Peter T. Rowley Breast Cancer Scientific Research Projects
FAU # 1003251030

QUESTIONS AND ANSWERS
October 19 – November 15, 2011
Including an applicant conference

General

1. How many applications were received in the last funding round, how many were funded, and what types of projects were they?

   A. In 2009, 22 applications were received and 8 were approved for funding. There were many topic areas, including basic research, epidemiological studies and translational research. The Health Research Science Board recommends the most meritorious applications for funding. A listing of the awards is listed on the program website at http://www.wadsworth.org/extramural/breastcancer/.

Letter of Intent and Pre-application

2. How do I submit a letter of intent?

   A. Please use Attachment 4 of the RFA and follow the instructions given in Section IV.C. of the RFA.

3. When is the Letter of Intent due?

   A. The Letter of Intent form (Attachment 4) is not mandatory but is **strongly recommended** and will aid in developing the peer review panels. Letters of Intent should be received by the due date (November 15, 2011 by 4 pm). See Section IV.C. of the RFA.

4. Do we need to include any information (e.g., the title of the proposed project) in addition to the Letter of Intent form?

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

5. Who should we list on the Letter of Intent form?

   A. Identify all participants involved in the proposed project, 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. Sections may be added, if necessary, to list all participants.

6. If I didn't submit a Letter of Intent, can I still apply?

   A. Yes, you may still apply. A Letter of Intent is not mandatory.

7. What is the purpose of Letters of Intent?

   A. Letters of Intent provide the program with a rough estimate of the number of applications to expect and helps determine if an in-person or an on-line peer review meeting should be held. It also allows the program to begin to evaluate potential conflicts of interest.

8. What is the purpose of the applicant conference? Do I have to attend if I plan to submit an application?

   A. The applicant conference is described in Section IV.D of the RFA. It is an opportunity to receive an overview of the RFA and ask specific questions that might facilitate completion of the application forms or the competitiveness of the application itself. There are no scientific presentations; the first part is a presentation about the RFA and the program, and the remainder is an opportunity to ask questions and listen to the answers given to the questions of others. Attendees can learn a lot about the program that will help with application and management of contract awards. Prospective applicants do not have to attend in order to apply.

<u>PIs, Co-PIs, Co-Investigators and Collaborators</u>

9. Can I be a Principal Investigator (PI) on one application and a Co-PI on a different application?

   A. Yes, as long as they are separate projects.

10. Can a Wadsworth Center or other NYSDOH researcher be a collaborator or subcontractor on an application?

    A. Yes.

11. Can a collaborator be from outside of New York State?

    A. Applicants for Rowley funding must be New York State institutions. However, those institutions are permitted to subcontract with collaborators world-wide.

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

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

Submitting the Application

13. What is the application due date and time?

    A. The application must be received by 4 pm on December 16, 2011.

14. When do requests for exceptions to the contract have to be submitted?

    A. Requests for exceptions to the contract must be submitted before the application is submitted.

15. Do you allow resubmission from previous submissions?

    A. Yes. Concerns raised from previous peer review should be addressed in the resubmission.

16. What size should the application electronic files be?

    A. The size of the electronic file should be less than 12 MB.

17. If my project will be for less than 24 months, can I still apply for the full amount of funding?

    A. Yes, as long as adequate justification for the budget is provided.

Subcontractors in the Application

18. Do I need to fill out a separate face page on my application for subcontractors and consultants?

    A. A separate face page should be filled out for each subcontractor. If your consultant is being paid as a subcontractor, a separate face page will be needed.

Scope and Content of the Proposed Research

19. My project is for an observational study – does it qualify for funding?

    A. Yes. Section I.B. of the RFA states that applications may address any topic or issue related to breast cancer biology, causation, prevention, detection or screening, treatment (including treatment of its effects), survivorship or cure. Any investigative approach appropriate to the application topic may be pursued, including, but not limited to, basic, translational, clinical, demographic, epidemiological, environmental, behavioral or psychosocial research.

