

Pilot/Methodological Study Award Application

Application Guidelines and Instructions

Overview

The Scripps Translational Science Institute's Pilot/Methodological Study Award is an NIH funded internal study award to assist investigators in developing preliminary data that will have a significant impact on the understanding, prevention and treatment of disease. Collaboration between basic and clinical researchers is required to be considered for funding.

Eligibility and Criteria for Review

STSI Investigators with an M.D. or Ph.D. at any of the participating institutions will be eligible for project funding. All projects will specify two Liaisons; one representing translational science and another in a clinical discipline.¹

The Criteria for funding is as follows:

- Multi-disciplinary; connecting basic and clinical science
- Likelihood of having an impact on medicine
- Soundness of methodology and statistical considerations
- Track record of the Applicant and the Co-Investigator(s) selected
- Likelihood of leading to independent funding

We highly recommend submission from individuals of under-represented minorities and junior faculty.²

Application Submission and Deadlines

Application Due Date: April 1, 2015
Notice of Awards: Mid-April, 2015
Project Period Award Date: May 1, 2015 - April 30, 2016

Forms for application submission are located at: http://www.stsiweb.org/index.php/pilot_studies/

Be sure to fill in all of the fields so that your application is not unnecessarily delayed for review.

Applications submitted through The Scripps Research Institute are REQUIRED to be submitted to the Office of Sponsored Programs for RACO review prior to STSI submission.

To submit your final application to STSI:

- Convert your application word document into a pdf file
- Send to Michelle Miller at mmiller@scripps.edu

Specific Instructions

Cover Page

Complete all fields as accurately as possible, including Translational/Research and Clinical Liaisons.

It is preferred that you utilize a digital signature for the cover page once you have converted to a pdf document or by inserting a scanned image of your signature.

Alternately, you may forward the original signed cover page to the Contact address below, within two days after submission.

If you have more than one Prime Investigator, please list them under Co-Investigator.

It is required by NIH that you list your eRA user commons name on your application. There has been a specific field created for this on the face page.

Abstract/Project Summary and Relevance to Disease/Health

Abstract should be in Lay format and should not exceed approximately 500 words.

Relevance to Disease/Health should be in Lay format and should not exceed approximately 200 words.

Project/Research Proposal

If Human Subjects will be utilized, check whether the SOPRS IRB protocol is approved, pending or a JIT (Just in Time form) has been submitted.

If Animal Subjects/Models will be utilized, check whether the IACUC protocol is approved, pending or a JIT (Just in Time form) has been submitted.

You must submit a copy of your IRB or IACUC JIT, or full approval face page, as part of your application. **If the project is awarded funding, then a copy of the approved protocol page(s) will be REQUIRED within 30 days of funding notice.**

Human Subjects Minimum Education Documentation – For all proposals, if human studies are involved, provide a copy of your Institutions training certificate of completion.

The Project/Research Proposal may not exceed THREE (3) pages (Proposals exceeding this limit will not be considered for funding) and must include the following sections:

- Specific Aims
- Background and Medical Significance
- Preliminary Data (if any)
- Research Design and Methods
- Figures are allowed within the Proposal, but must remain within the page limit
- Margins must remain at 0.5 inches on all sides with STSI Logo in the header

Literature Cited and Other Support

List references for your proposal and any Other Support for the Prime and/or Co-Investigator.

Budget and Justification

Applications may be submitted for one year projects only

Projects may request from \$20,000 up to a maximum of \$50,000 (plus current Indirect Cost Rates).

Budget Justification may be itemized by category, but must include the following sections:

- Personnel (list title, percent effort on project and requested salary including benefits)
- Supplies (itemized)
- Other Expenses

To enhance the pilot study funding, candidates are encouraged to solicit matching funds. Sources of matching funds would be patient advocacy programs and societies, industry collaborations and /or unrestricted grants.

If there are Matching Funds available for this application, please include the Source of the funds.

Additional Information to upload with Final Application

- Biosketch(s) for **all personnel** listed on the Budget Justification that are receiving salary support and for the Prime/Co-Investigators
It is preferred that you use the NIH formatted Biosketch with your submission (see page 4 of Instructions), or an abbreviated Curriculum Vitae (approximately four pages total)
- Letters of Support (Translational and Clinical Liaisons, Additional Collaborators, etc)
Submit a scanned pdf or word document of original letter (including signature)
- IRB or IACUC Just in Time form with approval signatures and your IRB Certificate of Completion (if applicable)
- Letter of Staff Appointment for applications submitted by Postdoctoral Fellows (TSRI only, if applicable) ²

Review and Award Process

Recipients of the pilot study awards must adhere to all Federal, state and local guidelines with respect to scientific conduct, conflict-of-interest policies, participation of human subjects, the use of animals, hazardous or radioactive materials and recombinant DNA in their research studies.

The review and notification process will be completed within 45 days from the deadline of the receipt of proposals. All proposals will receive a written critique and, for those awarded, justification for the budgetary allotment.

All awards that will involve “Applicable Clinical Trials”³ are required to register on clinicaltrials.gov before enrollment of the first subject. For more information visit: <http://prsinfo.clinicaltrials.gov/fdaaa.html>

All funded pilot studies will be required to submit a progress report at **six months** and a final report within **30 days** of the end of the grant award. The progress report will be a one page form briefly outlining findings. The final report will summarize the data obtained, publications submitted or accepted (with required PMID numbers:

<http://pubmed.ncbi.nlm.nih.gov/>) and grant funding as an outgrowth of the study.

Projects with significant justification for completing a competing continuation may be submitted at the time of the final report for consideration of an additional year of funding, competitively reviewed during the open application cycle.

¹ *For a list of Investigators and their disciplines please refer to the Pilot/Methodological Study Award section on the STSI website and download the searchable Excel files to locate potential Collaborators. Alternately you may visit the Support Services section of the STSI website to request suggestions for potential collaborators for your project. Please briefly outline your project needs in the Comments section. <http://www.stsiweb.org/index.php/infrastructure>*

² *All Faculty and of “Subject” Appointees within The Scripps Research Institute (TSRI)*

TSRI investigators have inquired about the possibility of having postdoctoral fellows in their Laboratories submit an application for these awards. According to the TSRI Administrative Guidelines, postdoctoral fellows cannot apply for grants, either as a principal investigator or co-principal investigator, without prior approval from the corresponding departmental chair. Even in those circumstances the intent is for the postdoctoral fellow to carry the grant forward to an independent investigator position.

³ *Definition of “Applicable Clinical Trials”:* Interventional Trials, Phase II – IV drug, biologic, device and \geq one site in the US.

Contact Information

Attn: Pilot/Methodological Study Award Applications

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