

Translational Medicine and Therapeutics (ITMAT)

“Improving enrollment in clinical trials”

Submission Requirements

Overview

The concomitant problems of under-enrollment and selective enrollment in randomized clinical trials (RCTs) often plague efforts to evaluate medical interventions. These problems often arise due to unexpected impediments to participant recruitment, which represents one of the largest costs of conducting RCTs. In recent decades, behavioral economics has provided considerable insights into how people make decisions, blending findings from economics and psychology to generate better descriptive and normative models of behavior. However, systematic efforts to apply behavioral economic approaches to improve patient enrollment in RCTs have rarely been attempted.

Potential ways to address low enrollment in trials through behavioral economics include more effective information provision, different ways of presenting choices (choice architecture), and monetary or non-monetary incentives. A taxonomy of such approaches can be found in: Van Epps EM, Volpp KG, Halpern SD. A nudge toward participation: Improving clinical trial enrollment with behavioral economics. *Science Translational Medicine* 2016; 8: 348fs13. This taxonomy is far from exhaustive, but rather highlights some possibilities among many for surmounting the public health threats of under enrollment and selective enrollment in clinical trials. However, achieving this goal requires experimental evaluations to determine which strategies are most effective, and which engender the fewest unintended consequences, such as undue or unjust inducement. **The goal of this pilot program is to help investigators at UPENN develop more successful strategies to increase the efficiency of clinical trial enrollment across a range of different types of interventions.**

Guidelines

- **The project period for this pilot program is 6 months.**
- Given the limited duration of the available budget period during this first solicitation for pilot grants under this funding opportunity (see below); priority will be given to projects that are ready for rapid implementation. **NO COST EXTENSIONS ARE NOT ALLOWED.**
- We are interested in supporting experimental evaluations of interventions embedded within actual, on-going clinical trials, and will also consider carefully designed lab experiments of promising strategies.
- ITMAT grants are available to registered members of the Institute for Translational Medicine and Therapeutics (ITMAT) including Associate Members who hold Instructor A or Research Associate positions. You can register to become a member at <http://www.itmat.upenn.edu/membership.shtml>
- Novel collaborative applications between faculty located in different Schools at Penn are encouraged but not required.
- All proposals are due by **November 4, 2016 at noon** for a project start date of **December 1, 2016**. **LATE SUBMISSIONS WILL NOT BE ACCEPTED NOR WILL EXTENSIONS BE GRANTED.**

Required Documents

- **Submission:** Please submit online at www.med.upenn.edu/apps/itmat/pg. **PLEASE ENSURE THAT YOU CHOOSE THE Improving Enrollment in Clinical Trials PROGRAM WHEN SUBMITTING YOUR GRANT.** Please refer to Document Submission Section for specific instructions related to this system.
- **Abstract Page:** The abstract text should be no longer than 250 words.
- **Budget:** Please use the excel template budget page and provide detailed expenses.

- **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 resources are to be spent on services provided from outside Penn.
- **NIH Biosketch:** An NIH format biosketch must be submitted for the **PI and the Co-PIs only**.
- **Research Proposal:** The research proposal should be no longer than two single-spaced pages with one-inch margins and should include the essential background information relative to the project. Please use Arial size 11 font. Please indicate the importance of this funding to the feasibility of your research proposal and potential for future funding. Please indicate if any other funds are available to you for the proposed research. References should be attached to your research proposal and will not count toward your two page limit. Please provide a timeline of implementation to ensure meeting the end date of May 31, 2017. **NO OTHER SUPPORTING DOCUMENTATION WILL BE CONSIDERED.**
- Copies of **IRB approval letters** will be required if an application is funded. Funding will be delayed until these approval documents are received. Applicants are encouraged to submit documentation of IRB “approval in concept” along with their submission. Applicants proposing studies embedded in ongoing “parent” trials are encouraged to include a letter of support from the parent trial PI.

