

BOOST AND PROPEL RESEARCH AWARDS

REQUEST FOR APPLICATIONS (RFA)

Deadline: Monday, December 16, 2019 at 11:59 PM

Eligible: All Johns Hopkins University faculty

Grant Period: One year, with possible renewal

Program Overview

BOOST and POPEL awards are clinical research grants that will be accepted on a quarterly basis, that award [Clinical Research Unit \(CRU\) resources](#) such as research space including overnight beds, phlebotomy, specialized research nursing, and CRU-based imaging (i.e. DXA, CV core) to investigators, based on scientific merit. Research studies will be monitored by the Translational Research Evaluation Committee (TREC) for study-specific milestones.

The goal of the BOOST and PROPEL award is designed to accelerate meritorious protocols to produce efficient, high quality, safe and disseminatable research. PROPEL and BOOST awards are unique within the ICTR in that: 1) awards are for CRU resources, and 2) applicants undergo a rigorous, NIH-style, multidisciplinary review process via the TREC review committee. BOOST and PROPEL projects are monitored on a quarterly basis for attainment of milestones.

Program Details

Applicant Eligibility Requirements

BOOST: BOOST awards are for junior investigators, first-time R01 awardees, K awardees, and KL2 scholars to generate pilot data for a larger grant submission or to supplement research funds for the K project.

- Researchers with advanced degrees (PhD, MD, or equivalent) and are in an Assistant Professor or equivalent position can apply for funding.
- Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators 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.

PROPEL: PROPEL awards are intended for established investigators who are performing early stage clinical trials, deep phenotyping studies, or studies that address Maryland health priorities. PROPEL can augment resources of a funded project or provide resources for small pilot and feasibility studies.

- Researchers with advanced degrees (PhD, MD, or equivalent) and are at least an Assistant Professor or equivalent position can apply for funding.
- Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators 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.

Project Eligibility Requirements

- Projects must be clinical research projects performed in at least one ICTR Clinical Research Unit (Johns Hopkins Outpatient CRU (Carnegie 3), Johns Hopkins Bayview CRU (301 Building), Johns Hopkins Pediatric CRU).
- Priority will be given to federally funded projects (NIH, FDA, DoD, PCORI etc.).
- Pilot projects and feasibility studies are eligible. Milestone achievement is of heightened importance with pilot awards for continued funding.
- Investigator initiated projects that have industry support for drugs or devices are eligible. A detail project budget is required and will be used to determine the eligibility of investigator-initiated, industry-sponsored projects.

Awards and Terms of Awards

- Awards are in the form of CRU resources not dollars.
- Amount of the award will vary depending on the resources required for the project.
- BOOST and PROPEL grants are for one year with possible renewal based on study progress and achieving pre-determined milestones.
- Awards cannot be carried over beyond the award period.

- A quarterly progress report will be required to monitor project milestones and determine continued funding. Progress reports are reviewed by the TREC 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 early barriers and those groups who might benefit from additional ICTR resources to reduce barriers that are encountered. The TREC may query awardees and/or request additional information 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, failure to submit progress reports in a timely manner can have significant implications for a project and, as such, may result in termination of award funding.

Regulatory Requirements/Approvals

IRB submission is required for BOOST and PROPEL applications. All applicable institutional (i.e. Institutional Review Board [IRB]), external (i.e. FDA IND or IDE) and NIH must be submitted before applying for BOOST and PROPEL.

Application and Submission

Applications must be submitted through ICTR Connection Request, located on the ICTR website at <https://ictrweb.johnshopkins.edu/ictr/connection/>.

An IRB application must have already been submitted and ICTR-CRU selected as a research site (by completing eIRB application, Section 9, question 9 and Section 10).

The BOOST and PROPEL submission is comprised of the application components described below. These documents may be in Microsoft Excel, Adobe PDF or Word format. Questions about the application process should be directed to **Shernice Madison** at smadison@jhu.edu or crus@jhmi.edu.

Materials required to be submitted via ICTR Connection Request include:

- **Instructions** (BOOST and PROPEL Checklist, Milestone Project Instructions, CRU price lists) This document is for informational purposes ONLY.

