38 Questions & Answers and *Modifications*
to RFA #0804180400
Investigator Initiated Research Projects and Innovative, Developmental or Exploratory Activities (IDEA) Awards for Stem Cell Research

NOTE: These questions & answers and modifications supersede any previously received written or verbal responses.

Letter of Intent

1. The Letter of Intent form is posted as a .pdf file. Is it available in another format?
   Yes. The Letter of Intent form was reposted to the DOH web site as a Microsoft Word (.doc) document Monday, May 12, 2008. It can be downloaded from: http://www.health.state.ny.us/funding/ .

2. The Letter of Intent form and instructions do not indicate where I should include the research project title and summary paragraph of the proposed research. What should I do?
   Only complete the information requested on the Letter of Intent form. Information regarding the title and scope of the proposed research should not be submitted.

3. Can I add additional pages to the Letter of Intent form if I do not have room to list all my collaborators?
   Yes. Be careful to retain the signature boxes and have the Letter of Intent signed.

4. The Letter of Intent form asks for the primary contact at a collaborating institution. Should this be the senior scientist involved?
   Yes. The primary contact person should have knowledge of the proposed application and the intent to form collaboration should funding be approved.

5. If I file a Letter of Intent, do I have to file an application?
   No. Filing a Letter of Intent does not require submission of an application (see page 5 of the RFA).

6. When is the Letter of Intent due and is it mandatory to file a Letter of Intent?
   The Letter of Intent is due May 28, 2008 by 1 PM and must be filed and accepted before an application can be filed in response to the RFA (see page 5 of the RFA).

7. How will I know if my Letter of Intent was accepted?
   The submitting Principal Investigator will receive written (e-mail) acknowledgement from NYSTEM indicating:

- **Accepted Letters of Intent – notification will include assigned application number(s) to be used when filing the application(s) (see page 5 of the RFA); or**
- **Declined Letters of Intent (received after the due date or not properly signed) – notification will include reason for the declination.** ***This answer represents a modification to the RFA.***

8. What if the applicant institution decides to change the Principal Investigator after the Letter of Intent is filed?
   If the applicant institution decides to change the Principal Investigator after the Letter of Intent is filed, the institution must notify NYSTEM in writing prior to or at the time of application (see page 5 of the RFA).

9. Can you define a collaborator?
   A collaborator is any individual outside the PI's laboratory who will be participating in or contributing to the research project. This individual can be within the applicant institution or from another institution, and may or may not receive funding support.

10. Can a collaborator be from outside New York State or from outside the United States?
    Yes.

11. Where do I send the Letter of Intent and to whom should it be mailed (couriers generally require a name)?
    Letters of Intent can be addressed to the attention of Michael Heeran and should be mailed to:

    Regular mail (US Postal Service only):
    New York State Department of Health
    Wadsworth Center, Room D350
    Extramural Grants Administration
    Empire State Plaza
    PO Box 509
    Albany, NY 12201-0509

    Courier (Express Mail Services and any non US Postal Service carrier):
    New York State Department of Health
    Wadsworth Center, Room D350
    Extramural Grants Administration
    Empire State Plaza
    Dock J – P1 Level
    Albany, NY 12201-0509

12. For mailing purposes, can I bundle a Letter of Intent from this RFA with Letters of Intent from other NYSTEM RFAs from my institution that are due on the same day?

Yes. Be sure to include the appropriate number and types of Letters of Intent as directed in each RFA (see Attachment 4 to each RFA). However, note that the due date of the Letter of Intent for RFA #0802071100 (Planning Grants for Emerging Opportunities and Consortia Development for Stem Cell Research) has been extended to June 4, 2008, while the due dates for the other NYSTEM RFAs have not been extended.

13. I do not know yet if I am filing an IDEA or an Investigator Initiated application. What should I do?
    File a Letter of Intent with both boxes checked to indicate this uncertainty. However, upon submission of the application, a single funding mechanism must be identified for the application. *This answer represents a modification to the RFA.*

14. Do I need separate Letters of Intent with signatures for each application I intend to file?
    No. Please file one Letter of Intent per PI (see page 5 of the RFA). On the form, indicate the number/types of applications the PI intends to submit. Include all collaborators from each intended application on the Letter of Intent form.

General Questions

15. What is the difference between RFA 0804180400 and RFA 0804221050? They both discuss investigator initiated and IDEA applications and the instructions from page 3 on seem to be the same)?
    RFA 0804180400 is open to all stem cell related research, while RFA 0804221050 is specific to iPS and other derivation approaches.

16. Is it possible for one PI to submit more than one grant in the same category (e.g., two IDEA grants or two investigator-initiated), and/or to participate in more than one grant from different categories (e.g., consortia and independent investigator)?
    Yes, provided that the research projects are separate and distinct. The applicant should be aware that there is a minimum of 20% effort required of the PI for each application.

17. With respect to Facilities and Administrative costs for subcontracts, does the same 20% maximum apply?
    Yes. Subcontractor F&A costs are likewise limited, and must be included in the applicant's direct costs.

18. Form 1: If there is not an DHHS Agreement for the F&A rate, what information is required for documentation and in what format should it be presented?
    The RFA states "In the absence of a DHHS agreement, an equivalently documented rate for the organization may be used." An institution's

Certified Financial Statements could be submitted if other documentation does not exists.

