The Johns Hopkins Institute for Clinical and Translational Research (ICTR) REQUEST FOR APPLICATIONS

ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) PROGRAM

Deadline: February 22, 2015 at 11:59 PM

Eligible: All Johns Hopkins University faculty

Budget: Up to $100,000 in direct costs. No faculty salary.

Grant Period: twelve months; No NCE permitted

Application: Online at http://ictrweb.johnshopkins.edu/ictr/connection/

PROGRAM OVERVIEW

The Accelerated Translational Incubator Pilot (ATIP) grant program is designed to accomplish the following objectives and goals:

- To promote innovative translational research by providing starter funds that will support projects specifically focused on the translation of laboratory and/or clinical research into new interventions that improve outcomes for patients. Particular focus will be on the development of new therapies (medications, devices, nutrition, behavioral interventions, etc.) or diagnostics, new approaches to prevention or translation of knowledge through the health care system.

- To employ a milestone-driven approach to research projects that will ensure the timely generation of tangible products and outcomes. Thus, all projects must be designed so that it is feasible to complete the project within the 12-month funding period.

- To promote cross-disciplinary collaboration, especially new and novel types of collaborations. The program encourages the participation of new and/or junior investigators and the participation and/or training of new or inexperienced junior translational clinical scientists with an established team.

- To support investigators in the efficient attainment of translational milestones by providing guidance, resources, and feedback from the ICTR. All of the research teams receiving ATIP funds will also have regular contact with an assigned ICTR Research Navigator to discuss best strategies for meeting translational research goals.

- To facilitate the progress and completion of all projects through the Research Navigator relationship. The Research Navigators serve as the primary link between ATIP Investigator and the ICTR both by providing their expertise to the study team as project managers and by monitoring study progress and milestone achievements as representatives of the ATIP Executive Committee. The Navigators maintain an active role in the grant throughout the course of the award period.

PROGRAM DETAILS

Eligibility

Eligible submissions must be oriented towards specific milestones, with clear endpoints and a realistic timeline for completion within the twelve-month funding period.

Any faculty member at Johns Hopkins University is eligible to apply for an ATIP grant. Junior faculty in all schools, particularly those new to translational research, are encouraged to apply and will receive extra consideration. However, please be aware that, while most study expenses are eligible for ATIP coverage, faculty salaries are not.

Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators for pilot grants but can be incorporated as team members into any proposal.

All grants that involve human participants or animals must be approved by an Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC) prior to initiating Human Subjects or animal research activity. All other required institutional approvals (e.g. Biosafety registrations, HSR compliance and HIPAA certification of staff, Clinical Engineering clearance of devices, ISCRO approval for stem cell research, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required. Similarly, grants for projects subject to oversight by external regulatory agencies such as the FDA or the NIH/OBA are also required to obtain these approvals **before** initiating human subjects research activities. Copies of all approvals, renewals, certifications, protocols and amendments must be made available to the Research Navigators throughout the course of the grant award period upon request. While advance approval by these bodies is not a prerequisite for submission of an ATIP application, investigators should be aware of the impact of these and other necessary administrative or regulatory reviews on project timeline and feasibility. In other words, investigators with necessary regulatory approvals pending or in-hand will receive higher feasibility scores for their projects than those with regulatory submissions that have not been prepared or submitted for review. If awarded, the start date of the 12-month grant will be provided in the award notification letter, but is expected to be on or about July 1, 2015. The start date may be revised as circumstances require.

Awarded ATIP PIs are not eligible to apply for a new ATIP project in the twenty-four month period following the receipt of their initial award funds.

Resubmission of denied grants is not permitted. However, unsuccessful applicants may apply in consecutive rounds with substantially different proposals.

Conflicts of Interest

At the time of application, before funds are awarded, and throughout the project period, it is the responsibility of the awardee and all members of the study team to report any financial or fiduciary interests that might appear to present a conflict of interest. These interests must be reported to the ICTR and the University Office of Policy Coordination. The presence of a conflict of interest does not disqualify investigators from receiving this award but will require the review and management of this conflict by the Committee on Outside Interests. The failure of any member of the study team to disclose all outside interests could result in the termination of this award and the disallowance of all study costs.

More information about the University's Conflict of Interest Policy, including examples of what constitutes an outside interest, may be found at the Office of Policy Coordination website (http://www.hopkinsmedicine.org/Research/OPC/Outside_Interests/).

