JUNIOR INVESTIGATOR PRELIMINARY/FEASIBILITY GRANT PROGRAM (JIPGP)

UNIVERSITY OF PENNSYLVANIA & CHILDREN'S HOSPITAL OF PHILADELPHIA
CLINICAL TRANSLATIONAL SCIENCE AWARD
CLINICAL & TRANSLATIONAL RESEARCH CENTER (CTRC)
SUBMISSION REQUIREMENTS

PURPOSE:

The primary goal of the Clinical Translational Research Center (CTRC) Junior Investigator Preliminary/Feasibility Grant Program (JIPGP) is to encourage junior investigators to develop clinical research projects that will ultimately lead to extramural NIH funding. The CTRC's at the University of Pennsylvania (PENN) and The Children's Hospital of Philadelphia (CHOP) are programs under The Clinical & Translational Science Award (CTSA) funded by the NIH National Center for Research Resources. The JIPGP awards are designed to allow junior faculty members, clinical fellows and both M.D., Ph.D. and D.M.D. post-doctoral trainees with appropriate mentors to obtain funds for pilot/preliminary data projects that are investigator-initiated, human-based, CTRC studies that will enable an applicant to obtain preliminary data for an NIH K or R grant submission. Projects should address CTSA themes of multidisciplinary research, translational research and research across the age groups. It is anticipated that the award will lead to a competitive extramural grant application and to a career in Clinical Translational Research Center-focused clinical investigation. Award is \$20,000 over one or two years.

GUIDELINES:

Applicant requirements:

- Be a full time faculty member or postgraduate fellow (for fellow applicants, preference will be given to those with an offer for a faculty position involving clinical research) at PENN or CHOP.
- Hold a doctoral degree from an accredited institution.
- Have a rank equal to or less than Assistant Professor, including Post-Doctoral Fellows. Be within
 five (5) years of completion of their clinical training, or be in an approved fellowship-training
 program, unless the project is a clear change in emphasis or direction of research (especially
 from bench to translational research).
- Have an interest in patient-oriented research.
- Have no past or active K- or R-award (excluding R03) NIH funding prior to the start date of the
 JIPGP. An applicant with current institutional K (such as a K12), foundation or industry support is
 eligible for the JIPGP provided that there is no budgetary overlap with the funded research.
 There may be project overlap. Include K12 budget with application. Upload with required
 budgets as merged documents.(Applicants should provide NIH -formatted Other Support pages
 listing all current and pending research funding).
- Previous JIPGP awardees can apply for funding of a new and different project.

Proposal requirements:

- Applications must be submitted electronically by February 27, 2015 at 5:00 PM for a project start date of July 1, 2015. Late submissions – including letters of recommendation and/or biosketches - will not be accepted nor will extensions be granted.
- The proposal should clearly delineate the proposed use of CTRC resources. CTRC RESOURCES available can be found on the <u>ITMAT website</u> (Studies must involve **human subjects or human specimens** and must propose to utilize the **CTRC major core areas of service** for subject interventions, assessments or lab analysis. Biostatistical support only or Informatics support only studies without the use of a major CTRC Core Unit or in which the only subject intervention is a questionnaire will not be accepted by the JIPGP Committee. Please contact the CTRC Associate Directors (Dr Katz at CHOP and Dr. Gooneratne at UPENN) if you have any questions regarding adequate usage of CTRC core services.
- Studies should be designed to collect pilot or preliminary data with clear presentation of how results would be used for extramural funding applications.

- One proposal per investigator per year.
- "Sample Analysis Only" proposals
 - Studies that do not require CTRC support for subject visits or interventions but do require the CTRC Core Laboratory may be submitted, HOWEVER, the proposal must be discussed with CTRC Associate Directors Lorraine Katz (CHOP) or Nalaka Gooneratne (UPENN), prior to submission. Although these types of proposals will be accepted, a lower priority score may be given because a variety of CTRC resources are not being utilized.
 - If "Sample Analysis Only" protocols are not discussed with the CTRC Associate Directors, the application will be rejected. To view CTRC Core Lab information and contacts go to: http://www.itmat.upenn.edu/ctrc/tcl/index.shtml. (Consult with CTRC Administrators for clarifications if needed).
 - "Sample Analysis Only" protocols must use and submit the attached checklist.
 - "Sample Analysis Only" protocols must only use human specimens.
- It is strongly recommended that each proposal is reviewed by a statistician prior to submission. A
 CTSA statistician can be used if the candidate does not have access to a statistician for
 guidance. CTSA statisticians
- If this proposal is to fund an existing CTRC or IRB protocol, address in the proposal whether the existing protocol was initiated by the JIPGP applicant or mentor. Proposals to support or supplement existing protocols that have been initiated by the mentor or that have gone beyond the initial study recruitment target must be discussed with the appropriate CTRC Associate Director, Dr. Katz (CHOP) or Gooneratne (UPENN). If this is an existing CTRC or IRB protocol, a copy of the IRB approval letter must be submitted.

