Consortia to Accelerate Therapeutic Applications of Stem Cells
FAU # 0911051012

QUESTIONS AND ANSWERS and MODIFICATIONS
Including an applicant conference
August 31 - October 25, 2011

General

1. Is it possible for DOH to move the dates for the applicant conference and the due date for Part One of the application? We are having difficulty choosing which program best fits the RFA and may benefit from discussion prior to submitting Part One.

   A. The dates are not able to be moved. Prospective applicants are encouraged to submit written questions through October 25, 2011 to nystemgrants@wadsworth.org.

2. Will there be an additional set of Questions, Answers and Modifications posted before Part Two is due?

   A. Because of the length of time between posting this document and the Application Part Two deadline, we have modified the RFA to add a second round of Questions and Answers and Updates posting (see Modifications, below).

3. How many awards will be given?

   A. Approximately five awards may be made in response to this RFA.

Eligibility

4. The third paragraph of Section II of the RFA limits applications to one per institution. Does that mean that our institution can only submit one application or just that no more than one will be awarded to our institution?

   A. Each institution may only submit one application in response to this RFA. The institution is the applicant, not the PI. However, it is possible for researchers at the institution to participate in applications submitted by other eligible institutions. Some institutional campuses are treated as separate applicants (e.g., Columbia University Morningside Campus and Columbia University Medical Center, or Cornell University in Ithaca and Weill Cornell Medical College). Investigators are encouraged to check with institutional grants offices and/or Vice Presidents of Research to ensure that only one application is planned per institution.

5. I am a small business owner; can my company apply for funding under this RFA?

   A. No, not directly. Eligible institutions are not-for-profit or governmental organizations in New York State, and the PI is employed by the applicant institution. A for-profit organization may be a subcontractor in collaboration with an eligible organization.

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

   A. Applicants for funding to the NYSTEM program must be New York State institutions. However, those institutions are permitted to subcontract with collaborators world-wide. The NYSTEM website provides information about New York State stem cell researchers with whom out-of-state collaborations might be forged.

7. Can subcontractors and collaborators be from outside New York State?

   A. Yes. Subcontracting and collaborating organizations may include public, not-for-profit and for-profit entities. Such entities may be located outside of New York State. See Section II. Who May Apply? of the RFA.

PIs, Co-PIs and Co-Investigators

8. Can the same investigator be part of two different applications with a largely overlapping project?

   A. Section II of the RFA states: “Individuals and institutions may appear in any number of applications as collaborators, subcontractors, consultants or contributors.” As long as the investigator in question is not the applicant PI on more than one application and that PI’s institution is not the applicant on more than one application, this would be allowable. The “largely overlapping project” is where the problem may lie. From a technical standpoint, assuming both applications were recommended for funding, NYSTEM would address the overlap after award recommendation and before contracting. The overlapping work would be paid only once but would be required to be completed for both contracts.

9. What’s the difference between a PI, a Co-PI and a co-investigator?

   A. See instructions for completion of the Part Two Face Page – Form 1. The PI is employed by the applicant institution and is responsible for planning, coordinating and implementing the contract if an award is made. The PI will act as a liaison between the awarded institution and NYSTEM, and be required to fulfill reporting requirements. A Co-PI shares responsibility and authority for ensuring the completion of the entire project and may be employed by the applicant institution or a subcontracted institution. A co-investigator may be responsible for a specific component of the project.

An investigator who is the lead on a subcontract but is not responsible for ensuring the completion of the entire project is not a Co-PI, but is the PI for the subcontract, responsible for the subcontract portion of the project acting as liaison for the subcontract with the project PI.

10. Is a Co-PI really just responsible for managing the budgetary aspects of the project?

    A. No. The status of Co-PI is determined by the PI to be responsible **with** the PI for the management of the entire scientific project. Regardless of Co-PI designation by the PI, NYSTEM will work directly with the PI on all matters related to the contract.

11. What if my Co-PI/PD or Co-Investigator is from a different institution?

    A. That is fine. Just be sure that each subcontracted institution includes its own signed face page (Form 1-S) as part of the application.

