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

ACCELERATED TRANSLATIONAL INCUBATOR PILOT (ATIP) PROGRAM

Deadline: **Friday, November 22, 2019 at 11:59 PM**

Eligible: All Johns Hopkins University faculty

Budget: Up to $100,000 in direct costs; No faculty salary with exception of Research Associates

Grant Period: Twelve months

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.

Projects poised to begin by February 1, 2020 (i.e. with regulatory approvals in place or underway at the time of submission, staffing in place, etc.) will receive additional consideration.

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.

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.

Applicants identified as the PI have primary responsibility for the grant submission, and if subsequently selected for funding, all work to be performed as well as all reporting requirements and other stipulations which must be satisfied as a condition of receiving this award. Awards WILL NOT be transferred to another investigator post-award.

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.

Regulatory Requirements/Approvals

Regulatory approvals are not required for ATIP application submission. However, before the project can be started all applicable institutional (i.e. Institutional Review Board [IRB]), external (i.e. FDA IND or IDE) and NIH (i.e. National Center for Advancing Translational Science' [NCATS])approvals must be obtained before the project can be started. NCATS' approval is only required for proposals involving human subjects research (i.e. as defined by NIH, 45CFR 46) or live vertebrate animals, though the corresponding approvals from the reviewing IRB or the JHM Animal Care and Use Committee (ACUC) must accompany the NCATS approval request.

Due to the accelerated nature of this program, investigators are strongly encouraged to initiate necessary approvals prior to grant submission or during the grant review period. Projects with regulatory approvals in place or underway at the time of submission will receive additional consideration.

If notified by the ICTR that their human subjects or vertebrate animal submission has been selected for ATIP funding, the applicant must immediately start working to obtain all institutional and external regulatory approvals and submit their study for IRB or IACUC review, if they have not done so already. The Navigators can assist with filing IND and/or IDE applications, and upon receipt of IRB or IACUC approval, they will provide further guidance and detailed instructions for preparation of the NCATS document package. **See Appendix I for additional information about the NCATs prior review requirement.**

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 and are strongly encouraged to fall within $25,000-$50,000 range. Budget estimates must be realistic and proportionate to the scope of the project. Requests for additional funding award approval are not permissible. **Requests exceeding $100,000 will not be reviewed.**

- **ATIP leadership may revise the award amount should the applicant's submitted budget, provide funds for activities or expenditures that are either not permitted or deemed to be more than is needed to complete the project. Applicants whose funding requests are revised by leadership for either of the above reasons, will be required to resubmit a revised research plan, budget, and project schedule, if applicable, for approval by ATIP leadership prior to being permitted to start their project**

- Funding will be for 12 months only. **No-cost extensions may be granted on a case-by-case basis with strong justification for those with funds remaining at the end of the award period.**

- For grants that include laboratory work for or clinical studies which will be conducted at sites outside of Johns Hopkins, the feasibility of the overall proposal will be prominently considered in any funding decisions. Leadership may revise the scope of the project and funds awarded if a proposal is not thought feasible within the 12-month funding period.
  - 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**.

- **Subcontracts may be permitted on a case-by-case basis. Applicants with projects requiring subcontracts must contact the ICTR Financial Office at (410) 361-7887 or the Research Navigators for authorization in advance of submission.** If authorized to include a subcontract in their proposal, applicants may be asked to 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 with the exception of Research Associates. While technically faculty, Research Associate salary support is permitted. ATIP funds may also be used for fellow salary support, as well as for stipends paid to undergraduate or graduate students at Johns Hopkins.

- ATIP funds may be used with **ATIP leadership approval** for travel **essential to the conduct of research**, but not for travel to present results at established meetings or conferences. If such travel is anticipated, a strong justification must be included in the budget justification document together with detailed meeting information (e.g. location, approximate date(s)), travel costs being requested, study team attending, etc.) for review and approval by ATIP leadership.

- 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.

- 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**: As a condition of accepting an ATIP grant, all awarded PIs will be asked to present their ATIP awarded project for discussion in an ICTR Studio consultation. The ICTR Studio is a multidisciplinary service center that was created to help investigators improve the quality and impact of their translational research. 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. Consultants are acknowledged authorities in their fields, who possess a broad spectrum of knowledge ranging from scientific and medical expertise to help the work focus on the most relevant research questions in the field, to methodological and technical specialists 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 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 or immediately following the end of the grant 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 a Studio consultation has not been initiated for the project by the beginning of the fourth quarter of the funding period, the PI will be required to submit to ATIP leadership a brief Studio consultation plan outlining issues to be addressed in the Research Studio. **Failure to submit a plan will result in forfeiture of ten percent (10%) of awarded ATIP funds which will be held in reserve at the outset of the funding period.** 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 applications is 11:59 PM on Friday, November 22 2019. All application materials must be received by this deadline to be considered. No exceptions will be granted.

