Empire State Stem Cell Scholars: Fellow-to-Faculty Awards in Stem Cell Research RFA
FAU # 0901051121

QUESTIONS AND ANSWERS and MODIFICATIONS
8/27/09 – 10/5/09
Including two applicant conferences

Letter of Intent and Pre-application Materials

1. Must applicants attend the Applicant Conference?

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

2. When is the Letter of Intent due?

   A. The Letter of Intent form (Attachment 4) is due September 25, 2009 by 2pm. See Section IV.C. of the RFA.

3. Letters of Intent are strongly encouraged but not required, why is it different this time?

   A. Early in the NYSTEM program, mandatory Letters of Intent were used to determine the maximum number of applications that would be submitted as a means to initiate planning of peer review logistics and shorten the timeline from application submission to award recommendation. While Letters of Intent are no longer mandated, the limited information they do provide does help to speed up the process. An application may be submitted even if a Letter of Intent was not.

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

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

5. On the Letter of Intent form, do we need to include all internal collaborators (staff from our institution that will help to design and/or operate the facility) or is this for primary contacts at our collaborating institutions and subcontractors?

A. Identify all participants involved in the application, 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.

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

   A. Yes.

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

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

8. Are Letters of Intent from one RFA able to be used for another RFA?

   A. No. The Letter of Intent is specific to the RFA. The heading at the top of the form indicates the RFA name and FAU# for easy identification.

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

   A. An application number will be assigned and sent to the PI prior to peer review.

10. Would it be helpful to submit the Letter of Intent even if I missed the deadline?

    A. It would be very helpful.

Eligibility

1. No more than two applications are permitted from an institution in response to this RFA. If you receive more Letters of Intent from the same institution when would you expect to identify this problem and notify the institution of the problem?

   A. It would be our goal to identify the issue and notify the institution as soon as possible. However, staffing shortages may preclude notification shortly after the deadline for the Letter of Intent.

2. How would the receipt of more than two applications from an institution be handled?

   A. The institutional official would be contacted and asked to determine which applications should be considered.

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

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

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

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

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

5. Are there restrictions on citizenship?

    A. No. The applicant must meet the eligibility criteria stated in Section II.

6. If we are planning to hire a postdoctoral fellow from another state, would they be eligible?

    A. Yes. As long as they meet the other eligibility criteria.

7. If we hire a postdoctoral fellow as an independent researcher, can they apply for the independent phase under this RFA?

    A. No. The fellow must expect to remain in fellowship training status for at least an additional six months. The need for additional mentorship experience and the time for transition are pivotal to eligibility for this award.

8. Am I correct that the applicant PI is the fellow?

    A. Yes. Section II states that for the purposes of this application and award, the postdoctoral fellow will be considered the PI.

Submitting the Application

1. Do I need institutional clearance to submit an application in response to this RFA?

   A. Those clearances would be an institutional requirement. Check with your grants office.

2. What is the application due date and time?

   A. The application must be received by 4pm on December 1, 2009.

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

   A. For any mail being sent via the US Postal Service, including its Express Mail option, use the “Regular Mail Services” address. For all other carriers (FedEx, UPS, etc.) use the “Express Mail Services” address. The application **must be received** at one of the addresses listed in Section IV.E. no later than 4pm on December 1, 2009. If sending the application on November 30, be sure to choose “morning delivery” to ensure that it arrives before 4pm.

4. Can applications be hand-delivered?

   A. Yes. They must be received by staff from the Extramural Grants Administration office by 4pm on December 1, 2009.

5. 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 a complete paper copy. The paper copy should include original signatures on all Face Pages (Form 1). The electronic files to be completed and included on the CD or DVD are:
      - Contractor Forms 1-5 in a single Microsoft Word (.doc) file. This version of Form 1 will not be signed. The contents will be extracted and used in various ways by NYSTEM and the peer review contractor.
      - Contractor Forms 1-5 in a single Portable Document Format (.pdf) file. This .pdf should be created from the electronic Word file of the contractor (not the subcontractors). This file will be sent to the peer reviewers.
      - Signed Forms 1 (Face Pages) for the contractor and all subcontractors in a single .pdf. The applicant will obtain original

signatures, scan the paper forms and save/print the file as a .pdf. This file will be sent to the peer reviewers.

