CTSI Pilot Project Awards
Request for Applications (RFA):

Patient-Oriented Clinical Research

Timeline: 2014-15 Open RFA (applications accepted on a rolling basis)

Applications can be submitted in response to this RFA on any date between April 1, 2014, and March 31, 2015. Reviews and funding decisions will be completed within six weeks of submission. Successful applicants will have 12 months from notice of award to complete their pilot projects.

Purpose

The UF Clinical and Translational Science Institute provides intramural awards to support the growth of interdisciplinary and investigator-initiated clinical and translational research across UF’s broad range of scientific disciplines. It is expected that all research supported by CTSI Pilot Project Awards will provide critical preliminary data to support extramural applications.

This RFA supports patient-oriented clinical research, which is defined as research in which an investigator (or colleague) directly interacts with human subjects.¹

The CTSI welcomes proposals in response to this RFA for patient-oriented clinical research to be performed at a UF Health facility. Both inpatient and outpatient research may be proposed in response to this RFA. Preference will be given to research conducted at the UF Clinical Research Center, which occupies the first floor in the north wing of the new Clinical and Translational Research Building (CTRB):

The UF Clinical Research Center supports clinical research involving any disease area or age group. It offers nursing, bionutrition and laboratory services. Its new facilities in the CTRB include pediatric and adult waiting areas, 14 exam rooms, 8 infusion bays, 2 procedure rooms, an on-site investigational pharmacy and a metabolic kitchen, plus reception, consenting, phlebotomy, sample processing and lab areas. It is also equipped with a treadmill, exercise bike, Bod Pod, pulmonary function and pain testing research equipment. On-site parking is available for research participants. The Clinical Research Center also has access to three beds for inpatient research in unit 42 of UF Health Shands Hospital. To request more information about the UF Clinical Research Center, please contact Glenna Paguio, RN, BSN, Nurse Manager (paguig@shands.ufl.edu) or visit http://www.ctsi.ufl.edu/crc.

Eligibility

- Applicants must be a UF faculty member or a UF trainee (residents, graduate students, post docs and fellows) at the time funds are awarded.

¹ For NIH definition of clinical research, please see: http://grants.nih.gov/grants/glossary.htm#C

The UF CTSI is supported in part by NIH awards UL1 TR000064, KL2 TR000065, TL1 TR000066.
• Recipients of previous pilot awards are eligible to apply for awards to support fundamentally new research projects.

Awardee Requirements

• Awardees must be in compliance with all IRB policies. Applicants whose proposals will require IRB approval should demonstrate they have taken preliminary steps to prepare submissions so minimal time will be lost in securing approval. Funding cannot be used until appropriate approvals are in place.

• Awardees must submit progress reports on the scientific and fiscal status of the project 6 months and 12 months after the notice of award is received.

• Awardees are expected to present their research during the annual UF CTSI Research Day in the form of a poster or presentation. Awardees are also expected to present the results of their research at scientific meetings and publish findings in scholarly journals.

• In accordance with NIH requirements:
  o All presentations and publications resulting from work funded by a CTSI Pilot Project Award must include an NIH funding citation. The following language should be used: *This work supported in part by the NIH/NCATS Clinical and Translational Science Award to the University of Florida UL1 TR000064.*
  o Awardees must ensure that electronic versions of any peer-reviewed manuscripts arising from CTSI-funded research and accepted for publication are deposited in PubMed Central, the NIH's digital archive of biomedical and life sciences journal literature. See [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html).

• Awardees must notify the CTSI at CTSIClinicalRFA-L@lists.ufl.edu during the funding period if there is a significant change in the scope of work that would affect the outcome of the project or necessitate re-budgeting.

Review Process and Criteria

**Scientific Reviews:** Upon passing an initial budgetary and biostatistical review, submissions will each be reviewed by two faculty members to assess the scientific merit of the application. Reviewers will use NIH review criteria to score submissions based on scientific merit.

**Optional Scientific Advisory Committee Review:** If desired, applicants have the option of presenting their proposal in-person to the CTSI Scientific Advisory Committee (SAC) after the initial budgetary and biostatistical review. The SAC presentation provides an opportunity for the investigator to receive feedback and protocol development assistance in a coaching/mentoring atmosphere. Investigators interested in submitting their application for SAC review should indicate this preference on the RFA application. Please note the SAC does not make funding decisions.

