

Junior Investigator Preliminary/Feasibility Grant Program
University of Pennsylvania & Children's Hospital of Philadelphia
Clinical Translational Science Award
Center for Human Phenomic Science
Submission Requirements

PURPOSE

The primary goal of the Junior Investigator Preliminary/Feasibility Grant Program (JIPGP) is to encourage junior investigators to develop research projects that will ultimately lead to extramural funding and to a career in clinical and/or translational research. The JIPGP 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.

The JIPGP awards are designed to allow junior faculty members and M.D., Ph.D., and D.M.D. post-doctoral trainees with appropriate mentors to perform investigator-initiated, human-based, studies utilizing the services of the Center for Human Phenomic Science (CHPS). Projects should address CTSA themes of multidisciplinary research, translational research, and research across the age spectrum. It is anticipated that the award will lead to a competitive extramural grant application (such as an NIH K or R grant). The award is \$20,000 total for up to two years, in addition to subsidized CHPS services.

GUIDELINES

Applicant Requirements

- Be an Assistant Professor (full-time faculty), Instructor, or postdoctoral fellow at the time of the award. For postdoctoral fellows, preference will be given to those who have an offer for a faculty position with protected time for clinical research. If the applicant is a resident, residency must be completed at the time the award is initiated.
- Hold a doctoral degree from an accredited institution.
- Be in an approved fellowship-training or post-doctoral program or have completed post-doctoral training after July 1, 2015. If the project is a change in emphasis for an applicant who completed training more than five years prior to applying, the applicant must obtain approval from the CHPS Associate Directors, Andrea Kelly, MD (CHOP, kellya@email.chop.edu) or, Raymond Townsend, MD (Penn, townsend@upenn.edu), for approval to submit a proposal.
- May not have been a principal investigator on an individual NIH K or R award (excluding R03 or R21) during or before July 2020. Applicants must provide NIH-formatted Other Support pages listing all current and pending research funding. 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. Please include the project budget for projects with project overlap with the JIPGP application and upload with required budgets as merged documents.
- Previous JIPGP awardees can apply for funding of a new project.

Proposal Requirements

- Applications must be submitted electronically by Friday, March 6, 2020 at NOON for a project start date of June 1, 2020. Late submissions (including letters of recommendation or biosketches) will not be accepted, nor will extensions be granted.

- The proposal should clearly delineate the proposed use of CHPS services which can be found on the ITMAT website and the table below. Studies must involve human subjects and must propose to utilize the CHPS major core areas of service for subject interventions or assessments. Biostatistical support only, informatics support only, samples only studies without the use of a major CHPS Core, or proposals for which the only intervention is a questionnaire or sample analysis will not be accepted. Please contact Dr. Kelly (kellya@email.chop.edu) at CHOP or Dr. Townsend (townsend@upenn.edu) at Penn if you have any questions regarding adequate usage of CHPS core services.
- Penn-based applicants can access CHOP-based CHPS Cores. CHOP-based applicants can access Penn-based CHPS Cores for studies recruiting participants age ≥ 18 years. If you are using cores at both institutions, please discuss with Dr. Kelly (kellya@email.chop.edu).

CHOP CHPS Core services (no cost) - *Informatics and Biostatistical support must be bundled with other services

Nursing Outpatient Visits – Services are provided in the CHOP CHPS outpatient area. CHPS Nursing core provides sample collection, storage and shipping, phlebotomy, PK sampling and other nursing services. <https://chps.research.chop.edu/services-facilities/research-nursing-core>

Inpatient beds - CHOP CHPS can assist you in accessing inpatient beds for research projects requiring overnight stays. <https://chps.research.chop.edu/services-facilities/research-nursing-core>

Nutrition Assessment – Provides DXA, pQCT, anthropometric measurements. <https://chps.research.chop.edu/services-facilities/nutrition-core/nutrition-assessment-unit>

Bionutrition – Diet questionnaires, analysis, 24-hour dietary recalls. <https://chps.research.chop.edu/services-facilities/nutrition-core/bionutrition-unit>

Sleep – Polysomnography testing, actigraphy. <https://chps.research.chop.edu/services-facilities/sleep-core>

Cardiovascular – ECGs, ECHOs, vascular testing, ambulatory blood pressure monitoring. <https://chps.research.chop.edu/services-facilities/cardiovascular-core>

Ophthalmology – Eye exams, OCT, Fundus photography. <https://chps.research.chop.edu/services-facilities/ophthalmology-core>

Neurobehavioral testing – Developmental testing. <https://chps.research.chop.edu/services-facilities/behavioral-neuroscience-core>

***Informatics Services** - Resource to investigators in designing and developing a cohesive data management plan and/or database. <https://chps.research.chop.edu/services-facilities/informatics-core>

***Study Design and Biostatistics** - Provides planning and analytic services, which include study design, sample size estimation, analysis planning. <https://chps.research.chop.edu/services-facilities/study-design-and-biostatistics>

Penn CHPS Services (no cost) - *Informatics, mHealth, and Biostatistical support must be bundled with other services. Subjects must be over 18 years of age to receive services.