- Forms 6-17 and all appendix material in a single .pdf not greater than 12MB. This file will be sent to the peer reviewers.

Forms can be downloaded from: http://www.nyhealth.gov/funding/rfa/0901051121.

Also see Attachment 2 of the RFA and Modifications, pages 22-24 of this document.

6. What is the electronic submission process?

   A. There is not an electronic submission process. The applicant must submit a CD or DVD with electronic files and a complete paper copy via mail, courier or hand delivery.

Application Contents and Forms

1. There are two RFAs out right now – are the forms interchangeable?

   A. No, the forms for each RFA are different.

2. What's the difference between the forms included with the RFA in the .pdf file and those attached underneath it on the web site?

   A. The forms posted underneath the RFA on the web site are fillable and should be used to ensure compliance with the submission requirements (see Section V.A., Application Content and Format). In addition, the fillable forms are formatted to be more user-friendly for the applicant.

3. Do I have to complete my application forms using Microsoft Word?

   A. No. However, one of the required submission formats is Microsoft Word (see Section V.A., Application Content and Format) and the copy/paste effort from other formats to Word is often difficult and more time-consuming than using Word from the beginning. Until NYSTEM and the Department can support other means of electronic submission, use of Microsoft Word and .pdf are the best options available.

4. Is there a required font and/or font size?

   A. The default set for the forms is Arial and is generally set to 11-12 point on most forms. Section V.A. states that "applications should be single spaced and typed using an 11-12 point font. Smaller font sizes are acceptable for use in tables and figure legends."

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

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

6. Form 2 asks for all staff, collaborators and contributors to the project/application. Must we submit a biosketch for everyone we list on Form 2?

   A. No. Form 2 is a list of all staff, collaborators, consultants and contributors associated with the application that is used to identify potential members of the Independent Scientific Merit Peer Review Panel. A biographical sketch (Form 9) must be provided for all key personnel listed on Form 8.

7. Is the abstract limited to 300 words or to one page?

   A. It is limited to 300 words. Notably, one constraint of this fillable Word form is that there is no ability to restrict the fillable section to contain only 300 words. Thus, the applicant must be careful to be thorough but concise and to count the number of words in the abstract to avoid a penalty (see Section V.A., Application Content and Format regarding this and other penalties).

8. Formatting headers and footers in these Microsoft Word forms can be particularly challenging. Is there a penalty for inaccuracies in them?

   A. If this is the only compliance penalty issue noted in the application (see Section V.A., Application Content and Format), no penalty will be assessed. Note, however, that properly completed headers and footers are intended to be assistive to the peer reviewers in the evaluation of the application.

9. Can you explain the definitions of Key Personnel and Support Personnel (Form 8)?

   A. These definitions closely mirror those used by the National Institutes of Health:

"Senior/key personnel are defined as individuals who contribute to the scientific development or execution of a project in a substantive measurable way. The program director/principal investigator (PD/PI) is always considered senior/key personnel. The PD/PI may designate other senior/key personnel if they fit the definition. Biosketches, other support information, and level of effort greater than zero percent professional effort are all required of senior/key personnel named in the application.

Other significant contributors are those that are committed to contribute to the project, but without measurable effort (zero person months or "as needed"). Biosketches of other significant contributors are required; however, other support information is not.

A consultant is defined as an individual hired to give professional advice or services for a fee. Generally, a consultant is not considered senior/key personnel. The application should describe the services to be performed by the consultant(s) in the budget justification and include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each. In those cases where a consultant may actually meet the definition of senior/key personnel, the applicant should list them as such and include the appropriate biosketch and other support information."

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

    A. To do so would cause a penalty of .01 point (see Section V.A., Application Content and Format, regarding this and other penalties).

