



CALL FOR APPLICATIONS Southwest National Primate Research Center (SNPRC) Pilot Research Program 2016 Competition

Important Dates/Timeline: 2016 Competition

Investigator contacts prospective SNPRC sponsor	30 November 2015
Submit Letter of Intent (LOI)	4 December 2015
Submit Veterinary Resource Request Form	18 December 2015
Submit Completed Application	15 January 2016
Scientific Review Meeting	15 March 2016
Earliest funding start date	01 May 2016

PURPOSE

The SNPRC Pilot Research program provides opportunities and support for investigators to use SNPRC nonhuman primate resources in highly focused, short-term studies with a high likelihood of enhancing the value, utility, feasibility, and attractiveness of nonhuman primates for biomedical research. High priority will be given to studies that propose to generate preliminary data for applications to the National Institutes of Health (NIH) for support of future research projects. Those proposing to develop new nonhuman primate models of disease, or develop and/or test new research methods, instrumentation, or approaches for biomedical research using nonhuman primates, also will be considered responsive to the goals of the program.

PROGRAM GUIDELINES

Eligibility

Investigators at the Staff Scientist (Research Assistant Professor) through Full Scientist (Full Professor) or equivalent positions at institutions meeting the requirements to apply for, receive, and administrate grants in aid of research from the NIH are eligible to apply.

Sponsors

Any applicant who is not an SNPRC Core Scientist **must** be sponsored by an SNPRC Core Scientist. Here is a link to core scientists by <u>unit</u> or visit: <u>http://www.snprc.org/about/core-scientists</u>. The participation of the Core Scientist in pilot studies funded by this program is an NIH mandate. The role and responsibilities of the sponsor are described in detail in the NIH Guidelines for National Primate Research Centers (PAR-11-36). Per the Guidelines, the sponsor is responsible for:

- Actively assisting the in the PI planning and conduct of all pilot research projects.
- Supervising the management and monitoring the progress of the on-site (SNPRC) activities of the research project.
- Ensuring the submission of regular progress reports.
- Facilitating publication of results of the pilot study.

Page 2 of 6

Supported Activities/Allowable Uses of Pilot Research Program Funds

- All research activities related to the use of nonhuman primates must be conducted at the SNPRC.
- Pilot research funds may not be used to provide interim or extended support for extant projects funded by other sources.
- Total direct costs of a pilot research project may not exceed \$100,000 over two (2) years.
- The maximum duration of a pilot research project is two (2) years.
 - NIH does not allow Primate Research Center base grant funds to be carried forward to the subsequent year for the base grant (unlike with other NIH awards, e.g., R01 s). One-year pilot studies must be completed within the year of funding, and 2-year pilot studies must be completed within 2 years of funding.
- Funds awarded in support of pilot research must be used for SNPRC goods and services.
 - o Animals and animal care costs (including per diem)
 - Animal research procedures conducted by SNPRC personnel
 - SNPRC Core laboratory services
- Funds awarded in support of pilot research may not be used to cover costs of supporting laboratory personnel, supplies, or work carried out at off-site locations.

PREPARING AND SUBMITTING AN APPLICATION TO THE PILOT RESEARCH PROGRAM

There are several steps to the application process. They must be taken in the order presented below. **1. Identify and Enter into an Agreement with a Sponsor**

If PI is not a Core Scientist at the SNPRC, s/he must do this before completing any of the other steps (below) in the application process. Click <u>here</u> for list of SNPRC Core Scientists. *Note:* SNPRC Core Scientists need not obtain a sponsor.

2. Complete and Submit a Letter of Intent

The PI/Applicant must submit a brief (1½ page maximum) letter notifying the Coordinator of the SNPRC Pilot Research Program of her/his intent to submit an application for review at the next deadline. The purpose of this letter is to provide the Program Coordinator with sufficient information to begin identifying appropriate potential outside reviewers (i.e., those not affiliated with the SNPRC or Texas Biomed) whose participation will be solicited when the application is received.

Format:

1½ page maximum length, Arial or Helvetica 11-pt font, single-spaced, on the PI's/applicant's institutional letterhead.

Required information:

- Descriptive working title for the planned proposal
- Names, degrees, ranks, and institutional affiliations of the PI/applicant and sponsor (if applicable).
- A brief statement of the objective and significance of the intended pilot research
- A brief statement that very generally describes the design of the tentative research plan -including methodologies (e.g, qPCR, HPLC, MRI, etc.), and species to be studied. This can be a bullet-point outline or numbered list.
- A brief statement regarding the role that results from the intended pilot research will play in the support of future applications for research funding.
- A brief affirmation that the intended study does not overlap (duplicate) the PI's/applicant's currently funded research.
- The applicant or sponsor (if applicable) is encouraged to nominate one (1) investigator as a potential external (not affiliated with SNPRC) reviewer of the proposal. Please include the name, institutional affiliation, and contact information for an established, active researcher who has a record of publications and funded research with relevance to the proposed pilot research.
- Signature of the Pl/applicant and, if applicable, the sponsor.