**Funding Decisions:** In addition to scientific review scores, the CTSI will consider the following criteria in making its funding decisions, specifically whether proposals:

• Pertain to patient-oriented clinical research in which an investigator (or colleague) directly interacts with human subjects;

• Are multidisciplinary, collaborative and/or inter-institutional in the clinical and translational research enterprise;

• Encourage the development or use of emerging methodologies and technologies that may affect future research;
Allow rapid acquisition of proof-of-principle data to proceed with full-scale investigations;
Support the participation of clinical and translational science trainees;
Show significant promise in securing external funding;
May lead to the adoption of best practices in the prevention and treatment of disease.

Budgeting and Spending Requirements

- Funds can only be used for direct costs.
- Funds cannot be used to support faculty salaries.
- Funds cannot be used for participant compensation.
- Funds must be used in the 12-month period following their release. Any un-spent funds will be returned to the CTSI at the end of the 12-month funding period.
- Funds must be used for the activities detailed in the application.
- Funds requested for CTSI services will be provided as non-transferable credit.
- Continued funding during the award period is contingent on compliance with awardee requirements.

Total Available Funding and Award Amounts

The CTSI will make a total of up to $200,000 available through this RFA for the period April 1, 2014, through March 31, 2015, depending on the quality of submissions and budget availability. Awards typically do not exceed $25,000. Larger awards may be considered based on the scientific merit of the project and support contributed to the project from other sources.

Budget Development and Examples

Investigators should develop budgets based on the number of subjects to be enrolled, the cost per subject, and any other services required by the protocol. All budgets will be judged on scientific merit related to the goals of the proposed work.

Applicants must include a written cost estimate for all requested services, including the Clinical Research Center, when applicable, in their proposals. To obtain a cost estimate from the Clinical Research Center, contact Jill Sandersen at sandejn@ufl.edu. A time and events table will be required to obtain a cost estimate. A list of CTSI services and the appropriate contacts can be found on the last page of this RFA.

Example 1: You justify the need for six subjects to be enrolled in your pilot study. Services for each subject will be $1,500, thus your subject-related expenses are $9,000. In addition, you need 10 hours of biostatistics data analysis at $120 per hour for presentation of findings in a manuscript. Biostatistics support is $1200. Your budget request is $10,200.

Example 2: You justify the need to enroll 100 subjects in your pilot study. Each subject will require services with a cost of $150. You have no other expenses. Your budget request is $15,000.
Application Instructions

Applications must include a cover sheet signed by the principal investigator and the PI’s department chair; page 2 (abstract, translational impact, external funding plan, mentoring plan); list of key personnel; NIH biosketches for PI, investigator(s) and mentor(s); estimated cost per participant; non-participant cost justification; research plan; and letters of support if applicable. See the application instructions and forms. Proposals that are incomplete or otherwise do not follow instructions will be returned to the investigator without review.

