Shared Facilities for Stem Cell Research

RFA # 1121110215

QUESTIONS AND ANSWERS and MODIFICATIONS

3/29/13 - 4/15/13

Including applicant conference

Letter of Intent and Pre-application Materials

- Must applicants attend the Applicant Conference?
 A. No.
- I missed the due date for the Letter of Intent. Will my application be accepted?
 A. Yes.
- Would it be helpful to submit the Letter of Intent even if I missed the deadline?
 A. Yes, it would be very helpful.
- 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 expected to be 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.
- Can the PI change after the Letter of Intent is submitted?
 A. Yes.
- 7. 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.

Eligibility – Also see Modifications below

- 8. How would the receipt of more than one application from an institution be handled? A. All applications from that institution will be disqualified. See RFA Section II.
- 9. Regarding the "one application per organization" requirement found in Section II of the RFA: if our organization has been treated as a separate organization from our "sister

organization" by NYSTEM in the past, will it be treated that way for this RFA? Specifically, will the New York University School of Medicine be considered a separate eligible applicant from New York University?

- A. Yes, NYU is treated as a different applicant from NYU School of Medicine. Be aware that this is not necessarily true for other institutions having separate medical schools or other affiliates.
- 10. If our organization has not applied for Shared Facilities under past RFAs, can it do so now?

A. Yes.

- If our organization applied for Shared Facilities under FAU# 0802150850 issued on 5/8/08, may it apply again now?
 A. Yes.
- 12. If our organization applied for Shared Facilities under FAU #0812260816 issued on 8/27/09, may it apply again now?
 - A. Yes, with some restrictions. See Q&A #13.
- 13. Please define the terms "funded project," "continuation" and "expansion" as they are used in Section II of the RFA, as **modified** by Amendment #1 on April 10, 2013.
 - A. The following definitions apply:

"Funded project": A facility, service or resource previously funded, in whole or in part, by NYSTEM under Shared Facilities RFA, FAU # 0812260816 issued on 8/27/09.

"Continuation": Support for the ongoing development or operation of a facility, service or resource that has received a Shared Facilities award from NYSTEM or another funding source.

NOTE: If the intent is to continue a facility that was funded by NYSTEM under FAU#0812260816 issued on 8/27/09, it is not eligible under this RFA.

"Expansion": (1) Adding a new capability, service, resource, technology, animal model or cell line to the existing capabilities of a facility; (2) Upgrading or replacing existing equipment, materials/supplies or staff to provide a new service or to enhance an existing service; (3) Increasing the square footage or capacity of an existing facility.

NOTE: If the intent is to expand a facility that was funded by NYSTEM under FAU#0812260816 issued on 8/27/09, it is not eligible under this RFA.

- 14. We will propose the enhancement of more than one core or function within our application. One portion of our application anticipates future clinical needs but we don't already have three major users for that portion. The other portion will include non-stem cell users but is expected to be fully utilized. Will this configuration knock us out of eligibility?
 - A. The two cores or functions must be clearly related to each other and be well-justified as a single facility, service or resource. It is not permissible to propose support for separate facilities in the application. Then, if there is a major user group of three or

more investigators who are PIs on funded peer reviewed stem cell research projects and at least 50% of the usage of the facility will be for stem cell related projects, the application would be eligible. See Section III.A for details. Also see Attachment 2 and evaluation criteria in Section VI.D. Section V provides instructions and forms for providing information regarding major users, key personnel, brief descriptions of the projects to be undertaken utilizing the facility, demonstration of institutional commitment, etc. Also see Q&A # 20 in Scope of the Proposed Facility and Competitiveness of the Application.

- 15. Can an individual qualify as one of the three major users of the facility if their peer reviewed funding is in a No Cost Extension period?
 - A. Yes.
- 16. We envision some out-of-state collaboration such as providers of specialized materials, perhaps co-authors on papers, and potentially users of the facility. Is this permitted?
 - A. Yes. Be sure to explain the collaboration and remember that the facilities need to be physically located in New York State.
- 17. Can an organization partner with an academic institution?
 - A. Yes, as long as the applicant is a not-for-profit or governmental organization in New York State. Be sure to explain the partnership clearly in the application.