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 eight 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. Should any of the eight 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 ICTR Connection Request application include:

- **Abstract**

  The abstract is NOT INCLUDED in the 5-page Research Plan and MUST BE SUBMITTED ON THE ABSTRACT TEMPLATE PROVIDED. It must be no longer than 600 words and follow the required font and margin specifications of the Research Plan (See Research Plan Guidelines to follow). **The abstract should not contain proprietary or otherwise confidential information**.

  The abstract must include:

  - a brief background of the project and introduction;
  - specific aims and objectives with hypothesis being tested;
  - the proposed methodology (action steps) to be used in each aim/objective;
  - significance of the proposed research
  - any other information that may be relevant to your project and was not already included in any of the above

- **Research plan** (5-page limit, content and format described below in "Research Plan Guidelines")

- **Comprehensive budget**

  - Applicants **MUST** use the budget template provided in the ATIP application but may customize it as their project requires.
  - The budget **MUST** be **itemized** to $1000 unless the unit cost is greater than $1,000.
    - 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
  - **If the ICTR Finance Office has authorized inclusion of a budget with a subcontract,** *(See Funding Restrictions above)*, the total requested funds (including subsite indirects, if applicable, and directs) 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**. The ICTR Finance Office may request additional documentation as necessary.

- **Detailed budget justification**

  - A **detailed** budget justification is required and **MUST** include salary, supplies, equipment, travel, and any other expenses required to complete the study.
    - Unjustified budgets and justifications not sufficiently detailed will be returned for correction.

- **Biographical sketch information**

  - A biographical sketch 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)**
  - **MUST include full "Other support" pages from PI and all named Co-Investigators**

- **Project schedule**

  - Applicants **MUST** use template provided within the ATIP application

- **Project readiness checklist**

  - Applicants **MUST** use template provided within the ATIP application
  - Incomplete checklists will be returned to the study team for completion

- **Reference list** of up to 30 references

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. **The abstract and references are not included in the five-page limit.** As described above, a bibliography containing up to 30 citations should be uploaded in the Reference List section of the application. 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: This section is intended to help orient the reviewer to better understand the scientific basis for the project, why the work is being proposed as well as the suitability of the research for ATIP funding. 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 required with the application* ***MUST*** *include the milestones described in the research plan AND a breakdown of all activities necessary to complete the milestone, as well as the time required for each named activity.*

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. The feasibility of using alternative approaches to complete the project within the constraints of the presented ATIP budget as well as the 12 month time limit of this grant must be assured in the application. All risks and drawbacks from using any proposed alternative approach must be addressed, especially if human subjects are involved.

ATIP Review Criteria and 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 and Core Management will all assess the application in terms of the fit, feasibility, and translational nature of the proposed project. **These assessments will each be assigned a numerical score. No reviewer comments will be provided to applicants whose proposals are declined in this round.**

- **Second Round:** Applications that achieve a minimum first round score established by ATIP leadership will be sent for 2nd round review to a minimum of two reviewers external to the ICTR 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 concurrently with the 2nd round review, Thus, each l application will be assigned a feasibility score, which , will be included in calculating a final second round score. PIs may be contacted for additional information to complete the project readiness assessment.

- **Funding Decisions:** The ICTR Leadership Committee will evaluate all second-round feedback and in-depth Navigator Assessments and make funding decisions. **Funding decisions for those pilot projects involving vertebrate studies and human subjects' research cannot be finalized until notification of NCATS approval is received** as described above.

- **Notification and Feedback:** All applicants will be notified of funding decisions approximately 10-weeks after the submission deadline. With the exception of projects involving live vertebrate animal studies and human subjects' research, **the start and end date of the 12-month funding period will be included in the notification of award.**

  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.**

Investigators whose ATIP applications were not funded are eligible to request the ICTR Research Studio's assistance with creating a more competitive grant application for eventual submission to other funding programs. Additional information about the Research Studio can be obtained by contacting Carol Kobrin at ckobrin1@jhmi.edu or ICTR_Navigators@jhmi.edu.

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.

Appendix I: *Regulatory Requirements/Approvals*

Animal Studies

Non-Vertebrate Animal Studies

All grants that involve **non-vertebrate animal studies** must be approved by the Institutional Animal Care and Use Committee (IACUC) prior to initiating any animal research activities. All other required institutional approvals (e.g. Biosafety registrations, Radiation Safety registration, etc.) must be obtained prior to initiating any research activities for which the certification/registration/approval is required. 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 with necessary regulatory approvals pending or in-hand may receive higher feasibility scores for their projects than those with regulatory submissions that have not been prepared or submitted for review.

If awarded, information regarding the start date of the 12-month grant will be provided in the award notification letter. The start date may be revised as circumstances require.

Vertebrate Animal Studies

All applicants with projects involving live vertebrate animals must now obtain approval before the study can be started, from the National Center for Advancing Translational Science' (NCATS). This is in addition to approval from the JHM Animal Care and Use Committee (ACUC) as well as all other applicable institutional requirement approvals (e.g. Biosafety registrations, Radiation Safety registration, etc.).

