Shared Facilities for Stem Cell Research RFA
FAU # 0812260816

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

   A. No.

8. 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.

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

   A. Yes. A new application number will be assigned.

10. 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.

11. 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.

12. How many applications do you expect to receive in response to this RFA?

    A. As of September 25, we received approximately 12 Letters of Intent. However, since Letters of Intent are not mandatory for this RFA, the number of applications we receive may be more (or less) than 12.

13. 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 one application is permitted from an institution in response to this RFA. If you receive two or 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 one application from an institution be handled?

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

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

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

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

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

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

   A. Be sure to designate participants correctly and attribute any time commitments in accordance with the role each will be playing in the completion of the Work Plan. This will be considered by the peer review panel (see RFA Section V.D., Review Criteria). Also see Application Contents and Forms, page 9 of this document.

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

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

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

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

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

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

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

<u>Submitting the Application</u>

1. What is the application due date and time?

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

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

   A. For any mail being sent via the US Postal Service, including 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.

3. 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.

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

   A. Refer to RFA Section V.A., Application Content. 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 1-4 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 1-4 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 5-11 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/0812260816.

      Also see Attachment 2 of the RFA and Modifications, pages 24-26 of this document.

Scope of the Proposed Facility

1. Is there any big change in the RFA in comparison to FAU# 0802150850?

   A. Yes. Applicants are advised to read the entire RFA carefully. Among other changes, this RFA does not support the purchase of shared equipment alone; it must be part of the development and/or operation of a shared core facility (see Section I.B.).

2. Who should the shared resource be for? Is the goal to benefit the major user PIs, collaborators, the applicant institution, all scientists in New York State, everyone?

   A. The scope and services of the facility should be well-documented to support the goals of the Empire State Stem Cell Board and demonstrate sufficient need. Several sections of the RFA address

these issues, including, Section I., Section III., Section V.A. and Section V.D.

3. Is there information available regarding the currently funded stem cell researchers and/or projects in New York State?

   A. Yes. One such resource would be the National Institutes of Health web site containing a searchable database of funded research projects at: http://projectreporter.nih.gov/reporter.cfm. Another resource is the NYSTEM website at: http://stemcell.ny.gov.

4. Are user fees appropriate and must they be described in the application?

   A. User fees are appropriate and should be described in the application. See Sections V.G., Organizational/Management Plan, of the Work Plan and Section III.A., General Expectations.

5. How much of a business plan do we need in the application?

   A. The Work Plan should present information in sufficient detail to clearly convey the operational plan to reviewers. See instructions for Work Plan – Form 10, in Section V.A., Application Content and Section V.D., Review Criteria.

6. Can users be for-profit?

   A. Yes.

7. Do the three major users have to be NYSTEM-funded investigators?

   A. No. The major user group must be PIs funded for stem cell-related research. Priority for use of the facility should be given to NYSTEM-supported and other New York State investigators. Fifty-percent of the usage of the shared facility supported by the award must be for stem cell-related projects. See Section III.A., General Expectations.

8. Do users have to be in New York State, can they be in foreign countries?

   A. The major user group must be PIs funded for stem cell-related research. They can be located anywhere, but priority for use of the facility should be given to NYSTEM supported and other New York State investigators (see Section III.A., General Expectations).

9. What kind of recommendations/documentation do you need from or about the users?

A. The application should demonstrate that: 1)the major users have funding for stem cell-related projects at the time of application and at the time of award, 2)this funding will continue through the start date of the contract, November 1, 2010, and 3)there will be sufficient projects to support 50% of the usage (see Section III.A., General Expectations). Section V., Completing the Application, provides instructions and forms for providing information regarding major users, key personnel, brief descriptions of the projects to be completed utilizing the facility, demonstration of institutional commitment, etc.

10. During the contract, can we change the users from those listed in the original application?

    A. Yes. The users will certainly change over time. However, the application must include a pool of users who will have stem cell-related funding at the time of application, award and estimated contract start date (see Section III.A., General Expectations). Users with funding beyond Nov 1, 2010 will help substantiate the need for the facility.

11. Do renovation costs include HVAC, plumbing, electrical, removing and putting up walls?

    A. Yes. The funds do not support "bricks and mortar." See Section I.C, Available Funds and Section III.B., Use of Funds.

12. The RFA suggests that users will assist with operating and maintaining the facility. Can you provide some clarification on the extent to which the PI, investigative or technical/operational staff are expected to maintain the facility?

    A. This issue should be addressed in the Work Plan and is likely to be dependent upon the Organizational and Management plan for the facility. For instance, some shared facilities are accessible to and used directly by PIs while other facilities have paid operators with technical expertise necessary to ensure proper use, data analysis, etc.