Scope of the Proposed Facility and Competitiveness of the Application

- 18. Is this RFA all that different from the last Shared Facilities RFA, FAU# 08012260816?
 - A. Yes. Applicants are advised to read the entire RFA carefully. In addition, because of the **modification** to eligibility criteria, several forms and instructions have been modified here; they differ from those posted on March 29, 2013. See **Modifications** below.
- 19. Will preference be given to continuation or expansion projects versus new or revised projects, or to new versus returning applicant organizations, or to enhancement of existing facilities versus new facilities, or basic or model organism versus applied or clinical work?
 - A. Each application will be evaluated and scored on its own merits in accordance with the instructions in the RFA and the evaluation criteria. In Section VI.D., note that 40% of the score is based on Justification of Need/Significance. The Funding Committee of the Empire State Stem Cell Board does have significant latitude in making award recommendations based on a variety of factors (see Section VI.E. for details).
- 20. Is there an ability to "split" the facility across separate locations and/or institutions?
 - A. Yes. Careful justification as to the accessibility of each location to the major user group, justification of a strong relationship between the functions of a single facility in multiple locations (see Q&A #14 in Eligibility above), the ability to accomplish sustainability in those locations and other factors would need to be well-explained and justified.

- 21. Is there information available regarding the currently funded stem cell researchers, projects and/or facilities 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: <u>http://projectreporter.nih.gov/reporter.cfm</u>. Another resource is the NYSTEM website at: <u>http://stemcell.ny.gov/grants-and-contracts-awarded</u>. 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 <u>http://stemcell.ny.gov/stem-cell-scientists-new-york</u>. For information about NYSTEM-funded shared facilities, see <u>http://stemcell.ny.gov/shared-facility-resources</u>.
- 22. Is work with cancer stem cells eligible under this RFA?
 - A. Yes. Projects related to cancer stem cells would be considered toward minimum utilization requirements and user projects that could be supported by the facility. See Section I.B, Purpose of the Funds.
- 23. A portion of our application will duplicate a service that NYSTEM has previously funded. How will that impact our chances of obtaining funding?
 - A. We cannot predict the outcome of peer review or Funding Committee deliberations. Please refer to Sections III.A, V, VI.D and VI.E. Demonstration of Need and Significance will likely be vital to the success of your application.

NOTE: A portion of the application cannot be "carved out" from consideration in scoring or award recommendation. The application is considered as a whole. Also see **Modifications** to the instructions for Form 11, Section b, below.

- 24. 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. Yes. They are considered eligible expenses as they are a natural resource produced/provided by the operation of the facility.
- 25. 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% 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.

- 26. We anticipate that the facility will also develop and house a database that will serve as a data source for pilot projects that could develop into funded research projects. Is development of the database an acceptable use of the funds? Is support for pilot projects using the database and other aspects of the facility an acceptable use of funds?
 - A. Development and maintenance of a database that would benefit others is considered an allowable expense in the development and operation of the facility. A "set-aside" for support of pilot projects that might use the data is not an eligible expense.
- 27. Our organization has an existing facility that has not been funded by a NYSTEM Shared Facilities award, but it has been used to support several NYSTEM-funded research projects. We are anticipating an increase in the number of stem cell projects but do not currently have 50% of active studies involving stem cells. Are we eligible to apply?
 - A. To be eligible, the application must demonstrate expected utilization of more than 50% stem cell projects. See application instructions, evaluation criteria and Attachment 2 in the RFA.
- 28. 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.
- 29. With these funds, can we develop an instrument with advanced capabilities beyond what is available commercially (e.g., customizing existing instrumentation)?
 - A. This would be allowable if it was very well-justified, needed for certain projects that would use the facility, unavailable commercially or at significant expense or delay.
- 30. Are user fees appropriate and must they be described in the application?
 - A. Yes. See instructions for the Organizational/Management Plan portion of the application in Section V and Section III.A., General Expectations.
- 31. 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 the application in Section V and Section VI.D., Review Criteria.
- 32. Should the facility be self-sustaining?
 - A. Yes. 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 Commitment. See Section V., Completing the Application. Also see Section V.D., Review Criteria.
- 33. Do renovation costs include HVAC, plumbing, electrical, removing and putting up walls?A. Yes. The funds do not support "bricks and mortar." See Section III.B., Use of Funds as well as the application instructions in Section V.