Nursing Outpatient Visits - Schedule research subjects in the Penn CHPS outpatient areas at HUP or Presbyterian Hospital for sample collection and conduct of outpatient study procedures. <http://www.itmat.upenn.edu/rnc.html>

Inpatient beds - Schedule research subjects in the Penn CHPS inpatient area for conduct of inpatient studies. <http://www.itmat.upenn.edu/rnc.html>

Nutrition - Metabolic kitchen, dietary assessment, and analysis. https://www.med.upenn.edu/chps/nutrition_assessment_core.html

Cardiovascular Phenotyping Unit – ECGs, ECHOs, Vascular testing. <https://www.med.upenn.edu/chps/cardio-phenotyping-core.html>

Exercise Medicine Unit - Provides structured exercise training interventions, exercise testing, and other related core services; staffed by a full-time exercise trainer. <https://www.med.upenn.edu/chps/exercise-medicine-unit.html>

***Informatics Services** - Resource to investigators in designing and developing a cohesive data management plan and/or database. https://www.med.upenn.edu/chps/informatics_related_core.html

***Study Design and Biostatics** - Provides planning and analytic services, which include study design, sample size estimation, analysis planning. <http://www.itmat.upenn.edu/sdab.html>

***mHealth Core** – Provides mobile and web application development services. https://mhealth.research.chop.edu/sites/default/files/documents/chps_itmat_mhealth_service_slides.pdf

- Studies should be designed to collect pilot or preliminary data with clear presentation of how results will be used for extramural funding applications. The "analysis" section of the research plan should be 4-7 sentences that explicitly identify: primary outcome measure, statistical test, and power calculation or a statement of how the pilot study will inform future power calculations, such as effect size estimates. (Of note, as a pilot study, most applications will not have adequate study power).
- One proposal is allowed per investigator per year.
- Review of the protocol by a statistician prior to submission is strongly recommended. A CTSA statistician can be used if the candidate does not have access to a statistician for guidance. Use this link for contact information for CTSA statisticians: <http://www.itmat.upenn.edu/sdab.html>.
- If this proposal is to fund an existing CHPS 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 are beyond the initial study recruitment target must be discussed with Dr. Kelly (kellya@email.chop.edu) at CHOP or Dr. Townsend (townsend@upenn.edu) at Penn. If the JIPGP proposal is or leverages an existing CHPS or IRB protocol, a copy of the IRB approval letter must be submitted.

Post Award Requirements

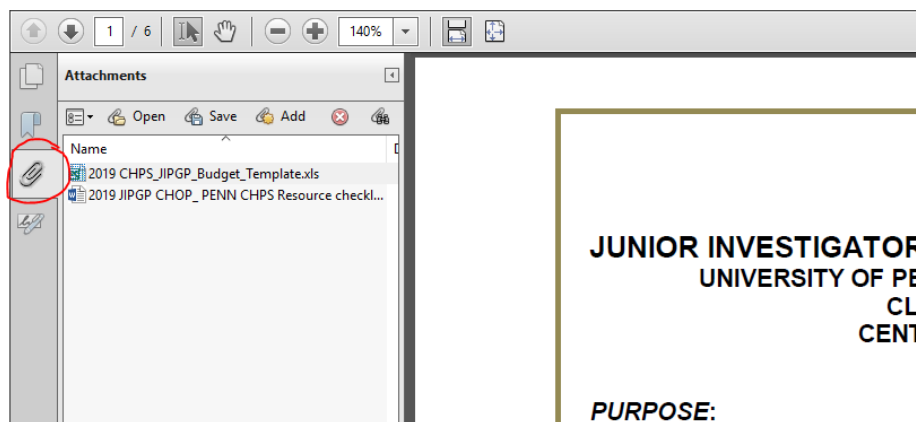
- The local IRB and CHPS Review Committees must approve the project before funds can be awarded.
- Awarded JIPGP protocols submitted to the IRB and CHPS must reflect the same aims, goals, sample size, and use of resources as initially submitted in the JIPGP proposal. Do not add or increase resources or change aims without prior approval by the CHPS program directors. If the proposal is to support/supplement an existing IRB approved study, the awarded JIPGP project should be written as a new unique submission to the IRB and CHPS.
- 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 UL1TR001878 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 John Krall (krallj@email.chop.edu) at CHOP or Charles Molli (cmolli@upenn.edu) at Penn.