Contact for Questions

Email questions to CTSIClinicalRFA-L@lists.ufl.edu or call 352-273-8700, and the CTSI Home team will connect you with the appropriate person based on the nature of your question. Applicants are encouraged to visit the CTSI portal at www.ctsi.ufl.edu to learn about additional CTSI services available to facilitate research at UF.
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<tr>
<th>Service</th>
<th>Description</th>
<th>Contact</th>
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<tbody>
<tr>
<td>UF Clinical Research Center</td>
<td>Facilities for outpatient and inpatient research including nursing, dietary and lab support</td>
<td>Glenna Paguio, RN, BSN <a href="mailto:paguig@shands.ufl.edu">paguig@shands.ufl.edu</a></td>
</tr>
<tr>
<td>Biostatistics</td>
<td>Assistance with development of research design, determining appropriate sample size and performing statistical analysis</td>
<td>Jon Shuster, PhD <a href="mailto:shuster@ufl.edu">shuster@ufl.edu</a></td>
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<tr>
<td>Research Electronic Data Capture (REDCap)</td>
<td>Secure, web-based application for capturing traditional case report form data for research studies</td>
<td>REDCap Support Team <a href="mailto:CTSI-REDCAP-SUPPORT-L@lists.ufl.edu">CTSI-REDCAP-SUPPORT-L@lists.ufl.edu</a></td>
</tr>
<tr>
<td>Informatics</td>
<td>Design and development of custom applications for research</td>
<td>Chris Barnes <a href="mailto:cpb@ufl.edu">cpb@ufl.edu</a></td>
</tr>
<tr>
<td>Regulatory assistance</td>
<td>Guidance with IRB submissions, informed consent forms, responding to IRB reviewer comments</td>
<td>H. Robert Kolb, RN, BS, CCRC <a href="mailto:kolbhr@ufl.edu">kolbhr@ufl.edu</a></td>
</tr>
<tr>
<td>IDE, IND submission assistance</td>
<td>Guidance on IND, IDE application requirements, reporting to the FDA, content related issues</td>
<td>Wajeek Bajwa, PhD <a href="mailto:bajwa@ufl.edu">bajwa@ufl.edu</a></td>
</tr>
<tr>
<td>RAC billing compliance reviews</td>
<td>Assistance from RAC submission specialist with prep for RAC Billing Compliance Review</td>
<td>Rebecca Wichman, MS <a href="mailto:rwichman@ufl.edu">rwichman@ufl.edu</a></td>
</tr>
<tr>
<td>ClinicalTrials.gov assistance</td>
<td>Guidance on ClinicalTrials.gov registration and compliance</td>
<td>Rebecca Wichman, MS <a href="mailto:rwichman@ufl.edu">rwichman@ufl.edu</a></td>
</tr>
<tr>
<td>Research Subject Advocate, Ethics consultation</td>
<td>Resource for study participants as well as investigators and study staff in the responsible conduct of clinical trials. Assistance with the establishment and activity of Data Safety Monitoring Boards (DSMB).</td>
<td>H. Robert Kolb, RN, BS, CCRC <a href="mailto:kolbhr@ufl.edu">kolbhr@ufl.edu</a></td>
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<tr>
<td>Quality Assurance</td>
<td>Consultation, auditing, SOP development, batch releases and training to ensure GCP, GLP and GMP</td>
<td>Corinne Abernathy <a href="mailto:cabernat@ufl.edu">cabernat@ufl.edu</a></td>
</tr>
<tr>
<td>CTSI Biorepository</td>
<td>Secure storage for biological samples. CAP certified, availability of monitored freezers.</td>
<td>Amer S. Abouhamze, MS <a href="mailto:amer@ufl.edu">amer@ufl.edu</a></td>
</tr>
<tr>
<td>CTSI Southeast Center for Integrated Metabolomics</td>
<td>Metabolomics services for clinical and basic science studies, including mass spectrometry, nuclear magnetic resonance and bioinformatics</td>
<td>Tim Janicki <a href="mailto:janicki@ufl.edu">janicki@ufl.edu</a></td>
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<tr>
<td>CTSI Human Imaging Core</td>
<td>Structural and functional MRI services for human-subject research</td>
<td>Song Lai, PhD <a href="mailto:songlai@ufl.edu">songlai@ufl.edu</a></td>
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<tr>
<td>Genotyping Core</td>
<td>Consultation on designing and performing genetics and pharmacogenetics studies. Targeted determination of genotypes on genomic DNA from biological samples.</td>
<td>Taimour Langaee, PhD <a href="mailto:langaee@cop.ufl.edu">langaee@cop.ufl.edu</a> Ben Burkley <a href="mailto:burkley@cop.ufl.edu">burkley@cop.ufl.edu</a></td>
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<tr>
<td>Biobehavioral Core</td>
<td>Broad expertise in application of human-validated assessment measures of behavioral concomitants of disease or therapeutic interventions</td>
<td>Sara Jo Nixon, PhD <a href="mailto:sjnixon@ufl.edu">sjnixon@ufl.edu</a></td>
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<tr>
<td>UF Health Integrated Data Repository</td>
<td>Access to data in the electronic medical record for research purposes, ability to query system for cohort identification, recruiting</td>
<td>Liz Horne <a href="mailto:ehorne@hhp.ufl.edu">ehorne@hhp.ufl.edu</a></td>
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<tr>
<td>HealthStreet</td>
<td>Assistance with recruitment</td>
<td>Darryl Pastor <a href="mailto:darrylp@phhp.ufl.edu">darrylp@phhp.ufl.edu</a></td>
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