12. Can I list more than one Co-PI from the same institution?

    A. A single PI and more than one Co-PI may be designated. The designation of Co-PI will be honored by NYSTEM. However, on each face page, there is room for only one Co-PI's name and information; the face page should not be altered or amended to include additional Co-PIs.

13. The RFA clearly indicates that the PI and Co-PIs cannot be removed between the submission of Part One and Part Two. But can Co-PIs be added? There seems to be some inconsistency between application instructions and Attachment 2B.

    A. Part One Application Form 3 (Consortia Leadership) states that “the PI and any named Co-PIs must be the same as those identified in Part Two of the application.” And Section V.B. states that “the consortia PIs and Co-PIs and the overall goals of the project proposed in Part Two must be the same as those described in Part One of the application, otherwise the application will be disqualified (also see note re: extraordinary circumstances).” Therefore, the PI must be named in Part One and must remain the same in Part Two. Any Co-PIs named in Part One must be the same as those named in Part Two. Any Co-PIs not named in Part One may later be named in Part Two. Co-PIs can be added, but not removed or substituted.

    Therefore, the related mandatory items on Attachment 2B (Part Two Application Checklist) are accurately stated. “The PI and **named** *[emphasis added]* Co-PIs are the same as those described in Part One of the application.” “The overall goals of the proposed project are the same as those described in Part One of the application.”

14. Can co-investigators be added and/or changed? And if so, how do we indicate a change?

    A. Co-investigators can be added, or changed/substituted. The applicant may wish to indicate in Part Two that Investigator X has been replaced by Investigator Y for specific segments of the workplan.

15. How does the naming of one or more Co-PIs impact the score?

    A. It does not impact the score. The score for Investigators and Leadership as described in Section VI.D. of the RFA.

16. What if the Oversight Panel recommends changing the Co-PIs?

    A. That would be acceptable if NYSTEM approved such a recommendation.

17. Does the RFA require a minimum percentage of effort for the PI? Does this also apply to Co-PI and co-investigators?

    A. Section III.A. of the RFA states that the percent effort of the PI must be at least 30% throughout the contract term. The percent effort required of each designated Co-PI must be at least 20% throughout the contract term. A full time, 100% effort Project Manager must be included in the staffing plan throughout the contract term. Minimum percentages of effort are not required for co-investigators and other participants.

Project Managers and Project Management

18. It's going to be quite difficult to find a single Project Manager with the combined management/administrative and scientific expertise. Can we split the functions of the full time project manager into two 50% positions - one with experience and the other with scientific background?

    A. No. RFA Section III.A. states that "a full time 100% professional effort Project Manager must be included in the staffing plan throughout the contract term." A single individual with expertise is expected. It goes on to say that "the Project Manager should have an advanced science or science management background and relevant experience."

19. We envision multiple roles for the Project Manager, from day to day coordination and supervision of the execution of the project, to managing the financial reporting, to arranging appropriate data storage, and coordinating progress input from each consortia site. What does the RFA intend the role of this position to be?

    A. Specific job duties of the Project Manager may be different for each consortium, depending on the goals of the project. The expertise of the individuals who make

up the leadership team for the project may also vary. See Section III.A.1. of the RFA for a discussion of the various leadership and oversight roles.

Overall, project management is a recognized discipline that uses techniques and tools to plan, control monitor and manage resources to achieve a time- and resource-limited specific end result. The consortium Project Manager will be in a leadership role as a partner to the scientific leadership (PI and any Co-PIs) to ensure that progress is advancing according to the workplan, timeline and established milestones. "Together, [the leadership team] will be responsible for developing and maintaining strategy, keeping the consortium focused, achieving expectations and milestones and providing ongoing communication with NYSTEM and the Independent Oversight Panel."

20. Is it appropriate to have additional individuals at various project sites who work to administer the project?

    A. Yes, that would be acceptable if strongly justified.

21. Can our Project Manager be listed as “to be determined” in the application?

    A. Yes. Just make sure that the roles and responsibilities of that position are clearly articulated in the application so the peer reviewers understand exactly how that person will fit into the project leadership team.