Potential Project Topics

Projects may cover a wide range of topics, including but not limited to the representative topics below:

- Pre-Clinical Translation
  - Development of pre-clinical research tools
  - Development of novel treatment platforms or therapies
  - Drug screening assays
  - Methods for generation of novel vaccines or peptides
  - Animal models for drug selection
  - Preclinical toxicology markers/assays
  - Surrogate marker assays, including genomic, proteomic assays, and metabolic, imaging methods

- Clinical Translation
  - Development of clinically relevant tools
  - Development and verification of surrogate marker assays
  - Clinical trial design paradigms (e.g. computer simulation)
  - Development or evaluation of diagnostic tests
  - Clinical trials
    - Pilot/Phase 0 or 1 trials
    - Collection of pharmacokinetics/pharmacodynamics data

- Post-Clinical Translation
  - Comparative effectiveness research studies
  - Knowledge transfer to providers or community
  - Novel approaches to partnering with communities to enhance research

Funding Restrictions

- Requests must be no more than $100,000 in direct costs. **Requests exceeding $100,000 will not be reviewed.**

- Funding will be for 12 months only. **No-cost extensions will not be granted. No exceptions will be made.**

- Funding requests that are significantly lower than the $100,000 ceiling (e.g., $25,000-$50,000) are strongly encouraged. More modest requests are welcome as they free up additional program funds. However, budget estimates must be realistic and proportionate to the scope of the project. Requests for additional funding after the award is made will be denied.

- Grants can be used only for support of laboratory or clinical studies conducted primarily at Johns Hopkins or by Johns Hopkins investigators. Subcontracts with outside institutions/facilities are permitted, but should be no more than 50% of total requested budget. Subcontracts greater than 50% of the total requested budget may be considered with a strong justification.

- Indirect costs should not be included in the budget, **except in the case of subcontracts**.

- **Applicants with projects requiring subcontracts** must provide the following in addition to an overall budget:

  - a separate budget and justification for the sub-award detailing the total funds required including **total direct costs** AND **total indirect costs of the outside facility**

- ATIP funds may **not** be used for faculty salary.

- ATIP funds may be used for fellow and staff salary support, as well as for stipends paid to undergraduate or graduate students at Johns Hopkins.

- ATIP funds may be used for travel **essential to the conduct of research**, but not for travel to present results at established meetings or conferences without strong justification and **ATIP leadership approval**. The review committee recognizes the high *per diem* costs of some international sites but expects investigators to exercise ingenuity and judgment in budgeting for overseas room and board.

- ATIP funds may be used for equipment specific to the development of an assay, diagnostic, or device, but unless otherwise noted, equipment costs should not be more than 50% of the total grant award.

- ALL changes to the original research plan or budget must be submitted ***BEFORE IMPLEMENTATION*** to the Research Navigators for review and final approval by the ATIP Executive Committee, and may result in withdrawal of funding if the project no longer meets ATIP criteria or does not receive the appropriate approvals.

- ATIP leadership may revise the award amount should the applicant incorporate into their submitted budget, allocations of funds for activities or expenditures that are not permitted or if reviewers feel that the amount requested is more than is needed to complete the project.

- All funded PIs will be required to submit regular (e.g. bimonthly) written progress reports, including supporting data, to the ICTR Navigators. Progress reports are reviewed by Navigators to ensure that projects are meeting their milestones and progressing according to the timelines submitted by the awardees. The progress reports are a means for identifying those groups who might benefit from Navigator/ATIP leadership intervention. **The Navigators may query awardees and/or request additional information and/or data from study teams after review of information provided so that they may fully investigate specific issues related to overall project progress.** Every effort is made to assist investigators and their teams in overcoming unforeseen obstacles encountered during the award period. For these reasons, due to the accelerated nature of the program, **failure to submit progress reports in a timely manner can have significant implications for a project and, as such, may result in termination of funding.**

- **Studio Requirement**: All awarded PIs will be given the opportunity to participate in an ICTR Studio consultation once during their funding period. The ICTR Studio is a new multidisciplinary service center created to help investigators improve the quality and impact of their translational research and is available to other JHU faculty by invitation only. This ICTR initiative is operated as a Master class, where sessions are organized with a panel of expert consultants specially selected to accommodate the specific needs of each project. Assistance is provided by consultants who are acknowledged authorities in their fields, and who possess a broad spectrum of expertise ranging from content experts to help formulate the most relevant research questions, to methodological and technical specialists available to address issues related to the use of institutional and CTSA resources for pre-clinical and clinical studies.

  Timing and organization of each awardee's Studio consultation will be encouraged based on the needs of the investigator and study team, the progress of the research with regard to the originally approved timeline, and input from ATIP leadership. For example:
  - If the project is progressing well, the Studio may be scheduled late in the award period in order to assist the PI with development of the next steps in the translational pathway.