13. Should the facility be self-sustaining?

    A. Yes. There has been no discussion by the Funding Committee with regard to providing continuing funding for operation of facilities beyond October 31, 2014, so in that respect, the facility should be self-sustaining. Section III.A., General Expectations, requires the development of a financial plan for long-term operation and maintenance during the post-award period, including the designation of reasonable, standardized use charges. The Work Plan requires a discussion of the Organization/Management Plan and Institutional

14. Would characterization and banking of cell lines generated by the facility be considered a resource of the facility, and thus, would expenses related to characterization, database development and maintenance, etc. be considered eligible operational expenses?

    A. These could be considered eligible expenses as they are a natural resource produced/provided by the operation of the facility.

15. Can there be a developmental aspect of the core service supported by these funds? For example, the type of core we envision will require continuous development of new techniques/processes/skills by core facility staff. Exploring these would not only provide the core service infrastructure in New York State but also exciting opportunities to advance the field through development.

    A. The application review criteria focus on the plans for development and operation of a facility, and the benefits of this facility for funded stem cell related research projects. The criteria do not include scientific review of these research projects. However, there is an understanding that some portion of facility usage will be for developing, refining and implementing methods and techniques that would benefit other (not specifically funded) stem cell research. Therefore, technique development activities would be considered allowable expenses in the operation of the shared facility. However, for purposes of this application, the time, effort and utilization of the core facility associated with technique development unrelated to a funded project may not be considered part of the requirement for 50 percent utilization of the facility for stem cell research, stated in Section III.A., General Expectations. Further, it is not acceptable to designate a portion of the application budget to support future development or implementation of methods as independent projects funded directly by the core. Projects not currently funded that are geared to methods development are not specifically included in this RFA and will not be scientifically reviewed.

16. If we propose a multi-institutional core, are video-conferencing facilities able to be funded by the award?

    A. Yes, if they are appropriately justified as a necessary component of core operations.

17. How firm is it that the space identified in the application is the space ultimately used?

    A. If alternative space is identified after award that is demonstrably better than the original space identified, the program would like to accommodate such a request, although no additional funding can be made available through the contract. Notably however, changes to the peer reviewed work plan, budget and time line/collaboration strategy, which all become part of the executed contract, may present administrative challenges and delays. There is not an opportunity to revise the plans and send them back to peer review for consideration; therefore, such revisions could not be approved. Because these are contracts, not grants, it is always best to contact your assigned Contract Manager from Extramural Grants Administration unit at Wadsworth as early as possible for discussion and exploration of the possibilities. Contract managers can be reached at 518-474-7002 or nystemgrants@wadsworth.org.

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). 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 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. 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.

5. 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 8) must be provided for all key personnel listed on Form 7.

6. 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 regarding this and other penalties).

7. 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), 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.

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

   A. In a research application, an administrative assistant position would likely not be considered key personnel and would be included as Support Personnel on Form 7. In this facilities development/operation application, the applicant should determine if such a position fits that definition, which closely mirrors the definition 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."

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

   A. See the instructions at the bottom of Form 8. Beyond these, the general grantsmanship principle is usually to present them in the order that would make most sense for the reviewers.

10. Can we insert an NIH biosketch form instead of using Form 8?

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

11. 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 regarding penalties) and administrative disqualifications for failure to include mandatory items in the submission (see Attachment 2 and Modifications, pages 24-26 of this document. Ms. Brautigam will provide as much assistance as is permissible under state procurement procedures.

12. What is the proper placement of line drawings? It seems that they must be placed within the page limitations of the Work Plan (Section V.A., Application Content) and in the appendices (Attachment 2) but Section V.A., Application Content, says we can't use the appendices to subvert the page limitations.

    A. Please see the Modifications to Section V.A. and Attachment 2, pages 24-26 of this document.

13. Regarding the Tables in Section E of the Work Plan, do you want to know the dollar amounts for funded projects that will be supported by the facility?

    A. No. However, please see the Modifications to Section E of the Work Plan, pages 24-26 of this document.

14. If we have a current cores supported by NYSTEM, is there a specific place where that should be noted?

    A. There is not any one area where such a core might be mentioned. However, Section II., Who May Apply?, states that applications that are deemed to be for the same project (as that funded under FAU#0802150850) will be disqualified. Therefore, the application must be clear to address this issue within the context and limitations of the application instructions.