22. How detailed should the Project Management and Coordination Strategy be?

    A. It should be descriptive enough that the reviewers have a clear understanding of how every aspect of the project will be “shepherded through” to completion. Also see questions above regarding the role of the Project Manager.

<u>Submitting the Application</u>

23. Can applications be hand-delivered by an individual rather than a courier service?

    A. Yes, applications can be hand-delivered by individuals. Upon entrance to the Corning Tower, phone 518-474-7002 and ask that a staff member meet the delivery person there to retrieve the application. Do not leave the application at the desk or with another person. The application must be in the hands of the staff member by 6:00pm on the due date.

Scope and Content of the Proposed Consortium Project

24. We do not have the GLP/GMP facilities referenced in Section III.A. of the RFA. Are they required for this application?

    A. Section III.A. states that “the experimental design and implementation is expected to be carried out in accordance with GLP and GMP standards.”

25. Is it acceptable to have an outside contractor/collaborator provide GMP-grade cells for our use in the project?

    A. Yes.

26. If GMP and GLP are not necessary at every stage of the project, do they really need to be used?

    A. The RFA states “It is expected that applicants will have previously established proof-of-principle data to support the feasibility and timeliness/readiness of the proposed project. Because GLP and GMP will be necessary for development of clinical therapies and devices, it is expected that the experimental design and implementation will be carried out in accordance with those GLP and GMP standards.” These standards are defined by the FDA and compliance with them is required. To do otherwise would require significant scientific justification in the application and would be subject to the Application Review and Award Process outlined in Section VI of the RFA.

27. So even in testing human cells in animals, the human cells would need to be GMP-grade?

    A. Yes, if the study requires GMP-grade cells to meet the FDA GMP and/or GLP standards.

28. Is the presence of pre-clinical data in a disease model required?

    A. Pre-clinical data in a disease model is not specifically required but would certainly be helpful in demonstrating the "readiness" of the project for a consortia award. A careful reading of the RFA and critical analysis of the proposed project against the requirements is advised.

       Without diminishing other parts of the RFA, Paragraph I.B. states that the purpose of the funds is to "accelerate translational and preclinical through clinical applications of stem cell research for prevention and/or treatment of disease. The intent...is to support disease-focused, health outcome-based, multi-disciplinary collaborative research proposals... Proposals will address an unmet medical need using stem cells as a basis for the development of clinical treatments/therapies or will apply a new technology or platform based on stem cells." Paragraph III.A. states "A successful application will present a strong, plausible explanation of the capacity to achieve a significant measurable advance toward clinical application

within the period of the award...The proposed project will have a patient-oriented, health outcome focus with the intent to proceed through clinical application. It may focus on any disease/condition, group of diseases/conditions or organ system(s)...it is expected that applicants will have previously established proof-of-principle data to support the feasibility and timeliness/readiness of the proposed project... it is expected that the experimental design and implementation will be carried out in accordance with GLP and GMP standards." Much of this text is then reflected in the instructions for Application Part One, Project Overview Form 2, and the Assessment Checklist Form 4. After critical analysis of the project against this Form 4, if the answers are "Yes" to each question, the project is likely to be considered responsive and "ready" for this Consortia funding mechanism. However, a much more detailed description of the project will be required in Part Two of the application (see instructions for completion of the Workplan - Form 13). If the proposed project does not rise to this level of readiness, perhaps it is better-suited to the Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) in Stem Cell Research RFA (FAU# 0912180242) that was also issued on August 31, 2011 and can be found at: http://www.health.ny.gov/funding/rfa/0912180242/index.htm.

29. How much emphasis should be placed upon clinical trial design in the application?

    A. This depends on how close the project is to entering clinical trial phases. If clinical trials are anticipated within the period of the award, then considerable emphasis on the related aspects would be expected in the workplan section of the application. However, if clinical trials during the project period are not anticipated, it would be useful to explain how trials could be conducted in order to convince the reviewers that the investigators are aware of the critical aspects of trial design and that the applicants will be able to conduct them. Too much weight on the details of the clinical trial structure and outcome measures in this instance would likely be premature.