11. When completing the Work Plan (Form 12), for the mentored phase of the award, we provide a detailed research plan to carry us through the mentored phase of the award. What do we include on Form 12 for the independent phase?

    A. The instructions for Form 12 (Section V.A., Application Content and Format) state that the Work Plan should clearly identify a reasonable and well-thought investigative path that has the potential to carry the PI through the independent phase of the award. So, while the research described in the Work Plan for the independent phase of the award need not be fully detailed, it should be evident to reviewers that the PI's overall goals and scope for this investigative path are sufficient to support an independent research career (i.e., specific enough for the mentored phase and open-ended enough to launch a research career). Section III.C., Reporting Obligations, and Attachment 1 to Appendix C of the Sample Contract provided as Attachment 5 provide further detail regarding preparations for the independent phase, which include submission of a fully detailed research plan and budget for the independent phase at that time.

12. How many pages of Form 12 should be devoted to the mentored phase, would a list of milestones be enough for the independent phase?

    A. That is up to the applicant and might depend on the intended length of the mentored phase. A longer mentored period may require a more lengthy research plan.

13. Is there a requirement for preliminary data?

    A. Yes, see section C of the Work Plan.

14. Does the 10 page limit for the Work Plan include references?

    A. No. The 10 page limit applies to sections A through D of the Work Plan. Literature citations are included in section E.

15. Does the bibliography have a page limit?

    A. No. There is no page limit for section E of the Work Plan.

16. The instructions for Form 13 regarding submission of various letters suggests that some letters may be included in the application appendices but some can be mailed separately to NYSTEM. Which is preferred?

    A. The Mentor's Letter and Institutional Support should be included in the application appendix material. Letters of Reference can be mailed, e-mailed or faxed directly to NYSTEM and must be received by 4pm on December 1, 2009 (see Modifications, pages 22-24 of this document). Late letters will not be forwarded to peer review.

17. When completing Form 16, where would we find the DOH Animal Care & Use Certificate Number and the USDA Registration Number?

    A. Your institutional animal care and use committee chairperson and/or the facility veterinarian should have this information.

18. If animal models, human subjects or human pluripotent cells won't be used during the mentored phase, do I need to complete the associated forms (Forms 15-17)?

    A. If the mentored phase does not require use of these models, subjects or cells, only the check box at the top of the form would need to be

19. Can we amend our IRB, IACUC and ESCRO protocols throughout the contract term?

    A. Yes. Documentation of the amended protocol approval would be forwarded to the assigned NYSTEM contract manager.

20. Questions on technical issues like filling out forms will be taken up to application deadline, correct?

    A. Yes. Applicants are encouraged to contact Bonnie Jo Brautigam at 518-474-7002 or nystemgrants@wadsworth.org with any questions about the application process, filling out forms, etc. so that compliance penalties (see Section V.A., Application Content and Format, regarding penalties) and administrative disqualifications for failure to include mandatory items in the submission (see Attachment 2 Modifications, pages 22-24 of this document). Ms. Brautigam will provide as much assistance as is permissible under state procurement procedures.

Selecting a Mentor

1. Can I choose co-mentors from different institutions?

    A. Yes but your primary mentor must be from the applicant institution.

2. Can I change my mentor after award?

    A. It would be best to carefully select a primary mentor prior to application. Changing the primary mentor during the award period would be extremely difficult since 25 percent of the peer review score is based on the mentor and environment and there is no mechanism to return the application with a new mentor back to peer review during the contract term.

3. If I have a team of mentors and want to change one, is that possible?

    A. Yes, but it is best to establish and not change the primary mentor for the length of the mentored phase of the award.

Budgeting

1. Is there a maximum allowable cost per year?

   A. Yes. The cap for the mentored phase is $100,000 in direct costs plus a maximum of eight percent modified total direct costs. A maximum of two years is available for the mentored phase. For the independent phase, the annual direct costs are limited to $250,000 plus a maximum of 15 percent modified total direct costs.

