

## Pilot/Methodological Study Award Application

### Application Guidelines and Instructions

**Application Deadline: SEPTEMBER 10, 2010**

#### 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.<sup>1</sup>

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.<sup>2</sup>

#### Application Submission and Deadlines

**Letter of Intent Due Date: AUG 06, 2010**  
**Application Due Date: SEPT 10, 2010**  
**Project Period Award Date: 10/01/10 – 09/31/11**

Forms for application submission are located at:

[http://www.stsiweb.org/index.php/funding\\_initiatives/](http://www.stsiweb.org/index.php/funding_initiatives/)

*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 for upload
- Conventional naming requested: topol-application.pdf, topol-biosketch.pdf, ect
- Locate Support Services on the STSI webpage
- Browse for your Application file and attach in the appropriate field
- Browse for your Response to Reviewers file and attach in the appropriate field (if applicable)
- Browse for your Biosketch and Letters of Support and attach in the appropriate fields
- Browse for your Letter of Faculty Appointment from Departmental Chair (TSRI only, if applicable)<sup>2</sup>
- Fill in your email address and check if you would like to receive email confirmation that your application has been received by STSI.
- Click SUBMIT APPLICATION

#### Specific Instructions

**Letter of Intent (due 08/06/10) – approximately one page**

Letter addressed to STSI, outlining project objectives, specific aims and Liaison/Collaborator connections.

**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 now required by the 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.

*If you do not have a registered eRA user commons name, contact the Sponsored Research Office (or equivalent) at your Institution to receive one. If you cannot locate the appropriate person for your Institution, contact the NIH eRA Commons Help Desk at [commons@od.nih.gov](mailto:commons@od.nih.gov)*

**NEW Pilot/SCRDA combined award submission**

The Principal Investigator must be the same on both the Pilot/Methodological and the SCRDA award applications, if it will be a combined submission. Please note the SCRDA award eligibility requirements:

- Scripps Health employees and affiliated health care providers, including attending physicians, nurses, pharmacists, and other allied health professionals caring for patients at Scripps Health facilities, are eligible to receive funds as the PI on a SCRDA award
- Scripps Health facilities and patients must be used for the study
- Scripps IRB must review the study
- Commitment by the investigator to use Scripps Health facilities and IRB for subsequent studies supported by the pilot study

**Abstract/Project Summary and Relevance to Disease/Health and Justification for Combined Pilot/SCRDA Submission**

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.

***New section for Combined Pilot/SCRDA submission:***

Scripps Health Investigators may apply concurrently for an STSI Pilot/Methodological grant award to supplement the aims of their SCRDA proposal, similar to matching funds. Examples include (1) submission of an STSI Pilot award to develop translational research to be carried out in a clinical trial setting using the SCRDA award, (2) submission of an STSI Methodological award to develop algorithms immediately useful in a clinical setting with funding and research time necessary to be covered by the SCRDA award, (3) submission of an STSI Pilot award with regards to community engagement research and the SCRDA award to further carry-out the research developed into the community at large.

**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 TWO (2) 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 5 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) <sup>2</sup>

### **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.

**NEW:** All awards that will involve “Applicable Clinical Trials” <sup>3</sup> are required to register on [clinicaltrials.gov](http://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 at 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 PMCID numbers: <http://publicaccess.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.

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<sup>1</sup> ***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/support/>

<sup>2</sup> ***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.

<sup>3</sup> **Definition of "Applicable Clinical Trials":** Interventional Trials, Phase II – IV drug, biologic, device and  $\geq$  one site in the US.

### **Contact Information**

Attn: Pilot/SCRDA Study Award Division

*Scripps Translational Science Institute*

3344 North Torrey Pines Court, Suite 300

La Jolla, CA 92037 USA

TELE: 858-554-5708

FAX: 858-546-9272

[stsi@scripps.edu](mailto:stsi@scripps.edu)

Program Director/Principal Investigator (Last, First, Middle):

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

Program Director/Principal Investigator (Last, First, Middle):

Program Director/Principal Investigator (Last, First, Middle):

Program Director/Principal Investigator (Last, First, Middle):