30. Can you define “clinical application” for us? Is the expectation that we are in clinical trials at time of RFA application, or entering them prior to the end of the contract term, or something else?

    A. “Clinical application” for purposes of this RFA is defined as “the ability to utilize the resulting outcome(s) of the research project to improve patient health in a clinical setting. Section I.B. and Section III.A. of the RFA refer to a desire to “accelerate translational and preclinical through clinical applications of stem cell research for prevention and treatment of disease…” and that there be “a significant measurable advance toward clinical application within the period of the award”… and that the “…proposed project will have a patient-oriented, health-outcome focus with the intent to proceed through clinical application.” The status of the project at any time will be dependent upon the specific nature of each proposed project. Recall that the overall goal is to “attain a specific measurable advance” toward the ability to use the end result to treat human disease.

31. Does the project need to be ready for a pre-IND (Investigational New Drug) application to the Food and Drug Administration?

    A. Not necessarily. The project may be very translational in nature at the beginning, and yet provide a "significant measurable advance toward clinical application within the period of the award."

32. Does NYSTEM expect that an industrial partner will be already lined up to move the GMP issues and the clinical trial issues forward within the term of the contract?

    A. It depends on the "readiness" of the individual projects as to whether an industrial partner is needed at the outset of the application. Some translational studies may not need an industrial partner until later in the contract term. Again, it is the "acceleration to the clinic" that these funds are intended to support.

33. If our project begins in an animal model and ends with readiness for Phase I clinical trials, is that sufficient progress toward clinical application?

    A. Again, it depends on whether that would represent a "significant measurable advance toward clinical application" that "addresses an unmet medical need." Please refer to the evaluation criteria listed in Section VI.D. of the RFA.

34. Is the intent of the RFA broad enough that testing therapeutics for their impact on particular types of cancer stem cells would be considered an eligible project?

    A. Yes.

35. Will the reviewers perceive that a project that explores more than one type of cancer stem cell is too broad?

    A. The reviewers will evaluate each application based on the criteria listed in Section VI.D. of the RFA.

36. Can reviewers suggest elimination of aims?

    A. The reviewers are required to evaluate the entire application using only the Review Criteria listed in Section VI.D. of the RFA. If a specific aim weakens their enthusiasm for the overall application that will be reflected in the overall application score.

<u>Oversight Panels</u>

37. Does the applicant establish the members of the Oversight Panel?

    A. No. Section III.A. of the RFA states that the applicant will have input to the composition of the Oversight Panel (see Part Two Application Form 2). NYSTEM will be working with an independent contractor that will establish and coordinate the

membership and the efforts of the Oversight Panel to work closely with NYSTEM and the awardees of Consortia contracts (see http://www.health.ny.gov/funding/rfp/1003250404/ for more information).

38. Is the design such that there will be overlap between members of Oversight Panels for the various consortia?

    A. Each Oversight Panel's membership will be constructed based on the expertise needed for each consortium. There may be individuals who serve on more than one panel because of their expertise, but there is no specific plan to do so.

39. If we identify someone to serve as an external advisor for our consortium, would it be inappropriate for them to also serve as a member of the Oversight Panel?

    A. If you choose to set up your own internal or external advisory board, it would not be appropriate for that individual to also serve as NYSTEM's advisor through the Oversight Panel for your consortium.

40. Are consortia budgets expected to absorb the cost of Oversight Panel members?

    A. No. Oversight Panel members will be compensated through the separate Consortia Oversight contract that NYSTEM will be entering. Also see the double asterisk (**) in the instructions for completing Budget – Form 8 in Section V.B. of the RFA with regard to meeting costs.

Application Forms

41. Part One Forms 2-4 are fillable and won't allow insertion of figures and Greek symbols. Can we make identical-looking forms and use them instead?

    A. As a result of this question, Part One Forms 2-4 were revised and re-posted. An e-Alert was sent out on 9/30/11 notifying interested parties of the need to download the updated forms.

42. Will Part One be peer-reviewed right away so that applicants will be notified whether Part Two will be accepted or will Part One serve only as an administrative review and reviewer selection phase?

