a conceptual framework with a coherent plan to achieve the goals are important (see Section VI.D., Review Criteria).

44. 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, but preliminary data may help establish the feasibility of the approach. However, IDEA awards 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 innovative, exploratory or developmental in nature.

45. 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.

46. In an IDEA application that is mostly exploratory, what sort of tangible results are you expecting to see? Are you expecting to see translational goals?

    A. It depends upon the project. Some will have distinct outcomes like a new method, others will have data that supports or disproves a hypothesis.

47. 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.

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

A. Form 12 of the application identifies Other Research Support. The information from this page is used in many ways, including an assessment of overlap in aims and similar work. Peer reviewers and NYSTEM staff may identify potential overlap. Concerns will be addressed after award decisions are made.

49. 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. states the Funding Committee is 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."

50. Is there a preference for clinical research versus basic or translational research?

    A. No. Historically, the Funding Committee has funded all types of research in fairly equal percentages relative to the types of applications received.

Application Content and Forms

51. Can an investigator request a later contract start date?

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

52. 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.

53. 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.

54. 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 is acceptable to mark specific sections of the Workplan (Form 14) 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.

An explanation of the rationale for protecting specifically identified text is advisable in addition to marking the actual text. 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.

55. 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.

56. I don't' seem to be able to format the page numbers in the footers. What am I doing wrong?

    A. You are not using the most recent forms set for Forms 7-18 that was posted to the internet on June 12, 2013. **Modified** forms and Amendment 3 can be downloaded from: http://www.health.ny.gov/funding/rfa/1206180230.

57. Do the signatures on Form 1 and Form 1-S need to be original signatures?

    A. Yes. The paper copy original signatures should be scanned and saved as PDF files for the digital submission.

58. 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.

59. 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.

60. 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 provide during the contract term.

61. Should we include the names of all administrative staff on Form 2?

    A. Yes, if they are to be paid as a direct cost under the contract.

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

    A. It is unnecessary to enter ALL abbreviations; common abbreviations such as hESC may be omitted. 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.

63. 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).

64. 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.

65. Form 7, the Table of Contents, indicates that Form 6 is not required but elsewhere the RFA says Form 6 may be left blank. Can we exclude Form 6?

    A. Form 6 cannot be excluded or omitted from the application. It may be left blank. Form 6 is protected in digital format and cannot be deleted from the form set. Form 7 has been **modified** to reflect this clarification.

66. When I type in the PI and institution names at the top of Form 7, it goes to two pages. Is this acceptable?

    A. Yes.

67. Can Form 7 be more than one page long?

    A. Yes. You may add rows for subcontractor budgets and justifications or appendix material that can force a second page for the Table of Contents.

68. Are postdocs, technicians and graduate students included in the definition of Key Personnel?

    A. Not necessarily. Key Personnel are defined as individuals who contribute in a substantive, measurable way to the scientific development or execution of a project, whether or not salaries are requested. Forms 10 and 12 must be provided for each person listed as Key Personnel on Form 9. Throughout the contract term, replacement of Key Personnel requires advanced permission from NYSTEM. Generally, postdocs, technicians and graduate students are not considered key personnel, as they often have skill sets that are replaceable within a short period of time.

69. What was changed on Form 12 in Amendment #1 to the RFA?

    A. The instructions for completion and the format of Form 12 have been **modified** because the original posting of Forms 7 – 18 did not allow it to be duplicated for multiple entries of Other Support.

70. What is included in the page limit for Form 14 - 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.

71. I have a subcontractor but I cannot duplicate Forms 16-18 for them like I can duplicate some of the other forms for them. What should I do?

    A. Download the Amendments 1 - 3, and the current form set for Forms 7 – 18 from http://www.health.ny.gov/funding/rfa/1206180230.

72. How many Forms 16, 17 and 18 are we required to submit in our application?

    A. Submit a Form 16 for your organization and a separate Form 16 for each subcontractor organization. Also submit as many forms as necessary to cover all the research protocols that will be required for completion of the project. The same is true for Forms 17 and 18. By way of example, if you have one subcontractor, your application will have two Form 16s, two Form 17s and two Form 18s. If your subcontractor has two human subjects protocols, your application will have three Form 16s, two Form 17s and two Form 18s.

73. 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 delays in contract execution (also see Award and Contracting Process, below).

74. If Institutional Review Board (IRB) review is not required for my research, can I skip Form 16?

    A. No. You must complete and submit this form. The same is true for Forms 17 and 18. See Section V for instructions.

75. 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 16, 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 0.1 penalty and may impact the peer review score.