Required Documents:

- Checklist
- Abstract Page: The abstract page should be no longer than 250 words.
- **Budget:** Please use the excel template budget page and provide detailed expenses. Investigators requesting a 2-year award should submit budgets for Year 1 and Year 2.
- Budget Justification: Please provide a short justification for all personnel, supplies, and
 equipment that will be expensed to this project. Please provide a distinct justification if JIPGP
 resources are to be spent on services provided from outside the CTRC.
- NIH Biosketch: An NIH format biosketch must be submitted for the applicant and his/her mentor. You can use the old 398 format http://grants.nih.gov/grants/funding/phs398/biosketchsample.doc → or the new RFR format: See sample form at http://grants.nih.gov/grants/funding/424/index.htm#format
- NIH Other Support page for the applicant. See sample form at: http://grants.nih.gov/grants/funding/phs398/othersupport.doc
- Research Proposal: The research proposal shall be no longer than three single-spaced pages plus additional pages for scientific literature references only. The description of the project should include a brief background, hypothesis, subjects, methods, analysis and study feasibility and recruitment sections as well as a paragraph on how you plan to use the resources of the CTRC. Your proposal must clearly indicate which CTRC resources you wish to utilize. Please indicate the importance of this funding on the successful implementation of your research proposal, as well as the feasibility of completing this project within one to two years. Appendix material is not allowed. Please use 1 inch margins and a font of Arial 11.
 - **References:** Scientific literature references should be uploaded separately and will not count toward your three page proposal limit.

- A Mentor's Support Letter: A letter from a senior faculty member who agrees to serve as a research mentor for the project. This letter should be a minimum of one page and maximum of two pages and should include:
 - An outline of the resources available to the applicant,
 - Protected time for research,
 - A clear plan for candidate's career development,
 - Candidate's current academic appointment,
 - Candidate's future academic plans,
 - Discussion of institutional commitment If the candidate is a fellow, a clear plan for participation in clinical research post-fellowship should be given,
 - All of the above documents must be uploaded to the Pilot Grant System.

Budget Guidelines:

 Maximum allowable expenditures are \$20,000 in total (whether the proposal is 1 or 2 years) for a minimum duration of 1 year and a maximum duration of 2 years Examples of JIPGP fund budget items include purchase of research supplies, assays, subject recruitment expenses, travel expenses to one scientific meeting to present study results, and salary support for awardee and/or study staff.

OTHER JIPGP PROGRAM INFORMATION:

- The JIPG awards are in partnership with the NIH Clinical and Translational Science Award (CTSA), the Institute for Translational Medicine and Therapeutics (ITMAT), and The Children's Hospital of Philadelphia (CHOP) Research Institute
- This financial award is in addition to standard CTRC support. A summary of PENN and CHOP CTRC services can be found at ITMAT or contact the appropriate institutional administrative manager for specific CTRC resource information (contact information listed below). Thus, the total resources available for the chosen projects may exceed the maximum monetary award of this grant.
- If there is a delay in study initiation and or recruitment, a one-year, no-cost extension can be requested after the initial period of funding.
- **Evaluation of proposals:** Applications will be reviewed by the CTRC JIPGP Review Committee and scored on the basis of:
 - Originality and scientific merit.
 - Potential for publishable data and for future funding,
 - Qualifications of applicant and mentor,
 - Use of CTRC resources, a summary of PENN and CHOP CTRC resources can be found at: http://www.itmat.upenn.edu/ctrc/index.shtml#Resources,
 - Subject Recruitment and Feasibility Ability to recruit subjects and the potential to complete the study within a 1 to 2 year time frame,
 - Addressing CTSA themes: multidisciplinary research, translational research and research across age groups,
 - All protocols are reviewed and discussed using an NIH review format. Protocols will be
 reviewed to ensure scientific validity and maximal patient safety. Applicants will receive a
 written critique.