Revised Applications

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

    A. Instructions for submitting a revised application are found in Section V.B. Revised applications **must**:
    - Have the same PI as the original application
    - Include a completed Form 9 "Revisions and Comments"

    In order to facilitate rapid and accurate processing of submissions:
    - Include the critique from previous submission in the appendix (request an electronic copy of the critique by sending an e-mail to nystemgrants@wadsworth.org)

    Also see Attachment 2 and its Modifications, pages 24-26 of this document.

2. Will my revised application be reviewed by the same people as reviewed my first submission? Can I request that?

A. Independent peer review panel members are selected separately for each round of funding and may not be the same as in prior reviews, depending upon the content of the applications received. Also see "Peer Reviewers," page 16 of this document.

Budgeting

1. Is there a maximum allowable cost per year?

   A. No. The only cap is the total direct cost of $5 million for the award period.

2. How much budget justification is necessary?

   A. Form 7 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.

3. What are the rules regarding equipment purchases?

   A. See Section V.A., Application Content and Format, where instructions regarding completion of the budget (Form 6) 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."
   Note that this last statement requires that any change in the equipment to be purchased will require advanced permission from Wadsworth's contract management staff.

4. 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.

5. Are service contracts allowable direct expenses?

   A. Many quotes include a warranty and/or service/maintenance for at least one year. Some quotes also include the cost of a maintenance

contract for future years. This is an allowable expenditure if well-justified.

Clarification: Section V., Completing the Application also states: "For equipment/instrumentation purchases, only direct cost for the purchase may be budgeted. Such purchases may not be made within 90 days of the end of the contract period." The portion of this statement regarding direct costs is made with reference to the exclusion of equipment purchases from the calculation of Facilities and Administrative Costs. The portion regarding purchases within 90 days of the end of the contract period does apply to maintenance/service agreements.

6. Will matching funds be looked on favorably?

   A. Section III.B., Use of Funds states: "Matching funds are not required for this RFA. However, the applicant institution should demonstrate an appropriate level of institutional support to ensure the associated infrastructure to support the continued operation of the equipment or facility will be made available throughout the contract period and continue thereafter." Also see Section V.D., Review Criteria. Further, see Modifications, pages 24-26 of this document.

7. The RFA indicates that approximately $15 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 has some flexibility to allocate more funds to an RFA. However, the Board's Strategic Plan estimate for infrastructure investments in the first five years of the program has already been exceeded by the assignment of approximately $15 million to this RFA.

8. How is the budget scored?

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

9. 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.

10. 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, cost-effective and sufficient to support the stated need. In no case will more than $5 million direct costs be awarded. Remember that 40 percent of the score is based on need and significance (see Section V.D., Review Criteria, also see Modifications, pages 24-26 of this document).

11. 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 7).

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

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

13. Does this RFA require a minimum percentage of professional effort on the part of the PI and/or Co-PI?

    A. No.

14. 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 6 in Section V.A.). A separate Form 6 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 6. 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.

15. 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.D., Review Criteria).

16. What is the allowable fringe benefit cost rate?

    A. The fringe benefit costs may be requested in accordance with institutional guidelines for each position and are not capped by New York State. However, the indirect cost rates (Facilities and Administrative costs) are capped at 20 percent.

17. What is the allowable Facilities and Administrative (F&A) rate for this RFA?

    A. These costs are capped at 20 percent of the modified total direct costs (see Section III.B., Use of Funds and Section V.A., Application Content).

<u>Peer Reviewers</u>

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 and facility design and operations?

A. Section V.C. 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.C. 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 24-26 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. NOTE: For Revised applications, there are two additional mandatory elements that must be met in order for the application to be forwarded to peer review.

      The peer review contractor then inspects the applications to determine if the scientific administrative requirements listed on Attachment 2 are met. If they are not, the application will not be forwarded to peer review. The applicant will be notified of this determination.

3. Section V.C. suggests that if we don't get a score of 2.5 or better, we have no chance of funding. Is that correct?

   A. Yes. The Funding Committee has decided that it will not consider applications that score in the range of 2.6 to 5.0.

4. Please explain the Funding Committee vote and notification process. Do they have full latitude or does everything that scores 2.5 or better get funded as long as there is funding available?

   A. Following the peer review scoring process, the resulting critiques, recommendations, comments and scores are distributed to the members of the Funding Committee for consideration at an upcoming meeting. During that meeting, as described in Section V.C. 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 not funded" application.

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

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

11. What 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.

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

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

    A. The scores of all panel members are weighted equally and scoring is not done until after panel discussion. Although only the primary and secondary reviewers provide written critiques for each criterion, they are generally reflective of the entire panel discussion. The Critique Summary is written to reflect the entire panel's views. Notably, Reviewer A and Reviewer B in the list of scores are not necessarily the primary and secondary reviewers for the application as identified in the subsequent text of the critique. Conflicts of interest and ad hoc review

assignments may result in fewer scores for a given application than the total number of reviewers assigned to the panel.