- If the project has met with an unforeseen obstacle affecting the original timeline and additional expertise or assistance is needed, a Studio can be scheduled immediately in order to help the PI address and move past the issue.
- If the project focuses on development of a new methodology, technology, or approach that may be of interest to the research community at large, a Studio may be scheduled at the convenience of the PI during the award period with the JHU research community invited to attend as IP considerations allow.
- If the project involves one of several previously identified areas of study including the Johns Hopkins Institute for Computational Medicine (ICM), Statistical Methods and Applications for Research in Technology (SMART), Institute for NanoBioTechnology, and Center for Clinical Trials – Prediction of Individual Treatment Outcomes in Patients, a Studio may be scheduled at the convenience of the PI during the award period with the JHU research community invited to attend as IP considerations allow.

While participation in the Studio Program is a condition of award, ICTR leadership believes that it will be a very rewarding process for ATIP grant recipients. For more information about the ATIP Studio consultation opportunity, please contact Carol Kobrin at ICTR_Navigators@jhmi.edu.

Dissemination Plan

ATIP grant proposals will be accepted annually, with submission deadline announced at least one month in advance. University-wide web and email announcements will be sent at least twice for each application period. In addition, solicitation will be displayed on the ICTR web site and sent upon posting to individuals who opt in for ICTR updates via email or news feed. Any changes or alterations to the program and/or the RFA will also be broadcast through these methods. In addition, ICTR-associated faculty and staff are encouraged to assist in communications efforts through their own email contacts and word of mouth.

The submission deadline for the next round of awards is **Sunday, February 22, 2015.** All application materials must be received **by 11:59 PM on February 22, 2015**.

APPLICATION PROCESS

Grants must be submitted through the ATIP ICTR Connection Request form, located on the ICTR web site at https://ictrweb.johnshopkins.edu/ictr/?RequestATIP.

The grant application is comprised of the five mandatory application components described below. These documents may be in Microsoft Excel, Adobe PDF or Word format and must be uploaded into the on-line application form in the corresponding section. **New biosketch and budget templates are available within the online application form for applicants to use.** Use of these templates is not mandatory. Should any of the five required documents be omitted from the application, the Connection Request system will not allow the applicant to complete submission of the grant. Questions about the application process should be directed to the ICTR Research Navigators either through the Connection Request system to the "Ask a Navigator" service at or by emailing the Navigators at ICTR_Navigators@jhmi.edu.

Materials required to be submitted via the online application include:

- Biographical sketch information:
  - A biographical sketch in in NIH-format for the PI (5-page limit)
  - A biographical sketch in NIH-format for the co-Investigator (5-page limit)
  - A brief identification and biographical description of all other study team personnel named in the ATIP application **(4-page limit total)**

- Comprehensive budget and justification:
  - The budget **MUST** be **itemized** to within $1000.
    - List each component of equipment with amount requested separately and justify each purchase
    - **Itemize supplies in separate categories**, such as glassware, drugs, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized.
    - If animals are to be purchased, state the species, number to be used, and cost per animal.
  - The budget **MUST** include an explanation of other funding sources that will be used to cover costs not covered by ATIP
  - The budget **MUST** include the name and email address of the applicant's financial contact
  - A **detailed** justification is required and **MUST** include salary, supplies, equipment, travel, etc., and any other expenses required to complete the study.
    - Unjustified budgets will be returned for correction.
  - **If the budget includes a subcontract**, the total requested funds (including subsite indirects, if applicable) for the subcontract must be listed in the overall project budget; **additionally, a separate detailed subcontract budget, justification, and scope of work must also be submitted**.

- Research plan (5-page limit, content and format described below in "Research Plan Guidelines")
- Project schedule
- Project readiness checklist
- Reference list of up to 30 references *(optional)*

RESEARCH PLAN GUIDELINES

Presentation and Formatting: The research plan must be no longer than five single-spaced pages (including figures) in a font no smaller than 11 points, with margins of at least 0.5 inches on all sides. **References are not included in the five-page limit**. The name of the PI should appear in the top right-hand corner of each page. Page numbers should appear on the bottom right-hand corner of each page.

The Research Plan must include the following components:

Brief Introduction/Abstract: This section is intended to help the author orient the reviewer with respect to the sections that follow. It may be in the form of a comprehensive abstract or a more limited introduction. Any new collaborations or highly innovative aspects should be succinctly noted. Relevance to the translational nature of the ATIP program should also be indicated.