2. How much budget justification is necessary? Is there an example on the web site that we can follow?

   A. Form 8 requires applicants to describe and fully justify all elements of the budget, including personnel roles, responsibilities and percent of professional effort committed to the application. See the instructions for completion of the form in Section V.A., Application Content and Format. There is no example, as each budget will be dependent upon the scope and content of the research proposal.

3. Can other staff (i.e., graduate student, technicians) be supported on this award?

   A. Yes, these are allowable expenses if they are well-justified.

4. What are the rules regarding equipment purchases?

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

5. During the contract, what budget modifications are permitted?

   A. Budget modifications that result in a change of 10 percent or more require approval of the Office of the State Comptroller. This process can take several months. Therefore, it is advisable to plan the application budget carefully, and during the term of the contract, to plan ahead and contact the assigned contract manager as soon as possible to discuss the situation.

6. What is the minimum percent professional effort for each phase of the award?

   A. During both phases of the award, the PI must maintain a minimum of 75 percent professional effort. During the independent phase, if other sources of funding are obtained, the PI may request a reduction to not less than 50 percent professional effort for the remainder of the contract (see Section III.A., General Expectations).

7. What is the matching funds requirement?

   A. For the mentored phase, the mentor's salary is not supported by the award and the PI must be paid stipends, etc. that "adhere to NIH guidelines for postdoctoral fellows and be consistent with both the established salary structure for equivalent qualifications…" (see Section V.A., Application Content and Format, Budget Form 7 instructions). For the independent phase, the hiring institution must provide a start-up package of at least $400,000 in addition to salary (see Section III.A., General Expectations and Section III.B. Use of Funds).

8. Is the letter of institutional commitment a good place to address the $400,000 start-up plus salary commitment?

   A. Yes, it could be addressed here if the applicant institution will be the hiring institution at time of transition to the independent phase. At the time of transition to independence the hiring institution will be required to document such support (see Attachment 1 to Appendix C of the Sample Contract included as RFA Attachment 5).

9. The RFA indicates that approximately $5.4 million is set aside for these awards. Is there a possibility that this amount would be increased?

   A. The Funding Committee of the Empire State Stem Cell Board does have some flexibility to allocate more funds to an RFA.

10. How is the budget scored?

   A. The peer reviewers are required to score each criterion listed in Section V.C. They will determine the score for this criterion (weighted at 20 percent of the overall score of the application) based upon the appropriateness of the budget allocations to the accomplishment of the proposed internship program, including an assessment of cost reasonableness and cost effectiveness. In other words, is the budget reasonable for implementation of the program as described in the application? Section V.B.1. also states "The Panel will also consider

11. Is it possible that the Funding Committee will decide to fund applications at amounts lower than requested so that additional applications can be supported?

    A. Yes. The review criteria require that the budget be scored by the peer review panel. The budget score represents 20 percent of the overall score. The Funding Committee does consider recommendations of the review panel with regard to budget, so it is possible that the Committee would award a lesser amount than was requested by the applicant. If the Committee were to recommend further budget reductions, it is likely that these would need to be justified by the Committee in writing.

12. Can you give us guidance on funding? Should we request the maximum amount, or are more, smaller awards likely to get funded?

    A. The amount requested should be appropriate, reasonable and sufficient to support the research project (see Section V.C., Review Criteria).

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

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

14. Would a PI with an academic year appointment be able to use more effort in the summer months and less in the academic months or would it need to be 75 percent throughout the 12 month period?

    A. The percentage of professional effort should be attributed evenly across the project time period, or 75 percent throughout the 12 month period.

15. 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 entered 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.

16. Should the budget include costs for travel to meetings?

    A. Yes, this is expected. Contractors are required to travel to and participate in at least one ESSCB-sponsored meeting or symposium during the contract period (see Section III.C., Reporting Obligations). Such meetings will be held at various locations throughout New York State. Costs for attendance at these and other meetings will be considered by the peer reviewers as part of the budget score (see Section V.C., Review Criteria).

17. What is the allowable fringe benefit cost rate?

    A. The fringe benefit costs are determined by the institutional insurance coverage and are not capped by New York State. However, the indirect cost rates (Facilities and Administrative costs) are capped at eight percent during the mentored phase and 15 percent during the independent phase.