    A. No. Parts One and Two will be peer-reviewed at the same time, as one whole application. The primary reason for requesting Part One is to allow sufficient time to gather the highest-quality reviewers for the full applications based on the content of Part One. Secondarily, Part One Form 4 should serve as an assessment for the applicants that the application is appropriate for this funding mechanism and is likely to be considered responsive to the RFA (see Section V.A.).

There will be no "invitation" to submit Part Two. There will be an Administrative (Pass/Fail) review for both Parts (see Attachment 1B and Attachment 2B). All Part Two applications that "pass" the administrative review that were preceded by Part One applications that also "passed" the administrative review will be forwarded together as one package to the peer reviewers. The only notification between submission of Parts One and Two will be to provide either an application number to be included in the Part Two application or a notification that Part One did not "pass" administrative review and that therefore, a Part Two application will not be accepted.

43. For Part One, Form 2, are literature citations allowed on a different page, must they be included in the three page limit, or should they not be included?

    A. Part One Form 2 is a Project Overview. If you choose to include citations on this form, they would be counted toward the page limit.

44. What is the New York State Vendor ID number required on the Face Page?

    A. This is a new requirement of the Office of the State Comptroller. All entities that do business with New York State will need to have this number. In essence, it will be used by New York State in lieu of the organization's Federal Employer Identification Number (FEIN). This change is tied to the conversion of the current financial system to a single Statewide Financial System. That systems conversion is expected to "go live" January 1, 2012.

45. How should the 40 page workplan be structured, like an NIH P01 where each project is separate?

    A. This is not a program project or center-type of award where separate but inter-related projects are done under one umbrella. The application and the workplan should "present a coherent, goal oriented project."

<u>Budget</u>

46. How much budget justification is necessary?

    A. Form 7 requires that the application **describe and fully justify all elements of the budget.** Also see the instructions for completion of the form in Section V.B. and budget review criteria in Section VI.D.

    Starting with personnel, fully justify amounts requested in each budget category. Regardless of whether financial support is requested, describe the roles and expected contributions to the project of the PI and other staff involved in the project.

In addition, provide a detailed justification for each 'Other Than Personal Service' (e.g., supplies, equipment, travel, consultant costs and other expenses).

47. Are we expected to justify each annual budget or just Year One?

    A. Justify the budget lines for each year. The instructions for completion of the Personal Effort and Budget Justification – Form 9 state "For each budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered…"

48. How is the budget scored?

    A. See Section VI.D., of the RFA for budget review criteria. Budgets are critically analyzed by peer reviewers just as are the scientific aspects of the applications. Peer reviewers are given very specific guidance consistent with the review criteria for the Budget score.

49. For our project, we will need large quantities of specific drugs to be manufactured for testing. Would this be considered an eligible expense?

    A. Yes.

50. Should we assume a 3% increase each year? And will the contract budgets be increased by NYSTEM each year during the contract?

    A. Ask your grants office what they anticipate in terms of actual increases for each budgeted line and use those in the application budget. There will be no increases to contract budgets by NYSTEM during the contract term.

51. What about the salary cap? Will it be adjusted throughout the contract term?

    A. No. The RFA states "No individual salary rate paid through this award will exceed $199,700 for the term of the award.

52. In Section V.B. of the RFA, there's a table in the instructions for completion of Budget – Form 8. Is that a sample?

    A. No. The amounts listed there are annual caps to the amounts that can be requested in each budget year.

Awards and Contracting Process

53. Section VI.A. references a set of mandatory requirements and refers to Attachments 1B and 2B. Would you explain this process?

    A. After application parts are received, they are inspected for the mandatory elements listed at the top of those attachments. 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. If Part One is not forwarded for peer review, Part Two will not be forwarded for peer review.

54. Is there an appeal process if Part One or Part Two of our application is deemed to have "failed" the administrative review?

    A. Yes. Administrative rejection of an application could be challenged through an appeal to the Director of Extramural Grants Administration. If necessary, that should be done quickly so that if the decision is reversed, the application can get to peer review quickly.

55. How does the peer reviewer process work in terms of selection and conflicts of interest assessments? Will we have the opportunity to identify competitors and others who may have bias or conflict of interest?

