

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

## ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) PROGRAM

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**Deadline:** October 1, 2009

**Eligible:** All Johns Hopkins University faculty

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

**Grant Period:** twelve months

**Application:** online at <http://ictr.johnshopkins.edu>

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### 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 treatments, interventions, or cures that will result in better health care. Particular focus will be on the development of new therapies (medications, devices, nutrition, behavioral interventions, etc.) or diagnostics, the improvement of clinical trials and clinical data collection, and/or knowledge translation.
- To employ a milestone-driven approach to research projects that will ensure the timely generation of tangible products and outcomes.]
- 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. Progress on all grants will be shared in a group setting at bimonthly ATIP Investigator meetings and at an annual review meeting. All of the research teams receiving ATIP funds will also meet regularly with an assigned ICTR 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 and by monitoring study progress and milestone achievements as representatives of the ATIP Executive Committee.

## PROGRAM DETAILS

### ***Eligibility***

Eligible submissions must be oriented towards specific milestones, with predicted 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) and/or the Institutional Animal Care and Use Committee (IACUC) to receive ATIP funding. 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.

ATIP PIs grants will not be 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 strongly discouraged except by invitation from the ATIP Executive Committee. However, unsuccessful applicants may apply in consecutive rounds with substantially different proposals.

### ***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
  - 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 should be no more than \$100,000 in direct costs. Requests exceeding \$100,000 will not be reviewed.
- 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 should be realistic and proportionate to the scope of the project.
- Indirect costs should not be included in the budget
- Grants can be used only for support of laboratory or clinical studies conducted primarily at Johns Hopkins or by Johns Hopkins investigators.
- Funds may not be used for faculty salary.
- Funds may be used for fellow and staff salary support, as well as for stipends paid to undergraduate or graduate students at Johns Hopkins.
- Funds may be used for travel essential to the conduct of research, but not for travel to established meetings or conferences. 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.
- 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 fifty percent of the total grant award.
- Funding will be for twelve months. No-cost extensions or second year funding may be available on a case-by-case basis, but such exceptions will be extremely rare and should not be a part of the research plan.
- All funded P.I.s or their designates will be required to present their ongoing research at bimonthly meetings as determined by their ICTR Research Navigators. In addition, they will be required to present their results in an annual meeting of ATIP advisors. Failure to participate in the bimonthly meetings by P.I.s or designates will result in termination of funding.
- Any substantive changes to the original research plan must be submitted to the ATIP committee *before implementation* for review and may result in withdrawal of funding if the project no longer meets ATIP criteria.

### **Dissemination Plan**

ATIP grant proposals will be open for submission two times a year. 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, <http://ictr.johnshopkins.edu>, 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 **October 1, 2009**. All application materials must be received by midnight of the deadline day.

### APPLICATION PROCESS

Grants must be submitted through the ATIP ICTR Connection Request form, located on the ICTR web site at <http://ictr.johnshopkins.edu>. Supplemental materials described below may be uploaded through the application form in either Adobe PDF or Microsoft Word. Questions about the application process should be directed to the ICTR Research Navigators through the Connection Request form at <http://ictr.johnshopkins.edu>.

Materials requested during the online application process will include:

- A short c.v. or biographical sketch (NIH-format or similar) for the P.I. (2-page limit total)
- A brief identification and biographical description of all study team personnel (4-page limit total)
- A comprehensive, itemized budget with detailed justification that includes salary, supplies, equipment, travel, etc., and any other expenses required to complete the study. The budget should also include an explanation of other funding sources that will be used to cover costs not covered by ATIP. (Budgets may also be submitted in Microsoft Excel format).
- Research plan (5-page limit, content and format described below in "Research Plan Guidelines")
- 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 .5 inches on all sides. References are not included in the five-page limit. The name of the P.I.(s) 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.

**Specific Milestones:** The research plan should include a twelve-month timeline of milestones. 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. Some examples of milestone activity: purchase and delivery of equipment, a certain number of compound screens or secondary assays, successful IRB application, hiring of required staff, etc.

**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 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. Risks and drawbacks of this approach should be addressed, especially if human subjects are involved.

## REVIEW PROCESS

**Applications will be evaluated using the following five criteria:**

- Relevance to translation: Are there plans to move a project through to the next step along the research pathway?
- Scientific merit, including feasibility and experimental design
- Scientific impact and novelty
- The creation or potential for creation of collaborations between investigators

- Whether or not the project 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 staff will review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in this document and on the ATIP Connection Request form. Incomplete or noncompliant applications will be returned without scientific review.
- **First Round:** Members of the ATIP Executive Committee will assess applications in terms of the fit, feasibility, and translational nature of the proposed project.
- **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. They will then provide written feedback addressing the merits of the application based on the five criteria listed above. The ATIP Executive Committee will review this feedback and make final funding decisions.

**Notification and Feedback:** All applicants will be notified of funding decisions within two months of the submission deadline. Applicants that receive second-round reviews will be provided with feedback from the external review process. Resubmission is strongly discouraged except by invitation.

**Feedback about the ATIP Program may be directed to [ictr@jhmi.edu](mailto:ictr@jhmi.edu).**