18. If the postdoc finishes the mentored phase earlier than anticipated, would funds be available to be carried forward into the independent phase?

    A. No, funds cannot be carried forward from the mentored phase to the independent phase.

Peer Reviewers

1. 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).

2. Will the peer reviewers have experience in all types of stem cell research?

    A. Section V.B. states that peer reviewers will be “experts in the appropriate fields based on the nature of the applications received.” See also Section I.B., Purpose of the Funds.

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

   A. No. This would be an extremely difficult process to manage without adding considerable time to the review process. Our peer reviewers are held to a strict conflict of interest policy. Further, the peer review contractor and panel chairpersons are very cognizant of the need to promote and ensure robust and fair discussions.

4. How many applications are reviewed by each panel?

   A. Panels vary in size and number based upon the number of applications received and the commonalities and differences among them.

5. How many applications are assigned to each panel member, and is there one primary reviewer for each application?

   A. As a general rule of thumb, reviewers are assigned as a primary or secondary reviewer on no more than six applications. However, all panelists are responsible for being familiar with each application on which they do not have a conflict of interest and for participating in the discussion and scoring of those applications. Each application has two to three reviewers, one of whom is the primary reviewer.

6. Do the peer reviewers meet in Albany?

   A. No, none of the peer reviewers are from New York State, so a meeting in Albany would not provide a cost savings to the program.

<u>Awards and Contracting Process</u>

1. When is the Funding Committee expected to review the critiques and make award recommendations?

   A. This will depend on the number of applications received and the length of time it takes to complete the peer review process but is expected in Spring 2010. Applicants are encouraged to sign up for e-Alerts at http://stemcell.ny.gov/sign_up_ealerts.php and elect to receive RFA/RFP Announcements, Event Announcements and Award Announcements, then to check the agenda and attend the meeting or listen to the webcast live or via web archives for the next thirty days. Doing so will indicate whether the Funding Committee has voted to recommend the application for funding. It may be several weeks before staff will be permitted to provide any information about the status of applications.

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

   A. After applications are received, they are inspected for the mandatory elements listed on Attachment 2 (also see Modifications, pages 22-24 of this document). If any one or more of those criteria are not met, the application will not pass the preliminary review and will not be forwarded for peer review. The applicant will be notified of this determination.

3. Section V.B. suggests that if we don't get a score of 2.0 or better, we have no chance of funding. Is that correct?

   A. Yes. The Funding Committee decided that it will not consider applications that score in the range of 2.1 to 5.0.

4. Please explain the Funding Committee vote and notification process. Do they have full latitude or does everything that scores 2.0 or better get funded as long as there is funding available?

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

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

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

6. How long will it take to get feedback from peer reviewers?

   A. Critiques (without scores), summary statements and panel rosters will be sent to the PI shortly after the Funding Committee recommendations are made to the Commissioner.

7. When will an official notice of award be sent?

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

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

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

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

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

10. If my application is not funded, can I resubmit it?

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

11. What are the odds of the contract not being executed after the Funding Committee makes its award recommendations? What's the risk?

    A. There is always some risk, since the execution process requires the verification of several administrative, procedural and legal requirements before the final signatures can be affixed to the contract. Some examples of issues that might preclude contract execution include the institution: is debarred from doing business with New York State; doesn't have current worker's compensation or disability insurance; or has audit-violations. In general, the authority to enter into a contract (availability of funds, procurement rules followed, etc.) is obtained prior to the applicant receiving an official notification of award. However, there is no guarantee of funding until the contract is fully executed by the Office of the State Comptroller.

12. Is spending prior to contract execution and/or award notification permissible?

    A. If the institution allows the PI to work "at risk" prior to contract execution but on or after the contract start date, those allowable expenses would be eligible for reimbursement after the contract is executed. Under no circumstances can expenditures be reimbursed if they were incurred prior to the contract start date. For these awards, the contract start date is anticipated to be November 1, 2010 as noted on the RFA cover page.