    A. NYSTEM contracts with the American Institute for Biological Sciences (AIBS), which identifies reviewers and manages the peer review process. Peer reviewers are selected world-wide for their specific expertise and are approved by NYSTEM. AIBS has an extremely high standard and intensive process for identifying and eliminating the potential appearance of conflicts of interest and/or bias. As such, applicants do not have the ability to recommend panelists or identify conflicts of interest among potential panelists for NYSTEM RFAs.

56. Will the peer reviewers meet in person of via teleconference?

    A. We anticipate that the panel members will meet in person to review applications submitted in response to this RFA.

57. How are penalties assessed and for what types of infractions? Will the wrong font, for example, disqualify my application or result in a penalty?

    A. Penalties are applied by AIBS, upon the review and approval of NYSTEM, after the peer review scoring is completed. The bottom section of Attachment 2B lists the items that will result in a penalty (font is not one of them).

58. When should we expect the peer review to take place and for the Funding Committee to vote on the awards?

    A. Specific dates will depend on the number of applications and the length of time it takes to complete peer review. However, the peer review is expected to take place

in the spring of 2012 and the Funding Committee vote is expected in the fall of 2012. Meeting notices are sent to those who have signed up for e-Alerts at http://stemcell.ny.gov/sign_up_ealerts.php and elected to receive Event Announcements. The meeting agendas are posted on the website at http://stemcell.ny.gov/events.html.

59. Will there be a site visit or "reverse site visit" as part of the peer review process?

    A. No.

60. When will the applicants know the Part One application is accepted or not?

    A. In Section VI.A. of the RFA, notifications of disqualification or application number assignments (acceptance) may be anticipated within two weeks of the submission date for Part One.

61. When will the peer reviewers receive Part One of our application for review?

    A. Part One and Part Two will be sent to peer reviewers at the same time. Part One applications will first be examined against mandatory Pass/Fail requirements by NYSTEM administrators. Each eligible Part One application will be forwarded to the Peer Review Contractor (AIBS) to identify potential peer reviewers.

62. Is there any preference given to clinical versus earlier translational work or to the kinds of projects that cannot be funded by other sources?

    A. No such preference has been articulated by the Funding Committee, and no such preference is embedded to the application evaluation criteria stated in Section VI.D. of the RFA.

63. How much latitude does the Funding Committee of the Empire State Stem Cell Board have in making award recommendations and "programmatic adjustments"?

    A. Applications that do not attain a score of 2.5 or better will not be considered for award. Also, there is a process for reconciling scoring ties. Further, they can consider responsiveness to the mission of the board, responsiveness to the RFA, programmatic balance and other items in making recommendations for award (see Section VI.E. of the RFA).

64. How long will it take to get feedback from peer reviewers? When will we be given their names? When will an official notice of award be sent?

    A. After the Funding Committee meeting recommendations are made, critiques will be sent to the PIs, without scores. Panel member rosters will be sent at that time. Several administrative approvals to enter into a contract are needed before formal letters of award/regret can be sent from the Extramural Grants Administration office. These approvals generally take six to eight weeks. With that formal correspondence, the PI will receive a complete copy of the critique, including

scores. The letter of award is not a guarantee of funding; a contract must first be executed before funding is provided.

65. 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.

66. Are copies of sub-awards/sub-contracts required to be submitted with the application or at time of award?

    A. No. NYSTEM does not need to review or approve subawards (other than budget and workplan, signed face page and related portions required in the application) or subcontract language.

67. Are we able to negotiate our own subaward language?

    A. Yes. There is language in our contract that should be incorporated to subawards. It can be made more restrictive and additional language can be added (e.g., intellectual property sharing agreements, etc.) but it cannot contradict the NYSTEM contract. Subaward language may be reviewed by NYSTEM as part of monitoring at a later point during the contract term.

68. Will NYSTEM contract directly with each of the consortium partners and accept vouchers and progress reports from each partner separately, or will the applicant institution be required to establish subawards with each partner and manage them collectively?