- 34. How firm is the requirement that the space identified in the application be the space ultimately used?
 - A. If alternative space is identified after award that is demonstrably better than the original space identified, the program would consider such a request after contract award. However, such changes will require prior approval and strong justification.
- 35. Are we required to obtain letters of institutional support?
 - A. Section h of the Workplan (Form 11), Institutional Commitment, states "In the appendix, provide supporting documentation such as letters of support, cooperative agreements or memorandum of understanding (MOU).
- 36. Our institution has two projects. Can you give us some guidance regarding the funding priorities?
 - A. In addition to a careful review of the RFA, please see the NIH and NYSTEM websites listed in #21 in Scope of the Proposed Facility and Competitiveness of the Application.

Submitting the Application

- 37. What is the application due date and time? Has it changed because of the **Modification** issued to the RFA on April 10, 2013?
 - A. The application must be received by 5pm on May 29, 2013. The due date has **not** changed.
- 38. Can applications be hand-delivered?
 - A. Yes. They must be received by staff from the Extramural Grants Administration office by 5pm on May 29, 2013.

Application Contents and Forms

- 39. 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.
- 40. What is the proper placement of line drawings within the application?
 - A. Line drawings should be placed in Section D of the Workplan.

Budgeting

- 41. Is there a maximum allowable cost per year?
 - A. No. The only cap is the total direct cost of \$3 million for the award period.

- 42. 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).
- 43. How much budget justification is necessary?
 - A. Form 7 requires applicants to describe and fully justify all elements of the budget each year, including personnel roles, responsibilities and percent of professional effort committed to the application. See the instructions for completion of the form in Section V.
- 44. How do we go about budgeting and quotes for capital expenditures and equipment when we know things are bound to change over time costs going up or down and equipment capabilities improved?
 - A. If at all possible, obtain quotes that reflect the anticipated start date of the contract, April 1, 2014. Equipment quotes should reflect your best thinking at this time regarding equipment specifications needed and available to support the work. NYSTEM recognizes that those are likely to change over time and may need to be reconsidered. However, additional funds will not be made available under the contract should the cost for the revised equipment change. Unused funds due to cost reductions may be requested to be used for another purpose but approval is not guaranteed.
- 45. What are the rules regarding equipment purchases?
 - A. Section V instructions regarding completion of the budget (Form 6) states: "All equipment must be purchased and renovations completed within the first year." It also states: "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." It further states that during the contract term, requests for equipment that was not detailed in the application or its appendices requires prior approval from NYSTEM and that approval is not guaranteed.
- 46. During the contract, what budget modifications are permitted?
 - A. All budget modifications require prior approval from NYSTEM and are not guaranteed. For additional information, see instructions for the completion of Budget- Form 6 for details. It is important that you budget carefully for the amount of funds required to complete all of the aims outlined in your workplan and timeline. Contractors will be working at risk until modifications are approved. Some require approval of the Office of the State Comptroller and can take several months.
- 47. Are service contracts allowable direct expenses?
 - A. No. The NYS Master Grant Contract specifically requires contractors to maintain and repair property that is purchased or procured under the contract at its own expense.
- 48. Would expenditures related to the development of a clinical grade product in the facility be eligible?
 - A. Yes, if the purpose of your facility is to develop such products.