20. The RFA states that preliminary data are not required, but if I have some, is it a good idea to show it?

    A. Yes. While Rowley applications do not require preliminary data, if you have preliminary data, you should provide it in the application.

21. Does this funding mechanism provide funding for ongoing projects?

    A. No, funding in the program is limited, so there is not enough money to provide funding for long term projects.

Application Content and Forms

22. Can I use NIH forms or revise the provided forms in my application?

    A. You cannot use NIH forms or revise the provided forms. Failure to use the correct application forms and instructions for the RFA will result in a scoring penalty.

23. On Form 1, what is the New York State Vendor ID Number and where do I get one? Am I required to have this number before application submission?

    A. Effective January 1, 2012, in order to do business with New York State, you must have a vendor identification number. As part of the Statewide Financial System (SFS), the Office of the State Comptroller's Bureau of State Expenditures has created a centralized vendor repository called the New York State Vendor File. In the event of an award and in order to initiate a contract with the New York State Department of Health, vendors must be registered in the New York State Vendor File and have a valid New York State Vendor ID.

    If already enrolled in the Vendor File, please include the Vendor Identification number on the application cover sheet. If not enrolled, to request assignment of a Vendor Identification number, please submit a New York State Office of the State Comptroller Substitute Form W-9, which can be found on-line at: http://www.osc.state.ny.us/vendors/substitute_formw9.pdf .

    Additional information concerning the New York State Vendor File can be obtained on-line at: http://www.osc.state.ny.us/vendor_management/index.htm, by contacting the SFS Help Desk at 855-233-8363 or 518-475-7717 or by emailing at helpdesk@sfs.ny.gov.

    Yes, this number is required on Form 1.

24. What is the purpose of the Lay Abstract?

    A. The Lay Abstract (Form 4) is used for the peer reviewers, the program website, and biennial reports.

25. Do I need to provide proof of compliance protocol approval as part of the application? What if the protocol is still pending?

    A. No, proof is not required at time of application; simply write “pending” on the appropriate compliance protocol form on the application. Proof of all necessary protocol approvals will be required at time of notification of award and must be in place, for any activities that are expected to take place in Year One, at time of award. Delays in submitting protocol approvals to the program will cause additional delay in contract execution (also see Award and Contracting Process, below).

26. Should consultant bios be provided in the application?

    A. Anything that would help reviewers understand what is being done and why should be included in the application.

27. Should consultant charges be documented in the application?

    A. Yes, you can add a letter of support and commitment in the appendices.

<u>Budgeting</u>

28. How much budget justification is necessary? And is it required for the Year One budget only?

    A. Justify the budget lines for each year. The instructions for completion of the Personal Effort and Budget Justification – Form 8 state “For each budget line, provide sufficient detail to demonstrate that specific uses and amounts of funding have been carefully considered…” Be sure to include salary and fringe increases in your budget.

29. Do supplies need to be itemized in the budget?

    A. No, use general categories in your budget.

30. How much time should be budgeted to attend a Health Research Science Board meeting?

    A. Board meetings could be held anywhere in the State. Be sure to plan for one overnight stay.

31. Is the budget a modular budget, as is used by the NIH?

    A. No, the budget in the proposal needs to be as accurate as possible.

32. For equipment purchases, how many quotes are needed from vendors?

    A. Follow your institutional policies, and include a reasonably accurate estimate of the equipment cost. Quotes can be added to the application appendices.

33. Can equipment maintenance be added to the budget?

    A. Yes, but adequate justification needs to be provided.

Peer Reviewers

34. Are peer reviewers selected after application submission?

    A. Yes.

35. How are peer reviewers selected? Do peer reviewers represent the types of applications received?

    A. The Panel members will be selected from among non-New York State experts in the appropriate fields based on the nature of the applications received (see Section VI.B.)