    A. NYSTEM will contract only with the applicant institution. The applicant institution will be responsible for establishing subawards, and for submission of a consolidated progress report representing the full scope of the consortium's work for the reporting period. Vouchers from the applicant institution will include the verified expenditures of subcontractors for the reporting period.

69. Is there any pre-spending allowed?

    A. No. Awardees will not be eligible to submit expenditures incurred prior to the contract start date.

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

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

Post-Award

71. Could the contract be terminated or reduced if the fiscal environment worsens?

    A. Yes, the contract provisions do allow for that.

72. 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 March 1, 2013. 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.

73. 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 and none are guaranteed. A formal contract amendment process, which is both lengthy and time-consuming, is generally necessary. Careful budgeting and consideration of institutional support prior to application submission should reduce the need for contract amendments. Specific aims and milestones that are able to be accomplished within each year of the four-year award period will also be key to reducing the need for carry forward and no cost extension requests. Any proposed modification which results in a change of greater than 10% to any budget category for a budget period ultimately need Office of the State Comptroller (OSC) approval which can be a lengthy process.

74. How will Oversight Panel recommendations be dealt with in terms of budget modifications, etc.?

    A. Oversight Panel recommendations will be forwarded to NYSTEM. If NYSTEM agrees that a budget modification and/or a change in aims is necessary, that agreement will certainly support the request and should help to expedite it, but a delay in the execution of the amendment should still be anticipated. Essentially, the contractor will need to assume the risk of not being paid if the amendment cannot be executed and continue to work so that the contract milestones can be met.

75. Can we move money between budget years?

    A. Carry forward requests will be considered but may not be approved. It is not permissible to move funds from a future year "back" to an earlier (or current) year.

76. If the Oversight Panel recommends a no cost extension or continuation with additional funding (supplemental funding) for the contract, will that be honored?

    A. All recommendations of the Oversight Panel will be vetted by NYSTEM Scientific and Contract Management staff. Continuation with additional funding, without requiring a new RFA and competition, is an extremely rare event and requires extensive justification. Applicants should expect to finish up funded projects within the four-year contract term.

77. Will there be another round of funding offered to continue successful consortia contracts?

    A. That decision has not yet been made.

78. What kind of reporting is required?

    A. See Section III.C. of the RFA. Quarterly vouchering is required. Progress report due dates will be different for each consortium based on interactions with the Oversight Panel. Progress reports involve Oversight Panel and NYSTEM review. Due dates will be based on milestones and will be firmly established at the first meeting of the consortia and oversight panel. The PI and appropriate staff will also be required to attend and participate in on-site monitoring visits, and annual visits and other necessary Oversight Panel activities and meetings. The PI and Co-PI(s) will be required to travel to and participate in the NYSTEM annual meeting.

79. Where will the NYSTEM annual meetings be held and must the Project Manager attend?

    A. The meeting location and venue is not established beyond the year 2012. The RFA requires the PI and any Co-PI(s) to attend. If you believe that additional consortium members should attend, you may include funding for that in your budget. Be sure to justify it.

80. How much time will we have to voucher?

    A. Vouchers for this contract will be due 60 days after the end of each quarter.

81. We understand that NYSTEM will contract directly with the applicant institution and that all subawards will have to voucher and report through us to NYSTEM. But do we need to pay our subaward vouchers before we can include them in our voucher to NYSTEM?

    A. Yes. The contract is paid on a cost-reimbursement basis. All payments made by the applicant institution to the subawards should follow be consistent with the contracting institution’s policy and be in compliance with federal grant requirements found in Office of Management and Budget (OMB) circulars A-21, A-110 and/or A-122 as applicable.

MODIFICATIONS TO FAU # 0911051012

1. Part One Application Forms 2-4.doc was re-posted to the internet on 9/30/11 at http://www.health.ny.gov/funding/rfa/0911051012/index.htm following identification of a technical difficulty in completing the forms. An e-Alert was issued to notify prospective applicants of the need to download these forms.

2. A second set of Questions, Answers and Updates has been added to the RFA process. Additional questions may be submitted by January 10, 2012. Questions, answers and updates or modifications to the RFA will be posted on or about January 17, 2012.