If notified by the ICTR that the ATIP submission has been selected for funding, then the applicant must immediately start working to obtain all institutional regulatory approvals and submit their study for ACUC review. Upon receipt of IACUC approval, which can take several months, the applicant must then prepare a document package to be submitted for NCATS' review. Detailed instructions for preparation of the document package, required file naming conventions, and submission of the materials will be provided by the ICTR Navigators with the notification of selection of the project for award.

The NCATS review package will consist of applicable materials that are either already part of the ACUC application, or should be readily available from the applicant including:

- Animal Welfare Assurance #
- IACUC Approval letter
- Vertebrate Animal Section
  - *Description of Procedures*
    A concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the Research Strategy section. The species, strains, ages, sex, and total number of animals by species to be used in the proposed work must be identified. If dogs or cats are proposed, the source of the animals must also be provided.
  - *Justification*
    Justification must be given that the species are appropriate for the proposed research, explaining why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
  - *Minimization of Pain and Distress*

Interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury must be described.

- *Method of Euthanasia*
  A description of the method of euthanasia must be provided. Justification for any methods of euthanasia that are not consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals will also be required.

- If the proposed research is ancillary to another research protocol, the title and PI of the parent protocol

Human Subjects Research

All applicants with projects involving human subjects research as defined by NIH must now obtain approval before the study can be started, from the National Center for Advancing Translational Science' (NCATS), in addition to an Institutional Review Board (IRB) as well as satisfy other institutional requirements (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.). Research with human cell lines or tissue repositories that meet the definition of human subjects research requires prior approval. 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.

If notified by the ICTR that the submission has been selected for ATIP funding, then the applicant must immediately start working to obtain all institutional and external regulatory approvals and submit their study for IRB review. Upon receipt of IRB approval, which can take between 3-5 months, the applicant must then prepare a document package to be submitted for NCATS' review. Detailed instructions for preparation of the document package, required file naming conventions, and submission of the materials will be provided by the ICTR Navigators with the notification of selection of the project for award.

The NCATS Human Subjects Research Prior Approval (HSRPA) review package will consist of applicable materials that are either already part of the eIRB application, or should be readily available from the applicant including:

- Brief summary of the specific aspects of the proposed study that will be supported by NCATS funds and include a line item budget for each aspect (list supplies, services, and personnel costs)
- IRB approval of the proposed clinical study (if applicable) or institutional exemption determination
- NIH Biosketch for the pilot project investigator and for each Key Personnel involved in the proposed human subjects research study (if applicable)
- Complete clinical research protocol-[1]
- Informed consent document (if applicable)
  - and assent document (if applicable)
- If the proposed clinical research protocol is considered an amendment to a parent protocol, and the entire parent protocol is to be included in the NCATS HSRPA submission [1]:
  - Identification of the specific amendment/ancillary study or portion of the protocol that is supported by the NCATS funding
  - An explanation of exactly what is being supported by NCATS pilot funding
- Product information such as the clinical investigator brochure, package insert, or description of the device, if a clinical trial is proposed (if applicable)
- Documentation that an IND or IDE has been obtained, or letter from the FDA that the study is IND-exempt or the IDE has been waived (if applicable)
- A new or revised "Protection of Human Subjects" section for the pilot that:

- clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities (as detailed in **Section 3.1 in the GENERAL INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES** (See page G-234)" of the NIH competing application instructions (if applicable)-[2]
- clearly identifies the information relevant to the pilot project

- Inclusion plans for women, minorities, and children (if applicable)
- Targeted enrollment table or inclusion data record (IDR) (if applicable)Recruitment and retention plan and recruitment status (if applicable)
- Study timeline (if applicable)
- Data and safety monitoring plan (DSMP) or Board (DSMB) (as applicable)
- Assurance or certification that the pilot project awardee and any key personnel directly involved in the study have taken appropriate education in protection of human subjects (if applicable)

[1]-Except for studies meeting the criteria for exemption under **45 CFR 46**

[2]- If the JHM IRB determines that the project is exempt from formal IRB Committee review, in place of a full Protection of Human Subjects section, a document justifying why the research meets the criteria for the exemption(s) claimed and explaining how the proposed research meets the criteria for the exemption claimed will be required.

NCATS Review and Funding Timeline

NCATS has up to 30 days from the date of **receipt of a complete packet,** to review and respond. Every effort is made to expedite the process and grantees are asked to respond promptly to any requests for additional information or clarifying questions. Based upon experience in the last ATIP funding cycle, these reviews were completed within 30 days.

If approved by NCATS, the start date of a 12-month ATIP grant will be determined upon receipt of the approval notification. 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.

IMPORTANT NOTE: Should a project NOT satisfy NCATS' requirements for approval, and the issue cannot be readily resolved, the pilot award will be disallowed despite being selected for funding by the Johns Hopkins ICTR ATIP program.