76. Which individuals on our application are required to complete Forms 10 and 12?

    A. All Key Personnel named on all Form 9s (those for the applicant and all sub-applicants) are required to complete both Forms 10 and 12.

77. Form 18 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).

78. 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 for types or research requiring ESCRO review.

79. 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, with the possible exception of Form 1-S.

80. 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 12 – Other Support is where you would report this information for active and pending applications. Also see # 48 above.

81. 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. When resolving potential overlap, note that the NYSTEM award must be accepted as a whole; parts of it may not be supported by another funder.

Revised/Resubmitted Applications

82. 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 "Resubmission" application is defined in Section V of the RFA as one that includes proposed research that was reviewed by NYSTEM during a previous cycle, but was not funded and is being resubmitted for new consideration. Instructions and requirements for submitting a revised application are found in Section V of the RFA, instructions for Form 13.

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

    A. Form 13, Introduction, is limited to one page.

84. Can I attach a letter that discusses the critiques from the last peer review and outlines the revisions made to this submission?

    A. No. Responses to past critiques must appear on Form 13.

85. 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.

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

    A. No.

87. Do I have to submit it as a Resubmission or can I submit it as New?

    A. You are free to decide if you'd like to submit it as New or a Resubmission - the application instructions include specifics for a Resubmission and require completion of Form 13.

Continuation Applications

88. 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.

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

    A. No.

Budgeting

90. What are the dollar limits for IDEA and IIRP applications?

    A. Annual direct costs for IDEA applications are capped at $150,000 with a maximum of $275,000 in direct costs to be spent over the two-year period. Annual direct costs for IIRP applications are capped at $300,000. Indirect costs (F&A) are capped at 20% of Modified Total Direct Costs.

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

    A. Percent of Total Professional Effort is to be reported (see Form 9).

92. 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.

93. Under what circumstances would administrative staff be included in the budget?

    A. If the application is funded and their work will be billed as a direct cost to the contract, they should appear in the budget.

94. Can we list To Be Named positions in the budget?

    A. Yes. Each position needs to be fully justified.

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

    A. Yes, the salary limit for PIs is $199,700. All other staff must be paid according to organizational policy and applied consistently (see instructions for Budget – Form 8).

96. 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.

97. 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 9 state "For each budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered…"

98. Is it permissible to budget travel funds for meetings?

A. Yes, with sufficient justification. Please note that all travel that is not requested and justified in the application budget will require advance approval from NYSTEM if an award is made. Also note that contractors are required to travel to and participate in any NYSTEM-sponsored annual or other meeting during the contract period (see Section III.C., Reporting Obligations). Such meetings will be held in New York State.

99. Is foreign travel permitted in the budget?

A. Foreign travel is not specifically prohibited. Be sure to identify and justify each trip fully. Any travel outside the state of New York that is not requested and justified in the application budget will require advance approval from NYSTEM if an award is made.

100. 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 and not part of otherwise necessary patient care. NYSTEM will reimburse expenses that are incurred as a direct result of the individual's participation in the research study. Ineligible patient care costs are those that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for "usual patient care".

101. 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 8 in Section V). A separate Form 8 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 8. 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.

102. 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. F&A costs will not be paid for equipment. However, please note that the final contract will define property as "real property, equipment, or tangible personal property having a useful life of more than one year and an acquisition cost of **$1,000** or more per unit." If your institution has a more strict definition, it will be followed. It is recommended that you consult with your office of sponsored programs on the budget.

103. 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 there 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.

<u>Peer Review</u>

104. How will the peer reviewers be selected?

    A. Section VI.B states: "The Review 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).

105. 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.

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

    A. Yes.

107. After application submission, is there an opportunity to provide updates to peer reviewers such as recent publications?

    A. Not after the application deadline is passed.

108. Historically, what percentage of the applications does not get forwarded to the Funding Committee for consideration due to scoring below the threshold of 4.0 (or as in past rounds of funding, 2.5)?

    A. In the most recent round of funding for IDEA and IIRP awards, 22% of the applications did not score a 2.5 or better. This is an improvement over previous rounds.

Awards and Contracting Process

109. Section VI.A. references a set of Pass/Fail requirements and refers to Attachment 1. How is this done?

    A. After applications are received, they are inspected for the mandatory elements listed on Attachment 1 (Application Check List). 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.

110. 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) in relation to a "gold standard" budget, which would rate a 1.

111. 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 December 2013. Meeting notices are sent to those who sign up for e-Alerts at: http://stemcell.ny.gov/node/318 and elect to receive Event Announcements. The meeting agendas are posted on the website at: http://stemcell.ny.gov/meetings.