Page 3 of 6

Letters of Intent should be sent as PDF files attached to an e-mail addressed to the current SNRPC Pilot Research Program Coordinator, Dr. Suzette Tardif (<u>stardif@TxBiomed.org</u>). Investigators are requested to please cc these documents and all other correspondence related to the Pilot Research Program to Ms. Deborah E. Newman (<u>dnewman@txbiomed.org</u>) and Ms. Wanda Altamira (<u>waltamira@txbiomed.org</u>).

3. Complete and Submit a Veterinary Resources Request Form to Obtain a Budget Estimate for the Proposed Pilot Research Project.

This form informs the SNPRC Research Resources staff of the investigator's plans and needs so that they (SNPRC's Research Coordination staff) can work with the investigator to develop a reasonably accurate, modular budget for the pilot study that will be included as part of the completed application.

- To ensure that this budget estimate can be made in time for it to be included in the completed application, the Research Resources Request Form must be submitted no later than Dec. 18, 2015.
- The form can be found at: <u>http://www.snprc.org/primates/research-resources-request</u>.

4. Complete the Application

Applications must adhere to the PHS 398 format with the exceptions listed below (under "Exceptions to the PHS 398 Instructions").

- Instructions for completing PHS 398 can be found in the PDF file at this link: <u>http://grants.nih.gov/grants/funding/phs398/phs398.pdf</u>
 - The organization of content in the Research Plan is explained in detail in section 5.5.
 - Some sections may not be applicable to the proposed pilot research project. Examples of these could include: Cumulative Inclusion Enrollment Report, Protection of Human Subjects, Inclusion ofWomen and Minorities, Planned Enrollment Report, Inclusion of Children, Select Agent Research, Multiple PD/PI Leadership Plan, Consortium/Contractual Arrangements, Letters of Support (e.g., Consultants), and Resource Sharing Plan. The title/header for each of these sections must be provided in the order prescribed in the PHS 398 Guidelines and those that are not applicable to the proposal must be identified as such. That is: the section title/header should be included and followed by the text string "Not applicable." These section titles/headers can be presented as a list on a single page.

Exceptions to the PHS 398 instructions

- The Other Support sub-section of the Biographical Sketch must also include a list of all previous pilot study awards received by the applicant from any source.
- A copy of the budget developed by SNPRC Veterinary Resources staff must be included in the application. It should be inserted into the application immediately following the PHS 398 Budget for the Entire Proposed Period.
- The text of the Research Plan is limited to a maximum of six (6) pages.
- At the end of the Research Plan (and within the 6 page limit) the applicant must include at least one

 paragraph detailing a) the applicant's plan for using the results of the proposed pilot study in a
 future application for funding (NIH preferred) in support of research using nonhuman primates, or b)
 how the results of the pilot study (data, models, technologies, etc.) will enhance the value of
 nonhuman primates for future research by others.
 - This information is factored into the assessment of the likelihood that the present application, if funded, will lead to successful leveraging.

Resubmissions: Notes and additional requirements

- A previously reviewed, but unfunded, pilot research application may be resubmitted only once.
- An Introduction to the Application, not to exceed 1 page in length, must precede the Specific Aims in the Research Plan (note: This is an additional page that increases the page limit for resubmissions to 7 pages).

- In the Introduction, the applicant should outline weaknesses identified in the earlier review and indicate if and how the applicant has revised her/his proposal to address them. The applicant also should identify and succinctly justify any other substantive changes to the earlier research plan.
- Revised/New text in a resubmitted application must be distinguished from that in the original
 application by using a different font (we recommend Palatino 11-pt or Palatino Linotype 11-pt to set
 off revised/new text from the Arial or Helvetica 11-pt base font used in the original application).

Multiple submissions

Multiple submissions by the same PI/applicant for the same deadline are not allowed. Also, an application from a PI/applicant who has an active pilot study funded by the SNPRC Pilot Research Program will not be accepted for review.

5. Submit the Completed Application

Letters of Intent and Completed applications should be sent as PDF files attached to an e-mail addressed to the current Coordinator of the SNRPC Pilot Research Program, Dr. Suzette Tardif (<u>stardif@txbiomed.org</u>) please copy (cc) these documents to Ms. Deborah E. Newman (<u>dnewman@txbiomed.org</u>) and Ms. Wanda Altamira (<u>waltamira@txbiomed.org</u>).

Important note: If a PI and an SNPRC Core Scientist have entered into an investigator/sponsor agreement, there must be evidence that each is aware of all correspondence related to the application. If the PI submits the application (or other documents), the sponsor's e-mail address must be included in the 'To" distribution list; conversely, if the sponsor submits the application (or other documents), the PI's e-mail address must be included in the "To" distribution list; conversely if the sponsor submits the application (or other documents), the PI's e-mail address must be included in the "To" distribution list).

EVALUATION OF PROPOSALS

Reviewers

Each proposal is critiqued and scored by at least three (3) reviewers. At least one of the three will be a member of the SNPRC Research Advisory Committee (RAC), selected by the Program Leader based on correspondence between their research expertise, experience, and/or interests and aims and/or research design components of the proposal. At least one reviewer will be external to the host institution and not affiliated with the SNPRC. They are subject matter experts with a record of successful research, including NIH funding and publications, directly relevant to (but not in competition with) the proposed study.