Post-Award

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

   A. Most often, if the PI is transferring to another New York State institution, and if the awarded institution and the new institution agree, the contract can be assigned to the new institution. This process takes approximately six months to complete. If the PI is transferring out of state or there is no agreement reached between the current and new institution regarding the assignment, the contract can be retained by the current institution under the direction of another PI designated by the institution, provided that NYSTEM agrees that the new PI has the proper experience, training and resources to complete the work as described in the contract work plan. Otherwise, the contract is terminated. NOTE: this is a much longer and more cumbersome process if the PI transfers to a new institution before the contract is executed.

2. What kind of reporting is required?

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

General

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

   A. Common mistakes have included: submission of a DVD instead of a CD; 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 # 0812260816

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

Section E., How to File an Application, page 5, last paragraph now reads

For detailed content requirements, see Section V., Completing the Application. Applications should be submitted in a single mailing package that is clearly labeled with the FAU number listed on the cover of this RFA document. Inside the mailing package, a separately sealed package should contain the application, CD or DVD and supporting documents clearly marked with the PI's name, the institution name and the FAU number. Hand deliveries will be accepted but should be in a sealed envelope as described in the previous sentence. Applications WILL NOT be accepted via fax or e-mail.

Section V.A., Application Content, page 10 second paragraph now reads

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.

Section V.A., Application Content, page 10, third paragraph now reads

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 – 4 in a single Microsoft Word (.doc) file;**
- **Contractor Forms 1 – 4 in a single Portable Document Format (.pdf) file;**
- **Forms 5 – 11 and all appendix material in a single .pdf file not larger**

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**.

Section V.A., Application Content, page 10, fifth paragraph now reads

Do not exceed 10 pages for the Work Plan (Form 10) sections A through C (see below). Figures and illustrations referenced in the Work Plan are included in the page limits. Appendices may not be used to circumvent page limitations.

Clarification: Line drawings are to be included in Work Plan section D and should not appear in the appendices.

Work Plan – Form 10, Section E. Tables, page 16, now reads

Provide a table to list the names of the users, brief project titles, award type, funding source and end date of the award for each project proposed to use the facility. Also indicate the estimated percentage of facility use attributed to each project.

Section V.B., Revised Applications, page 17, third paragraph now reads

If the following requirements are not met, the revised application will be rejected. A revision must include a completed Form 9, "Revisions and Comments." In no more than two pages, summarize the substantial additions, deletions and changes that have been made to the application. Also include responses to the issues and criticisms in the previous review evaluation. It is recommended that the Work Plan emphasize any relevant work done since the previous application.

Reviewers' comments from the previous application submitted are STRONGLY ENCOURAGED to be included in an appendix to the application in order to facilitate accuracy and timeliness of processing.

Section V.D., Review Criteria, 2. Technical Expertise and Design Considerations (20%), page 20, now reads

a. The institution has the technical expertise to make effective use of the facility.

b. Personnel and users are well-qualified to operate and maintain the facility and to conduct the projects and evaluate the research results.

c. The training, safety and other regulatory (e.g., biosafety, hESC) plans, policies and procedures are adequate.

d. The facility or renovation design is technically sound, appropriate and suitable for the proposed project and addresses current and future needs.

Attachment 2, Application Checklist, page 38, now reads

ATTACHMENT 2

APPLICATION CHECKLIST

Shared Facilities for 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 application, if from an institution previously awarded funds under FAU# 0802150850, does not request additional funding to support the same project
- ☐ One electronic (on CD or DVD) and one original paper copy of the application were submitted

Scientific administrative requirements:

- ☐ Three or more investigators are identified to use the facility
- ☐ A minimum of three major users are principal investigators on funded peer reviewed stem cell research grants at the time of application
- ☐ At least 50% of the usage of the shared facility is for stem cell related projects
- ☐ An internal advisory committee, pre-existing or new, is named to assist the PI in administration and oversight of the shared facilities

Revised Applications:

- ☐ Same PI as original
- ☐ A "Revisions and Comments" section immediately precedes the Work Plan and is no more than two pages, including responses to reviewers' comments

Appendices may include:

- ☐ Vendor Responsibility Attestation (Attachment 3)
- ☐ 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), if essential to document the investigator's capability to undertake the work proposed
- ☐ Facilities and Administrative rate agreements
- ☐ Equipment quotes
- ☐ Biosketches of Advisory Committee members
- ☐ Other