- 49. Will matching funds be looked on favorably?
 - A. Section III.B. Use of Funds states: "Organizational matching funds are not required for this RFA. However, the applicant organization should demonstrate an appropriate level of organizational support to ensure the associated infrastructure necessary to the operation of the equipment or facility will be made available throughout the contract period and continue thereafter. Also see Section VI.D.
- 50. How is the budget scored?
 - A. The criteria for scoring the budget are listed in Section VI.D. The Budget score will be 20% of the score.
- 51. Can you give us guidance on funding? Should we request the maximum amount, or are more, smaller awards likely to get funded? Are there guidelines regarding the "split" between capital expenditures and operational expenditures?
 - A. The amount requested should be appropriate, reasonable, cost-effective and sufficient to support the stated need. In no case will more than \$3 million direct costs be awarded.
- 52. Is there a limit to personnel costs?
 - A. There is a maximum salary for each individual. See instructions for completion of Form 6.
- 53. Should the budget include costs for travel to meetings?
 - A. Yes, this is expected. Contractors are required to travel to and participate in annual scientific meetings (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).

Peer Reviewers

- 54. How will the peer reviewers be selected? Will they be mostly bricks and mortar, mostly basic science-oriented, will they have cGMP and FDA experience?
 - A. Section VI.B states: "The Review Panel members will be selected from among non-New York State experts in the appropriate fields based on the nature of the applications received. NYSTEM does not convene pre-established peer review panels. Instead, each panel is formed based on the expertise needed to evaluate the merit of actual applications submitted in response to each RFA."

Awards and Contracting Process

- 55. Section VI.C references a set of Pass/Fail requirements and refers to the Application Checklist found in Attachment 2. How is this done?
 - A. After applications are received, they are inspected for the mandatory elements listed on the checklist (also see **Modifications** to Attachment 2 below). If any one or more of those criteria are not met, the application will not pass the preliminary review and will not be forwarded to the peer review contractor. The applicant will be notified of this determination.

The peer review contractor then inspects the applications to determine if the scientific administrative requirements listed on checklist are met. If any one or more of those criteria are not met, the application will not be forwarded to peer review. The applicant will be notified of this determination.

- 56. Please explain the application penalty process.
 - A. Penalties are assessed to each application that scores between 1.0 and 2.5 that deviates from the instructions in Section V of the RFA or those found on the forms. See **Modifications** to Appendix 2 and Section VI.C below.
- 57. Please explain the Funding Committee vote and notification process. Does the Committee have full latitude or does everything that scores 2.5 or better get funded as long as there is funding available?
 - A. See Section VI.E. of the RFA. The members have considerable latitude. 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. Official award notifications are sent to applicants as soon as internal approvals are obtained. This may be several months.
- 58. 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.
- 59. During the applicant conference, NYSTEM staff mentioned that the Sample Contract in the RFA will not be the same as the contract language sent out for the awarded institutions. Can you please explain the basis for that and highlight some of the differences?
 - A. A statewide NYS Master Grant Contract is being developed to standardize language across all state agencies. Its use will be required after April 29, 2013. The statewide language and a description of the Governor's initiative to transform contracting processes in New York State are available for review at <u>www.GrantsReform.ny.gov</u>.

- 60. What is a cost reimbursement contract?
 - A. The contractor must perform the activities outlined in the workplan and timeline at its own expense then request reimbursement for eligible expenditures through a voucher. Timely vouchering and progress reporting are essential. Funds are reimbursed in accordance with the payment and reporting schedule (See RFA Attachment 5, Appendix C to the contract for a sample). Expenses incurred prior to the contract start date are not eligible for reimbursement. Reimbursement generally occurs within 30-60 days of receipt of an approvable voucher.
- 61. What can we do to facilitate contract execution?
 - A. Upon receipt of the letter of award, PIs should gather any protocol approvals from IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) and/or ESCRO (human pluripotent stem cell) committees that are necessary to operate the facility. Simultaneously, Grants Offices should complete/update the Vendor Responsibility Questionnaire (see Section IV.J.) and get the Workers' Compensation and Disability Insurance forms (see Section IV.L. of the RFA) ready for submission/return with the signed contract.
- 62. How long will it take for the contract to be executed and funds to be reimbursed?
 - A. Upon receipt of the contract for signature, return all information to NYSTEM by the deadline according to the instructions provided with the contract. Upon review and acceptance of those documents, the signed contract will be sent through the Department to the Attorney General and the Office of the State Comptroller for final signatures, execution and return. The length of time from receipt of contract by the awardee and execution has averaged from two to six months. Allowable expenditures cannot be reimbursed until after all required signatures are affixed to the contract.
- 63. 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 is guaranteed. A formal contract amendment process, which is both lengthy and time-consuming, is often necessary. Careful budgeting in the application should reduce the need for contract amendments.