Evaluation

Pilot study proposals are evaluated according to guidelines and the nine (9) point scoring rubric used in reviews of research proposals submitted to the NIH (where 1 is the "best" score and 9 is the "worst"). Each reviewer's critique includes evaluations of a proposal's 1) Significance, 2) Innovation, 3) Approach, 4) Investigator(s), and 5) Environment. An added, 61h component of the critique is the reviewer's opinion of the proposal's potential for facilitating future research. Based on her/his assessments of these six (6) factors, the review provides an assessment of the proposed study's Overall Impact, also assigning it a score between 1 and 9. Each reviewer completes written critiques of the assigned proposals and presents these critiques during a meeting attended by all the RAC reviewers where all proposals are discussed. Following the discussion of a proposal, each committee member assigns an Overall Impact score proposal is scored (secretly) assigned by each committee member. After the meeting, the Program Leader ranks the proposals based on their mean Overall Impact scores and submits the results of the process to the SNPRC Director.

Funding Decision

The review committee is advisory to the SNPRC Director, who makes the final determination for funding.

Page 5 of 6

INFORMATION FOR FUNDED PILOT RESEARCH PROJECTS Funding level

As indicated in the Program Guidelines section above, the funding level is capped at \$100,000 for two (2) years (\$50,000 per year). All funds must be expended for SNPRC goods and services. Funds provided and budgeted by the Pilot Study Program will not support lab personnel, supplies, or any work carried out at offsite locations. Funds awarded to a pilot study can be used to cover only costs associated with animals (including per diems), procedures, and lab services provided by core SNPRC personnel.

Duration of funding

Also, as indicated above, NIH does not allow Primate Research Center base grant funds to be carried forward to the subsequent year for the base grant (unlike with other NIH awards, e.g., R01s). One-year pilot studies must be completed within the year of funding, and 2-year pilot studies must be completed within 2 years of funding. Please plan your protocol accordingly. We encourage the PI and sponsor (if applicable) to plan to initiate animal work on or as near as is possible to the date that funding will be made available and to complete all work with animals at least three (3) months before the end of the grant to allow for unanticipated interruptions or delays.

Progress reports

Pilot studies with 2-year durations are assessed at two (2) time points to ensure that adequate progress is being made. 1) At the end of the first year, the PI or sponsor (if applicable) must submit a one-page (maximum) progress report in which s/he provides the date SNPRC activities on the project began, a brief bullet-point outline of progress to date (including (e.g.) numbers of animals studied, procedures completed, assays done, etc.), the planned schedule of activities for the second year (with expected completion date), and a list of any presentations or publications resulting from the work to date. Also, any unanticipated changes, including adverse events or serious adverse events should be noted in this report. Following a review of the report, the Pilot Research Program Coordinator will make a recommendation to the SNPRC Director with regarding the continuation of the study into the second year. The SNPRC Director makes the final decision regarding continuation or discontinuation of funding.

Within one (1) month of completion of the funding period, for either a one or two-year award, a brief (maximum of three (3) pages) progress report also is due. The PI or sponsor (when applicable) should submit this report to the Pilot Research Program Coordinator. This report should formally notify the Program that the animal-related work is done and provide a brief outline of any non-animal work that remains (e.g., laboratory assays, data analyses), as well as plans for publication of results and/or submission of a research grant application based on the results.

One (1) year after the completion of a pilot study, the PI or sponsor (when applicable) is required to provide the following information to the Program Coordinator:

- A brief abstract of accomplishments
- Copies of any publications, reports, and/or meeting abstracts that arose from the pilot research*
 - It is expected that the award recipient and the sponsor {when applicable) will remain in contact during this time and that the sponsor will play an active role in facilitating the publication of results from the funded pilot research.
- Details of any grant applications that arose from the pilot research
- Details of any ongoing research projects that were enhanced by the pilot research
- **Note:** Progress on pilot research projects previously funded by the SNPRC will be evaluated by the Program Coordinator and members of the SNPRC Research Advisory Committee before new proposals are accepted for review. Applications from past award recipients who have successfully completed SNPRC-funded projects but not published (or submitted for publication) a report of the results of that research or used the results in an application for research funding are not likely to be accepted for review.

Page 6 of 6

The Program Coordinator will request updated information from each investigator or sponsor (when applicable) annually, until such time as the investigator reports that no additional publications or grant applications are expected as a consequence of the pilot study.

INQUIRIES, ADDITIONAL INFORMATION

Please direct all inquiries and requests for additional information by e-mail to the Coordinator of the SNPRC Pilot Research Program, Dr. Suzette Tardif at <u>stardif@txbiomed.org</u>. Please copy (cc) all e-mail correspondence to Ms. Deborah E. Newman at <u>dnewman@txbiomed.org</u> and Ms. Wanda Altamira at <u>waltamira@txbiomed.org</u>.