- **Study Schedule** (Please complete the table listing each visit on your study and resources required).
- **Project Milestones** (There are two required milestones prescribed by the ICTR, 1) study start up and 2) full study enrollment. The applicant is required to select at least two additional milestones.
- **Abstract (250 words)**
- **Research Plan** (5 page limit, Times New Roman font 12, 1 inch margins) must include:
 - Hypothesis
 - Specific Aims
 - Background and Significance
 - Preliminary Data (if any)
 - Research Design/Methods
 - Statistical Design/Analysis
 - Data and Safety Monitoring Plan (DSMP)
- **Reference List** of up to 30 references
- **Biographical Sketch Information** (NIH format 5 page limit)
- **Award Budget/Itemized Budget** (pilot awards exempted)
- **Summary Statement from Peer Review** (if applicable)
- **eIRB Documents** (Consent Form/Assent Form, eIRB Application, FDA Documents)

Application Review Criteria and Process

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

Administrative Triage. The Administrative Team will review applications for compliance with budgetary, content, eligibility, and other submission guidelines.

Peer Review. The Translational Research Evaluation Committee (TREC) will review all proposals. A multidisciplinary review will be conducted by one member each of the Leadership, Regulatory, Biostatistical, Community and Administrative Teams, and two scientific content reviewers according to the evaluation criteria listed below.

Scoring System and Criteria.

Applications are scored based on scientific merit, novelty, appropriateness of design, project feasibility and need for CRU resources to efficiently and safely conduct study. The maximum possible points allowed for each category are listed, with the **maximum cumulative being 45 points**:

1. Scientific merit, novelty, and impact (10 points),
2. Appropriateness of design, project feasibility (10 points),
3. Need for CRU resources to efficiently and safely conduct study (5 points),
4. Junior investigator (e.g., assistant professor, K awardee) (5 points),
5. Joint project between JH and Hub partner (University of Maryland, Kaiser, Morgan State) (5 points)
6. Diverse research population (5 points)
7. Research area: Maryland health priority, early stage clinical trial or deep phenotyping study (5 points).

Final Review and Funding Decisions. The Leadership Team meets to review scoring and comments from all reviewers, as well as the readiness assessments compiled by the Administrative Team. Applicants are notified of funding decisions within two weeks of the meeting. ICTR Leadership will be consulted as needed regarding funding decisions.

Funding/Award Information

Awards are for CRU resources. Funding will be determined by the CRU resources needed to perform the protocol.

You will receive a letter from the TREC that describes the outcome of the review including the CRU resources awarded.

If you are **approved** for funding, you will receive:

1. Letter of Agreement. The PI must:
 - o Agree to have prescribed study milestones monitored
 - o Adhere to reporting requirements
 - o Understand that failure to meet milestone objectives or reporting requirements may result in termination of support.
2. Resources: In addition to CRU resources that are requested, the TREC may suggest that the PI or study team access other ICTR resources to help successfully complete the project, including but not limited to, special populations

consultation, nutrition consultation, recruitment consultation, navigator consultation or biostatistical consultation.

3. An Award letter enumerating CRU resources awarded will be sent to the PI. (Renewal of resources will be determined annually).

If you are **not approved**, the protocol has been determined to have a serious design flaw or insufficient material to judge it fairly. An investigator may apply again in future award rounds.

Oversight Procedures During Funding. The Leadership Team will monitor the study progress through review of pre-planned milestones as reported by the investigator. Investigators will be required to submit a written progress report annually, which is reviewed by the Leadership Team. There will also be quarterly reporting requirements. If research teams are not meeting milestones, barriers identified by the Leadership team will be addressed by ICTR resources specific to the barrier. For instance, if recruitment is a barrier, consultation with the Recruitment Innovation Unit (RIU) will be facilitated. Repeated failure to meet milestone objectives or reporting requirements may result in termination of support.

For questions (see FAQ) and more information, please contact **Shernice Madison** at smadison@jhu.edu or crus@jhmi.edu.