MODIFICATIONS TO RFA # 1121110215

underlined text emphasizes changes

 The first paragraph of Section II of the RFA, "Who May Apply?" has been modified. It now reads:

The applicant must be a not-for-profit or governmental organization in New York State. Organizations awarded funds will be expected to monitor funds, maintain individual accounts and fulfill other fiscal management criteria. Subcontracting and collaborating organizations may include public, not-forprofit and for-profit entities within New York State. Institutions awarded funds for facility development and/or operation under the previous RFA "Shared Facilities for Stem Cell Research (FAU# 0812260816 – issued on 8/27/09)" are not eligible to apply through this RFA for continuation or expansion of the funded project.

This modification was previously posted to the website on 4/15/13.

- 2. Section VI.C of the RFA, "Application Penalties" has been modified. It now reads: The Peer Review Contractor will assess a penalty point of 0.1 point for each application that scores between 1.0 and 2.5, and deviates from the instructions in Section V. above or those found on the forms (also see Attachment 2). The Peer Review Contractor will calculate final scores and compile a Summary Statement for each application <u>discussed by the Review Panel</u>. The Summary Statements will document the scientific merit evaluation and serve as the primary basis for the panel recommendation for the applications.
- **3.** A typographical error has been corrected by **modification** to Section III.A., "General Expectations." The last paragraph on page 2 of the RFA now reads:

"Such guidelines **must** be developed not later than six months after the start of the contract term. The PI and advisory committee will be expected to review, monitor and modify such guidelines throughout the contract term."

 Instructions for Form 11 – Workplan Section b have been modified as follows: Justification of Need/Significance

Describe the need for the facility to the overall stem cell research program at the institution and/or among the collaborators/users. <u>Provide background</u> information and describe its relationship to <u>relevant</u> existing facilities and plans, <u>including but not</u> limited to facilities, services and resources awarded NYSTEM Shared Facilities funds at the applicant or other organizations in New York State. This section should also demonstrate that there is a strong logical tie/relationship and/or economy of scale between the proposed facility, service or resource and relevant existing facilities <u>and</u> users. Describe the significance of the proposed facility to the users and the greater stem cell community and describe the stem cell research projects that will benefit from use of the facility and the greater stem cell research community. Describe how successful development and use of the facility will conform to the purpose defined in Section I.B. and advance the ESSCB's mission. Describe how existing resources at the applicant institution enhance the likelihood of the facility's success.

If the proposed facility, service or resource will continue or expand existing facilities, services or resources funded by NYSTEM under FAU# 0802150850 <u>or another funder</u>, this section should clearly demonstrate what has been accomplished to date under that award, describe the relationship between the newly proposed facility/services to the previously awarded facility(ies), and fully justify the need for continued support from scientific/technical, administrative, environmental, and budgetary perspectives (also see Section VI.D., Review Criteria). Detail efforts made to recover costs via user fees and explain progress toward sustaining operations without continued support from NYSTEM <u>or another funder</u>.

5. Instructions for Form 1 – Applicant Face Page have been modified as follows:

<u>NYSTEM Rd1 Contract #.</u> This field is for NYSTEM USE ONLY; do not enter any data in this field.

This field will be now used by NYSTEM to enter the contract number of any NYSTEM Shared Facilities award(s) associated with the current application. Form 1 – Application Face Page has **not** been changed.