Project Milestones and Timeline: In the research plan, which is to be no longer than 5 pages in length, a **summary** of specific milestones and a 12-month timeline of the project must be included. This summary may be presented as a chart, a paragraph, or incorporated throughout the experimental design. Milestones should highlight specific goals to be attained and, when appropriate, hypotheses to be tested. Milestones must include both the scientific objectives of the application and the procedural issues involved in executing them in a realistic and achievable way. If new techniques, new populations, or new collaborations are utilized to reach these milestones, they should be emphasized.

Unlike traditional NIH grants, the majority of translational grants are designed to reach a specific, translationally oriented target (e.g. the screening of drugs, the generation of a diagnostic or assay). All grants must be organized towards the completion of project- and/or time-dependent milestones.

NOTE: *In contrast to the milestone/timeline summary presented in the research plan, the Project Schedule document that is required with the application* ***MUST*** *include the milestones described in the research plan AND a breakdown of all activities necessary to complete the milestone and the time required for each activity. For more information about creation of milestones and project timelines, please see the* ***"ATIP Application: Development of Milestones and Project Schedules****" document posted with this RFA.*

Background (including Preliminary Results, if available), and Significance: In addition to scientific background and significance, this section may indicate how success of the pilot grant will affect subsequent research and how it enhances translation (e.g. from lab to clinic). The material on Significance should indicate relevance to the overall target of clinical translation. It should also clarify how the research will advance the field, (e.g. development of new assays for drug discovery, new devices, and new screens for drug toxicity) and should also discuss the project's potential for improving the health of patients within the next 3-5 years.

Experimental Design: Method description should be sufficiently detailed to convince reviewers of feasibility and validity. Details should focus on the novel aspects of the project rather than published or standard techniques. Statistical approaches to data analysis should be outlined where applicable. Quantifiable goals for the completion of each milestone should be delineated. A brief section outlining any collaborative links to any other clinical or laboratory cores is necessary, as are details for outside contractual services (e.g. chemical synthesis, structure activity analysis, pharmacokinetics, or toxicology).

Anticipated Problems and Possible Solutions: Any anticipated experimental or interpretive problems should be addressed, with alternative approaches described when possible. It is assumed that all alternative approaches should be feasible with the fiscal and time constraints of the ATIP award. Risks and drawbacks of this approach inability to complete the project within the allotted 12 month time frame should be addressed, especially if human subjects are involved.

REVIEW PROCESS

Applications will be evaluated and scored using the following five criteria:

1. **Relevance to translation**: Are there plans to move a project through to the next step along the research pathway?
2. **Scientific impact, novelty, and merit, including experimental design**
3. **Feasibility of project completion within a 12-month period**
4. The **creation or potential for creation of collaborations** between investigators
5. Whether or not the project's PI is a **junior investigato**r and/or will promote the development of new translational researchers by **moving junior or senior investigators into a new research area**

Only complete applications received by the deadline will be considered. The review process will be conducted as follows:

- **Administrative Triage:** ICTR Research Navigators will review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in this document and the ATIP Connection Request form. **Incomplete or noncompliant applications will be returned without scientific review.**

- **First Round:** ICTR Deputy Directors, Core Management and the Navigators will all assess the applications in terms of the fit, feasibility, and translational nature of the proposed project. In addition, the ICTR Research Navigators will perform a preliminary feasibility review and assign a feasibility score that will be used in final calculation of the first round score.

- **Second Round:** Applications that pass the first round of assessment will be sent for scoring to a minimum of two external reviewers with expertise in fields relevant to the science in the proposal. These reviewers will be asked to disclose any relationships to the grant applicant. If not conflicted, they will then be asked to provide written feedback addressing the merits of the application based on the five criteria listed above and scored accordingly. Reviewer comments from this round will be provided to applicants, but reviewer identities will be kept confidential.

- **Second Round Navigator Assessment:** Due the accelerated nature of the program and the 12-month project timeline, an in-depth assessment of project readiness will be done on all applications in second-round review. The Research Navigators will perform these assessments, during which PIs may be contacted for additional information.

- **Funding Decisions:** The ICTR Leadership Committee will evaluate all second-round feedback and in-depth Navigator Assessments and make final funding decisions.

- **Notification and Feedback:** All applicants will be notified of funding decisions approximately two months after the submission deadline. **The start and end date of the 12-month grant will be included in the notification of the funding decision. Only those applicants who receive second-round reviews will be provided with feedback from the external review process**. Resubmission of denied grants is **not permitted.**

Questions about the ATIP application process should be directed to the ICTR Research Navigators at ICTR_Navigators@jhmi.edu.

Feedback about the ATIP Program may be directed to ictr@jhmi.edu.