19. Form 1: If the institutional affiliation of the Co-PI is different from that of the PI, a second face page must be completed. On that second face page, should all the information on the second page pertain to the Co-PI¹s institution - for example, the Co-PI institution¹s federal employee number or the Co-PI institution¹s F&A rate?

    Yes, all information on the Co-PI's face page should be specific to the Co-PI, the Co-PI's institution, and the work the Co-PI is putting forth on the research project.

20. Forms 3&4: I understand the scientific and lay summary pages are one limited to the space available. However, do you want me to adhere strictly to the current sub-division of these spaces into Background, Hypothesis etc, or is there flexibility as to the amount of space I give each subdivision?

    There is flexibility to the amount of space you use for the subdivisions, but the applicant must adhere to the overall page limits of the forms.

21. In Form 5, Program Responsiveness, I understand that we have to elaborate on how our application contributes to ESSCB's goals and serves in the best interest of New York State, within a one-page limitation. Is this similar to what the Significance subheading in the Work Plan, which addresses how our study will contribute to "advance stem cell biology or development therapies," with the addition of "future plans to bring anticipated research results to the next developmental stage in an effort to speed development of potential therapeutic applications"?

    The Program Responsiveness form should specifically address the goals and objectives of the Empire State Stem Cell Board (ESSCB) as stated in the RFA. Further information on the goals and objectives can be found by reviewing the draft strategic plan currently posted on the NYSTEM web page at: http://www.nystem.org/. The significance section of the Work Plan should address the significance of the research as it relates to the contribution to and advancement of the field.

22. Form 6 (the Subcontractor Personnel Effort and Budget Justification): should one provide a detailed listing of line items or is it meant to be a narrative?

    Both. The table needs to be filled out and narrative completed as described on the form.

23. For Form 7- Budget Justification if the key personnel and technical staff do not request financial support, should their role in the project still be justified? Also, do we need to provide descriptions for each “Other Than Personal Service” expense (for example, if we are using antibodies for immunohistochemistry, do we provide a list of each one to be used and for what purpose or is that too detailed)?

Key personnel should be listed regardless of their level of compensation. OTPS expense justification should be given in enough detail to enable the reviewers to assess the budget in relation to the Work Plan.

24. In Form 12 - Time Line and Collaboration Strategy, is there a page limit for the description of "strategies for information and/or resource exchange to ensure the efficient and effective completion of project"?
    No.

25. For Form 14- Vertebrate Animals, what is the level of detail necessary? I understand that there is no page limit for this section and we need to address the four points mentioned on pgs. 18-19 in the application form description. Should the level of detail be similar to what would be included in an IACUC protocol application?
    The responses to the four points should provide the reviewers with sufficient material to judge the merit of this aspect of the proposed project.

26. Where can I get the application forms?
    The Microsoft Word document forms can be downloaded from: http://www.health.state.ny.us/funding/ . Forms are specific to each RFA.

27. What are the margin requirements on the application forms?
    Applicants must adhere to the margin requirements as set in the application forms. Using the forms as posted at http://www.health.state.ny.us/funding/ without modifying the margins is strongly advised. Most, not all, margins are 0.5" top/bottom and 0.6" left/right.

28. Is there an official goal or mission statement for the Empire State Stem Cell Board?
    No. Currently the Board has not adopted an official mission statement. However, the Empire State Stem Cell Board draft strategic plan can be viewed at: http://www.nystem.org/.

29. Is there a page limit to the Work Plan?
    Yes. The Work Plan is limited to ten pages, including text and figures. References are not counted against Work Plan page limitations, nor are the number of references restricted. See RFA page 20.

30. Is there a percent effort requirement for a Co-PI?
    No.

31. Can an investigator who is in the process of getting their green card be a PI?
    Yes, as long as the investigator is an employee of the institution.

32. There is a 20% effort requirement for IDEA awards. Does this 20% need to be reflected in the PI's salary budgeted to the project?

    No. The Personnel and Budget justification form (Form 6) has columns which allow you to show percent of FTE on the research project and percent of FTE salary charged to the project. The percent of FTE "On Project" must be at least 20% for the PI, while the percent of FTE for "Salary Requested" can be less if the salary costs are being paid from another source.

33. We are a non profit (or public) institution that manages external grant funds on behalf of the institution that employs the PI. Does the PI meet the criteria of being "employed by the applicant institution" in this case?

    Yes. For purposes of this RFA, the PI can be considered an employee of the applicant institution.

34. Can the NIH "Biographical Sketch", "Facilities and Resources", and "Other Support" forms be pasted directly into the application (as they are identical to yours), or do these need to be retyped into your form?

    The forms provided for the RFA should be used.

35. Does an individual need to be an employee at the time of application or as of the contract start date?

    The PI needs to be an employee at the time of application.

36. Would there be an opportunity to submit additional material (e.g., supportive data) for the award subsequent to the submission deadline of the complete application?

    No. All material must be submitted by the application due date and time.

37. Do you require subcontracts to reimburse collaborators for their time and effort related to the research project?

    No. There are no specific requirements requiring subcontracts to be in place. The policies and procedure of the applicant institution should be followed in these matters.

38. Can someone on sabbatical from an out of state Institution who is working full time in our Institute with the position of visiting professor qualify as a PI? Does the position and time commitment suffice for "employee" status in the absence of payment?

    Yes, as long as the policies of both the home and visiting institution do not conflict with the RFA in this regard.