13. What is a Vendor Responsibility Questionnaire?

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

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

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

15. When does the Vendor Responsibility Questionnaire need to be submitted?

    A. There is a Vendor Responsibility Attestation (Attachment 3) that is to be completed and submitted with the application. In addition, for those institutions that are not exempt from filing, a current questionnaire should be updated on-line at the time the contract is submitted to the Department for signature, or submitted with the signed contract (see Section IV.I.). The contract cannot be forwarded for additional signatures and execution until the Department is able to review a current questionnaire and determine that the vendor is responsible. The Department strongly encourages the on-line submission since the questionnaire needs to be kept current throughout the contract period.

16. What can we do to facilitate contract execution?

    A. Upon receipt of the letter of award, PIs should gather, and submit to the assigned contract manager, any required protocol approvals from IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) and/or ESCRO (human pluripotent stem cell) committees. Simultaneously, Grants Offices should complete/update the Vendor Responsibility Questionnaire (see Section IV.I.) and get the Workers' Compensation and Disability Insurance forms (see Section IV.K. of the RFA) ready for submission/return with the signed contract.

17. 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 November 1, 2010. Eligible expenses incurred prior to contract execution are made at the applicant's risk. If the contract is not executed, no funds will be reimbursed.

18. 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.

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

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

20. 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 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. Carry-forwards are not allowed between the mentored and independent phases of the award.

<u>Post-Award</u>

1. What kind of reporting is required?

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

2. Can I transfer my award, during either the mentored phase or the independent phase, out of state or to a for-profit institution?

    A. No.

3. Can I accept a research position that is not a full-time tenure-track position and take my independent phase award with me?

    A. No. You may accept a full-time position that is equivalent to a tenure-track position but is not in a tenure environment only if it is a full-time independent research position.

4. Can I accept a full-time independent research position at the same institution where I am completing the mentored phase and continue the independent phase of the award there?

A. Yes, as long as the position is tenure-track or equivalent.

5. If the applicant PI leaves the institution before the contract is executed, during the mentored phase, or for some other reason is no longer a postdoctoral fellow with the applicant institution, what happens?

   A. The contract/award would be cancelled. No other PI can be substituted by the applicant institution.

6. What happens if the PI must go on medical or other leave?

   A. The applicant institution should notify the assigned contract manager as soon as possible to determine what actions might be appropriate. Such decisions would be made on a case-by-case basis and might be influenced by factors such as the phase of the award and the expected length of the leave.

General

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

   A. Common mistakes have included: submission of a blank or incomplete CD; failure to complete the forms as directed (especially human subjects, vertebrate animals and human embryonic stem cell forms); failure to appropriately justify the budget; failure to meet the minimum required percent of effort, where applicable; and failure to check the final Questions, Answers and Modifications to the RFA that are posted to the Department web site.

2. How many contracts does each contract manager oversee?

   A. Currently, two contract managers are responsible for approximately 150 stem cell contracts. The program is seeking additional staff to manage the workload. The contract managers are assisted in some facets of their work by the NYSTEM scientific officers.

3. Is there a list of the funded projects?

   A. At this time, limited information about funded projects is available at: http://stemcell.ny.gov/research_support_grants_awards.html. Following contract execution, the title and abstract of each award is expected to be posted there as well. For information regarding researchers in New York State conducting stem cell related research, see http://stemcell.ny.gov/publications.html.

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

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

MODIFICATIONS TO FAU # 0901051121

Cover page, Applications Due, now reads: December 1, 2009 by 4:00 pm

Section V.A. Completing the Application, Application Content and Format now reads:

ALL APPLICATIONS SHOULD USE THE FORMS (see Attachment 1 – Forms 1-17) AND FORMATS PRESCRIBED IN THIS SECTION V.A. APPLICATIONS THAT DEVIATE FROM THESE INSTRUCTIONS OR THOSE FOUND ON THE FORMS WILL BE PENALIZED 0.1 POINTS.