112. Please explain the Funding Committee vote and notification process. Do they have full latitude or does everything that scores 4.0 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 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, but there is no obligation to award all available funds.

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.

113. 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.

114. 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 "approve 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.

115. Is it possible that there will be so many applications from one institution that the Funding Committee may decide not to fund, or to approve but not fund, some or all of the applications?

    A. It is possible, but is not likely based on historical data. However, there is a provision in the legislation that limits the percentage of funds that can be provided to an institution from the RFA. So far, that has not been an issue in the consideration of awards.

116. If I submit both an IDEA and an IIRP, is it more likely that one will be funded than the other?

    A. The RFA expressly permits one award of each if they both score well enough. Historically, the success rates for IIRPs and IDEAs have been the same, without adjustments by the Funding Committee.

117. If my three-year application scores well but close to the end of the available funding and there's not quite enough money left, can the Funding Committee award a smaller amount of funding?

A. No. Historically, that kind of application could be "approved not funded," but the Funding Committee does not have the discretion to fund a portion of an award or adjust the budget without specific instructions from the peer review panel.

118. 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 if both are approved for funding?

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

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

A. Yes, when a future RFA is issued, a resubmission application will be accepted.

120. 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 the Updated Other Support and Certifications (see Section III.C), complete/update the Vendor Responsibility Questionnaire (see Section IV.J) and get the Workers' Compensation and Disability Insurance forms (see Section IV.L) ready for submission/return with the signed contract. Then, the institution can sign and expeditiously return all necessary documents to the Department of Health.

121. Do we have to have all our institutional information (Workers' Compensation forms, etc.) in the Vault before we submit the application?

A. No, but you should complete the on-line Pre-qualification process before submitting the application. The Grants Reform team has sent information about this to your institutional officials.

122. 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 approved by the Office of the State Comptroller) 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 June 1, 2014. Expenses incurred prior to the contract start date are ineligible and will not be reimbursed. If the contract is not executed, no funds will be reimbursed.

123. 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.

124. 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.

125. 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 often necessary. Careful budgeting in the application should reduce the need for contract amendments.

Learning from Previous Rounds of Funding

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

    A. In the last round of funding for these mechanisms, roughly 10% of the applications received recommendations for funding. The total dollar amount of funds set aside for this round is the same ($25 million).

127. How can I find out the reasons for the penalties applied to my application so that I don't make the same mistakes the next time?

    A. Contact Extramural Grants Administration at nystemgrants@wadsworth.org or 518-474-7002 within 10 business days after you receive your critiques with scores (this is the official de-briefing period).

Post-Award

128. Will my subcontractor also have to provide Vendor Responsibility information, Workers' Compensation forms, etc.?

    A. It depends on a variety of factors. The details of those requirements are outlined in the new Master Grant Contract that can be found on the Grants Reform website at www.GrantsReform.ny.gov.

129. 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. Contracts are written between NYS DOH and the institution, so one of three scenarios could occur:
        i. 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.

ii. 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.
iii. The contract is terminated.

130. What kind of progress reporting is required?

A. Written progress reports are required. NYSTEM has attempted to reduce the reporting burden by eliminating the first 6 month progress report and requiring semi-annual progress reports one month before that quarter's vouchers are due. 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.

131. 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, the budget modification must be requested in advance.

132. 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 been peer reviewed cannot be approved by NYSTEM. A divergence based on the scientific progress may be allowed but must be reviewed and approved by NYSTEM in advance.

**See Modifications to the RFA below**

## Modifications to this RFA.

### Amendment #1 – 5/6/13

Changed the instructions for completion of Form 12. The form set for Forms 7-18 was reposted to correct the format of Form 12. This change allows portions of Form 12 to be copied and pasted for additional entries of Other Support.

### Amendment #2 – 6/10/13

Changed the instructions for completion of Section A of Forms 16 – 18. The form set for Forms 7-18 was reposted to correct the format of these forms. This change allows Forms 16 – 18 to be copied and pasted for additional submissions by applicants and sub-applicants regarding research protocol approvals for use of human subjects, vertebrate animals and human stem cells. At the same time, a minor correction to formatting was made to Form 7 that expanded the data entry box for the PI and applicant institution name.

### Amendment #3 – 6/12/13

Reposted the form set for Forms 7-18 to afford the ability to modify the page numbers on these forms for inclusion in the application and proper completion of the Table of Contents, and to clarify that Form 6 may be left blank but must be submitted.