- All publications utilizing CTSA/CHPS resources must have a Pub Med Central (PMC) ID number when applicable. Please arrange for PMC submission at the time your manuscript is accepted by the journal via the NIH Manuscript Submission System at <http://nihms.nih.gov/db/sub.cgi>.
- JIPGP awardees are required to provide annual progress reports. Awardees will receive an automated notification from the ITMAT pilot grants system.

Required Documents

Proposal Submission: Submit the JIPGP application electronically utilizing ITMAT's PILOT GRANT SYSTEM which can be found at: www.med.upenn.edu/apps/itmat/pg. Please refer to the Document Submission section for specific instructions related to this system. A PennKey is required. JIPGP submission documents are attached to the 2020 JIPGP Guidelines Submission Instruction PDF file. When you open the PDF, on the left side of the document, there is a paper clip icon. Click on the paper clip to access the attachments.



- CHPS Resource Request Checklist (attached)
- Abstract Page: The abstract page should be no longer than 250 words.
- Budget Template (attached): 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 justification for each service performed outside the CHPS for which JIPGP funds are budgeted.
- NIH Biosketch: An NIH biosketch must be submitted for the applicant and the mentor. Form and instructions at <http://grants.nih.gov/grants/funding/phs398/phs398.html>
- NIH Other Support: Submit page for the applicant. See sample form at <http://grants.nih.gov/grants/funding/phs398/othersupport.doc>
- Research Proposal: Maximum of three single-spaced pages. The description of the project should include a brief background, hypothesis and aim(s), subjects, methods, analysis and study feasibility and recruitment sections as well as a paragraph on how you plan to use the resources of the CHPS. **Your proposal must clearly indicate**

which CHPS resources you wish to utilize. Please indicate the importance of this funding for 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.
- 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.

Budget Guidelines

- The required Resource Checklist identifies which services awardees will request for their JIPGP submission.
- Maximum allowable expenditures for other costs 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, core lab assays, subject recruitment expenses, travel expenses to one scientific meeting to present study results, and salary support for awardee and/or study staff.

Evaluation of Proposals

Applications will be reviewed by the 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 CHPS 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.

OTHER JIPGP PROGRAM INFORMATION

Please discuss and plan your CHPS services and JIPGP budget with the appropriate institutional administrative manager (contact information listed below). A summary of CHPS services can be found at ITMAT and the tables above. The attached Resource Checklist identifies which services awardees will utilize for their submission.

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.

Important Dates

Application Receipt Deadline	March 6, 2020 at NOON
Notification of Award (tentative):	April 17, 2020
Funding Period:	June 1, 2020 - May 31, 2021

PennKey

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 the PennKey two weeks in advance of the submission date 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: <https://intranet.research.chop.edu/display/deptatop/CHOP+PennKey+Administration>

Budget and Finances

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

CHOP Submissions: 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 CTFM is required. For ease of submission to eSPA, you may merge all JIPGP documents into one PDF. Go to the eSPA login page to start the grant submission: Contact your Sponsored Project Officer for assistance. Contact John Krall (krallj@email.chop.edu) if you have questions about CHPS services and how to access them. Contact Dr. Xiangdong (Sean) Ren, MD, PhD, Director of the Translational Core Lab directly for lab prices (renx@email.chop.edu).

OTHER HELPFUL HINTS

- The applicant for the proposal should log in at www.med.upenn.edu/apps/itmat/pg. Do not wait until the last minute to submit your protocol to the pilot grant system.
- 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 co-investigators 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 Brent Bell, Prema Sundaram, Michael Campbell, or Raylonda King.
- 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 documents. You cannot make changes to your application after clicking this button. Note, documents do not need to be uploaded all at once - BUT click this button only after you have uploaded them all.

For questions, please contact:

- Penn: Tracey Caputo, Penn CHPS Business Administrator, 215-898-8264, caputot@upenn.edu
- CHOP: John Krall, CHOP CHPS Administrative Director, 267-425-1790, krallj@email.chop.edu