Applications must be submitted in hard copy and electronic formats as described in this section. The paper copy will be used if the CD or DVD is damaged. Applications will ONLY be accepted in the formats detailed in this section. Applications sent in other formats or by fax or e-mail will NOT be accepted.

Electronic files must be submitted on a CD or DVD. The CD or DVD should be clearly labeled with the applicant's name and FAU number. The CD or DVD should contain:

- Contractor Forms 1 – 5 in a single Microsoft Word (.doc) file;
- Contractor Forms 1 – 5 in a single Portable Document Format (.pdf) file;
- Forms 6 – 17 and all appendix material in a single .pdf file of not greater than 12MB;
- Signed Forms 1 (Face Pages for the Contractor and all Subcontractors) in a single .pdf file; and
- Subcontractor Forms 1 (Face Pages for each Subcontractor) each in separate .doc file.

Instructions for the Mentor's Letter and Institutional Support now reads

Mentor's Letter and Institutional Support

The Mentor must provide a letter of support for the PI's application. The letter should be signed by the mentor and an institutional official (e.g., Dean or Provost) with the authority to ensure protected time for the minimum professional effort required. The letter must be incorporated to the appendix material for the application and should include:

- information regarding the accomplishments of the mentor(s) in training and mentorship of successful independent investigators
- an evaluation of the PI's ability to succeed as an independent investigator
- a demonstrated commitment to training, mentorship and career development of the PI

- identification of financial resources to cover the costs of the proposed research project and career development plan that are in excess of the allowable costs under this award
- assurance that the applicant will continue to maintain the minimum 75% professional effort available to devote to the proposed research as required by the RFA

Letters of Reference

The PI must arrange to have **at least three (but no more than five)** additional letters of reference, in addition to the Mentor's letter of support, submitted on his/her behalf as outlined in Section IV.C. or IV.E, above. The letters must be received by the application due date and time listed on the cover of this RFA.

The letters should be from well-established scientists addressing the qualities of the PI as well as his/her potential for becoming an independent investigator. At least two of the three required letters should be from individuals not involved in the application, but who are familiar with the PI's qualifications, training, and interests.

Applications for which at least three letters of reference are not received by the due date and time will not be reviewed. In the event that more than five letters are received by the due date and time, the first five received will be forwarded for review.

Attachment 2, Application Checklist, now reads

ATTACHMENT 2
APPLICATION CHECKLIST
Empire State Stem Cell Scholar:
Fellow-to-Faculty Awards in Stem Cell Research

All items are mandatory with the exception of those listed under "Appendices." Applications that do not include mandatory items will not be reviewed.

- ☐ Application was submitted by due date and time
- ☐ The institution is a New York State not-for-profit organization or a governmental organization within New York State that is an academic institution, a research organization, a medical center, or an entity with demonstrated capability to conduct externally- funded research
- ☐ The applicant investigator holds a doctoral degree and is conducting research relevant to stem cells and has no more than 3 years cumulative postdoctoral research training experience at the time of application.
- ☐ The applicant investigator is employed as a postdoctoral fellow by the applicant institution.
- ☐ One electronic (on CD or DVD) and one original paper copy of the application
- ☐ Professional effort of the Principal Investigator on the project is at least 75% throughout the contract term. See Form 8, 'Percent FTE', 'On Project' column.
- ☐ The Mentor's letter of support is included in the Appendix.
- ☐ Three to five other letters of support are received by the due date and time via e-mail, fax or mail.

Other appendices may include:

- ☐ Vendor Responsibility Attestation (Attachment 3)
- ☐ Any required documentation relating to the use of test subjects (human or animal) and human stem cells as described in the instructions to the application forms.
- ☐ Completed Vendor Responsibility Questionnaire
- ☐ Letters of collaboration or support; commitment(s) to provide research resources; subcontract letter(s) from consultant(s)
- ☐ Memoranda of Understanding, Subcontracts or Contractual Agreements
- ☐ Up to two highly relevant publications or manuscripts (published or in press) may be included if essential to document the investigator's capability to undertake the work proposed
- ☐ Facilities and Administrative rate agreements
- ☐ Equipment quotes
- ☐ Other