Consortia to Accelerate Therapeutic Applications of Stem Cells
FAU # 0911051012

QUESTIONS AND ANSWERS AND MODIFICATIONS – SECOND SET
Accepted October 26, 2011 through January 10, 2012

1. We expect to have made some significant additional findings between the application deadline and the start of the contract. Will there be an opportunity to submit that information for consideration of peer review?

   A. We are unable to accept additional information after the deadline. Also see Q&A # 7 below.

2. At the time of application, are we expected to have fully-established all agreements for sharing of intellectual property, data and resources among the participating organizations?

   A. While having such agreements established in advance is likely to strengthen the score for the related evaluation criteria, this is not a specific requirement of the RFA. See the instructions for completion of application Form 13 – Workplan, Section f, and the Review Criteria in Section VI.D. of the RFA.

3. Our consortium members have several NIH R01 awards that can be leveraged to strengthen the consortium research. There will not be overlap in aims, but findings from R01s will be incorporated to advance the work of the consortium. Is that allowable?

   A. Yes.

4. We anticipate that there will be opportunities to license and patent various technologies along the way to developing the final product that is the focus of our consortium. Is that allowable?

   A. Yes, provided that the terms of the contract regarding intellectual property (see Appendix C of the Sample Grant Contract, Attachment 4 to the RFA) are met.

5. Will the Oversight Panel also function partially as an advisory panel? We would like to have our own Internal Advisory Committee that we select, as well as an internal Data Safety Management Board (DSMB). We would need to compensate the members for travel and time. Would this be acceptable?

   A. The Oversight Panel will advise NYSTEM and the consortium about a variety of topics (see Section III.A., General Expectations, of the RFA). If you choose to set

up your own internal (or external) advisory board and/or DSMB, you will need to justify their roles and related expenses in the application.

6. Where will meetings of the Oversight Panel take place?

   A. Meetings of the consortium with the Oversight Panel are expected to be "held within the facilities of the consortium member institution most appropriate to the milestone(s) under review…" (see Section C of the RFP "Scientific Oversight of Stem Cell Consortia" posted at http://www.health.ny.gov/funding/rfp/10003250404).

7. We expect to have made some significant additional findings between the application deadline and the start of the contract. Will there be an opportunity to submit that information?

   A. We are unable to accept information after the deadline for the purposes of peer review. However, after letters of award are issued and the contracting process has begun, NYSTEM **may** request scientific updates to share with the Consortia Oversight Contractor. These updates will be used to ensure that membership of the Oversight Panel is consistent with research advancements made after the application deadline.

8. We have been ironing out the details of our experimental design and find that we need a large portion of our budget to go to another institution that is applying for a different project. We see this as an essential part of the success of the research project. Will the reviewers see this as trying to get around the requirement of one application per institution?

   A. When evaluating the applications, the reviewers will follow Sections VI.B and D and the board will follow Section VI.E. of the RFA. It is advisable for the application to clearly demonstrate that the best team and resources have been assembled to accomplish the research goals.

9. The RFA states "It is expected that applicants will have previously established proof-of-principle data to support the feasibility and timeliness/readiness of the proposed project. Because GLP and GMP will be necessary for development of clinical therapies and devices, it is expected that the experimental design and implementation will be carried out in accordance with those GLP and GMP standards."

   During a pre-pre-IND meeting with the FDA, we were advised that our pre-clinical studies, as we described them, can be conducted under GLP standards. Will NYSTEM require more rigorous standards than that required by the FDA in the conduct of NYSTEM-funded studies? Would we need to provide documentation of the FDA's guidance on this issue in our application?

   A. No. As stated in Q&A #26 in the first round of Questions and Answers posted for this RFA, NYSTEM expects that the experimental design and implementation will

meet the FDA's standards. It is advisable to justify experimental design decisions and to provide supporting documentation where possible.

MODIFICATIONS TO FAU # 0911051012

There are no additional modifications to this RFA. **Also see** Questions, Answers and Modifications to the RFA posted previously at:
http://www.health.ny.gov/funding/rfa/0911051012/