36. How are peer review meetings held?

    A. Meetings are held either in person, by videoconference or by teleconference.

37. Will every application be reviewed by a consumer reviewer?

    A. All applications that pass the administrative review will be reviewed by a consumer reviewer.

38. Do peer reviewers ever comment that a PI isn't budgeting enough time for a project?

    A. Yes, generally peer reviewers evaluate a PI's effort and level of commitment on a proposal.

39. Do study sections decide what gets funded?

    A. No. The peer reviewers score the applications, the Health Research Science Board makes recommendations on funding, and ultimately the NYSDOH approves or disapproves funding.

Awards and Contracting Process

40. When will the Health Research Science Board meet to make recommendations on awards? Will the meeting be posted on the website?

    A. We expect that the Board meeting will be held in Spring of 2012. The meeting will be posted on the website. To be automatically notified of the meeting, sign up for e-Alerts at http://www.wadsworth.org/extramural/breastcancer/.

41. Will I get feedback from the review of my application? When will an official notice of award be sent?

    A. Critiques, without scores, will be sent to applicants following the HRSB meeting where recommendations for award are made. Several administrative approvals are needed before formal communications and critiques with scores can be sent from the Extramural Grants Administration office. These approvals generally take six to eight weeks. Upon receipt of those approvals, letters of award or regret will be sent to the PI and the Grants Official from the applicant institution. With that correspondence, the PI will also receive a copy of the reviewer critiques, scores, summary statement and review panel roster. The letter of award is not a guarantee of funding; a contract must first be executed before funding is provided.

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

    A. A determination about when to re-issue the RFA has not been made. The future RFA will indicate whether resubmissions will be accepted.

43. How long does it take for the contract to be executed? What can I do to facilitate contract execution?

    A. The estimated contract start date is January 1, 2013. Upon receipt of the letter of award, it could take six months or more for the contract to be executed. To facilitate contract execution, PIs should gather documentation including any required IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) and ESCRO (human pluripotent stem cell) approvals. At the same time, Grants Offices should complete/update the Vendor Responsibility Questionnaire (see Section IV.I.) and get the Workers' Compensation and Disability Insurance forms (see Section IV.K.) ready for submission/return with the signed contract. Then, the institution can sign and expeditiously return all necessary documents to the Department of Health.

44. How long do you allow for providing required IRB (human subjects), IACUC (vertebrate animals), IBC (recombinant DNA) documentation?

    A. We recommend that these documents be provided as soon as possible, generally within two weeks of notice of award.

45. Can I count on receipt of the funds in this fiscal/economic environment? Is there a chance that, although recommended for award, the contract will not be executed?

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

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

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

47. Will taxpayer donation money continue to be matched by the State?

    A. We expect the State match to continue, unless legislation is passed that eliminates the State match.

48. Are “no cost extensions,” “carry-forwards” and “budget modifications” allowed?

    A. They are allowable under the contract but each must be formally requested in advance of the need and none are guaranteed. A formal contract amendment process, which is both lengthy and time-consuming, is generally necessary and could result in a period of time when funds are not available. Careful budgeting in the application should reduce the need for contract amendments.

49. If a key piece of equipment breaks down and I haven’t budgeted for it and need to request a budget modification, how much time does it take to get approval?

    A. It could take six months or more and there is no guarantee of approval, so it is very important to provide a well thought out budget in your application.

50. If I have to move money from one line to another, what is the process?

    A. If the requested change is less than 10%, it can be reviewed at the program level; if it is greater than 10%, the request must be approved by the Office of the State Comptroller. This process could take several months.

<u>Post-Award</u>

51. What kind of progress reporting is required?

    A. Once the contract is executed, periodic written progress reports are required. See Appendix C of the sample contract provided as Attachment 5 to the RFA for the reporting schedule. Progress report forms and instructions are available on the website.

52. Are vouchers submitted monthly?

    A. Vouchers are to be submitted quarterly, as indicated in Appendix C of the sample contract provided as Attachment 5 to the RFA.

There are no modifications to this RFA.