Budget Guidelines

- We plan to award up to \$100,000 in direct costs under this initiative. Budgets of any size up to \$100,000 may be submitted in support of projects for a maximum duration of 5 months beginning on December 1, 2016 and ending May 31, 2017. All funds must be expensed by this end date. **NO COST EXTENSTIONS ARE NOT ALLOWED.** Note, however, that the “cost effectiveness” of the budget will be considered in making awards. For example, if two proposals of equal scientific merit are submitted, the one with the smaller budget will be reviewed more favorably. Depending on the number, quality, and budget size of submitted proposals, we will fund between 1 and 6 pilots through this initiative.
- Budgets must be submitted on approved excel template.
- Name, title/role, percent effort, salary, and benefits must be defined in the budget for each grant participant. Note that salary support for faculty is discouraged. Applicants proposing faculty salary support should provide clear justification for why the pilot requires this. Please use the NIH salary cap limit.
- Supplies should be detailed by type and number in the budget and the budget justification.
- Equipment expenditures and service contracts should be detailed in the budget and budget justification. Please keep in mind that equipment is defined as any item costing more than \$5,000 with an estimated useful life greater than one year.

Other

- Any publications that are the direct result of this funding must reference:
 - **“Supported in part by the Institute for Translational Medicine and Therapeutics of the Perelman School of Medicine at the University of Pennsylvania.”**
 - **“Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR001878. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.”**
 - **If the Way to Health Platform is used for a pilot, please reference it by name in the methods section of the manuscript.**
- A progress report will be requested every year for 4 years so that we can track the success of supporting projects that result in the receipt of a grant, publication, or technology transfer. These summaries should be uploaded to ITMAT’s Pilot Grant System at www.med.upenn.edu/apps/itmat/pg. You will need your PennKey logon and password to access this system.

- You will be prohibited from applying for future ITMAT pilot funding if you do not reference the funding support on publications and if you do not submit progress reports.

Document Submission

All applications should be submitted via ITMAT's Pilot Grant System at www.med.upenn.edu/apps/itmat/pg. **PLEASE ENSURE THAT YOU CHOOSE THE "Improving Enrollment in Clinical Trials" PROGRAM WHEN SUBMITTING YOUR GRANT PROGRAM.** You will need your PennKey logon and password to access this system. If you do not have a PennKey, obtaining one will take at least 48 hours so do not wait until the last minute. We will not accept applications late because of this. Once you start an application, you can proxy someone (grants manager, post doc, etc.) to finish it for you.

- Each investigator and Co-Investigator must be an ITMAT member.
- Each Investigator and Co-Investigator must have the approval of their respective Business Administrator.
- **Penn Faculty should select the Business Administrator or Grants Manager that normally signs off on all of their research proposals.**
- **CHOP Faculty** must select Bernice Saxon, Brent Bell, Michael Campbell, or Robert DeNight as their Business Administrator. **PLEASE ONLY CHOOSE ONE.**
- **Wistar Faculty** must select Jessica Blodgett as their Business Administrator.
- **University of the Sciences Faculty** must select Karen Mitchell as their Business Administrator.
- If your grants are managed by a division within the **Department of Medicine, please select Susan Wahl as your Business Administrator.** She will coordinate divisional/departmental approval.
- **Please ensure that the documents you upload are the final documents. ITMAT will not update or replace files. This means that prior to hitting the submit button, all documents must be final.**
- When contacting the ITMAT business office, please use the same discretion you would employ if contacting an external sponsor.
- Please ensure that you have liaised with all of the Co-Investigators on your application. This will avoid proposals being rejected by their Business Administrator.
- All documents must be uploaded by **noon** on the due date of the proposal to ensure time for all approvals. All approvals must be completed by **5 pm** on the due date. **We suggest you do not wait until noon to start uploading documents.**
- Once all approvals are completed, the grant will be received by ITMAT.

Application or Funding Questions

For programmatic or budget questions please contact Joelle Friedman, Associate Director of the LDI Center for Health Incentives and Behavioral Economics (CHIBE), at joellef@mail.med.upenn.edu.

For technical questions related to completing the online application please contact Jessica Bickhart, bickhart@mail.med.upenn.edu or Jason Molli, molli@exchange.upenn.edu