<u>Status</u>. Select the appropriate type from the dropdown box. A "*New*" application is one submitted to NYSTEM for the first time, or one that includes substantial changes in all portions of the Workplan from an application previously submitted to NYSTEM but not funded. A "*Resubmission*" application includes proposed research that was reviewed by NYSTEM during a previous cycle, but was not funded and is being resubmitted for new consideration. Resubmission applications should be responsive to the funding mechanism as well as reviewers' comments on the original application (see Introduction, Form 10). If any part of the workplan is to continue operations or to expand a facility, service or resource that was funded either by a NYSTEM Shared Facilities award resulting from FAU# 0802150850 or another funding source, select the "*Continuation*" from the dropdown box. **NOTE:** Organizations awarded funds for facility development and/or operation under the previous RFA "Shared Facilities for Stem Cell Research (FAU# 0812260816 – issued on 8/27/09)" are not eligible to apply for continuation or expansion of that project/facility through this RFA.

- 6. Section VI.D.1.a Review Criteria has been modified as follows:
 - Justification of Need/Significance (40%)

The need for the facility and instrumentation features, and their relationship, if any, to the previously awarded facility and/or equipment are fully justified and cost-effective. If this is an expansion or continuation or upgrade of an existing facility, sufficient productivity and proper management, oversight and administration of the existing facility is evident. <u>NOTES: (1) Continuation or expansion of a facility, service or resource that was funded under the previous RFA "Shared Facilities for Stem Cell Research (FAU# 0812260816 – issued on 8/27/09)" is not eligible. (2) If multiple locations and/or facilities, services or resources are proposed, the cores or functions must be clearly related to each other and be well-justified as a single facility, service or resource. Support for separate facilities is not eligible.</u>

7. Attachment 2, Application Checklist, page 40, has been modified. See below:

ATTACHMENT 2 APPLICATION CHECKLIST

Shared Facilities for Stem Cell Research

The following items are mandatory (Pass/Fail). Applications that do not include mandatory items will not be reviewed.

- □ The application was received by due date and time (see cover sheet)
- □ The applicant is a not-for-profit or governmental organization in New York State (see pg. 1)
- Only one application was received from this organization (see pg. 2)

□ If the digital files are damaged, a paper copy has been submitted (see pg. 10) Scientific administrative requirements (see pgs 2-3):

- A minimum of three major users of the facility are principal investigators on funded peer reviewed stem cell research grants at the time of application, award and estimated contract start date
- □ The facility and equipment will be operated and physically located within New York State
- 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
- Advisory body guidelines are scheduled to be completed in the first 6 months of the contract.

The following items are not mandatory. Appendices may include items such as:

- Vendor Responsibility Attestation (Attachment 3)
- Letters of collaboration/support or of commitment to provide research resources
- □ 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
- Biosketches of Advisory Committee members

APPLICATION PENALTIES:

A total penalty of 0.1 point will be assessed to an application if:

- Application is not submitted digitally on a CD or DVD
- Digital submission is password protected
- Forms provided in this RFA are not used
- Submission does not include:
 - Applicant Forms 1 4 in a single Microsoft Word (DOC or DOCX) file;
 - Applicant Forms 1 4 in a single Portable Document Format (PDF) file;
 - Forms 5 12 and all appendix material in a single PDF file; and
 - Signed and dated Forms 1 and 1-S (Face Pages for the Applicant and all Sub-applicants) scanned into a separate PDF file (omit Form 1-S if there are no sub-applicants)
 - o Budget Form 6 one for the applicant and each sub-applicant institution
 - Personnel Effort and Budget Justification Form 7 one for the applicant and each subapplicant institution
 - Biographical Sketch Form 8 one for each key personnel listed on each Form 7
 - Other Support Form 9 for each key personnel listed on Form 7
 - Introduction Form 10 limited to 1 page (may be omitted, left blank, or marked "N/A" if application is not "Resubmitted")
 - Workplan Form 11 within page limits prescribed.