• Award Dates: Application Receipt Deadline

Notification of Award:

Funding Period:

February 27, 2015 April 10, 2015 7/1/2015 to 6/30/2016

For questions, contact your local CTRC Administrative Director:

PENN: Charlie Molli at Tel: 215-898-7335 Email: cmolli@exchange.upenn.edu CHOP: Veronica Kain at Tel 215-590-2215 Email: kainv@email.chop.edu

Document Submission:

Both CHOP and PENN applicants will need a PennKey logon and password to access this system. Please note that PennKeys cannot be processed without social security numbers. Also, it takes a few days for the PennKeys to be activated. Please plan accordingly and request in advance to ensure that you can submit your proposal.

- PENN STAFF: If you do not have a PennKey, please go to the URL below and print out/complete
 the sponsorship form. http://www.med.upenn.edu/pmacs/assets/user-content/documents/itmat.pdf. Fax completed form to 215-573-9135.
- CHOP STAFF: Go to CHOP PennKey Administration on the CHOP Research intranet

PENN Submissions: PENN Investigators must select the BA that signs off on their grants for approval. Grants will be received once the BA has approved them. PENN proposals are NOT routed through the institution's electronic grant system.

CHOP Submissions: Please note that CHOP Investigators must select Robert DeNight, Brent Bell, Michael Campbell, or Berenice Saxon as their BA in the ITMAT PILOT GRANT SYSTEM. Investigators are required to simultaneously submit the JIPGP application on the ITMAT site and CHOP's Sponsored Projects electronic submission: eSPA. An official price request via eTRACK system is NOT required but you must contact Veronica Kain for estimate prices if your proposal will include any costs for hospital based tests/services or CTRC costs such as lab kits. The eSPA grant submission will be an abbreviated application. For ease of submission to eSPA, you may merge all of the JIPGP documents into one PDF. Go to the eSPA login page to start the grant submission: Contact your Sponsored Project Officer for assistance.

Other Helpful Hints:

The Applicant for the proposal should log in at www.med.upenn.edu/apps/itmat/pg

- Project Title: Title is limited to 500 characters
- Funding Program: Choose the appropriate funding mechanism, JIPGP
- Business Administrator: Click "Select BA" and then search by name for the business
 administrator who normally signs off on your grants and select. Please note you should limit coinvestigators to maximum of two mentors because BA approval is needed for each investigator
 listed which can cause delays in the approval process. For CHOP applicants, please select
 Robert DeNight, Brent Bell, Michael Campbell, or Berenice Saxon.
- **Personnel:** Click the "Add another investigator" button for each mentor, then click the "select investigator" link to search for them by name.
- **Mentor's Biosketch and Other Support:** Click the "plus" icon to upload mentor's Biosketch and Other Support for applicant as a separate document.
- Save and Continue Later: click the "Save and Continue Later" button if you are working on this proposal in stages.
- **Finalize and Submit:** click the "Finalize and Submit" button only after you have uploaded all of your documents. You cannot make changes to your application after clicking this button. Note you do not have to upload your documents all at once wait to click this button only after you have uploaded them all.

Post Award Requirements:

- If selected for funding, the local IRB and CTRC Review Committees must approve the project before funds can be awarded.
- The IRB and CTRC submission must reflect the same aims, goals, sample size and use of resources as initially submitted in the JIPGP proposal. (If proposal is to support/supplement an existing IRB approved study, it is preferred the IRB and CTRC submission of JIPGP project be a separate IRB project).

- Any resulting publications in peer-reviewed journals must acknowledge the support of the CTSA grant as follows: "The project described was supported by Grant Number UL1TR000003 from the National Center for Advancing Translational Sciences, National Institutes of Health; the content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH". In addition, if support is provided by other grants or centers that specific citation should be included (contact the relevant program for citation content). Copies of publications should be sent to the appropriate administrative manager.
- JIPGP awardees are required to provide annual progress reports. Awardees will receive an automated notification from the ITMAT pilot grants system.