Nexus Award for Development or Evaluation of Biomarkers: *In Vitro* or *In Vivo* (Imaging) Diagnostics

Sponsored by the ICTR Devices
Biomarkers and Diagnostic Tests Translational Research Community

Deadline: May 11, 2021, 5:00 PM EST

Eligible: All tenure-track JHU junior faculty (e.g. Assistant Professor or equivalent); JHU post-doctoral fellows are eligible with a JH faculty mentor.
Special consideration will be given to current recipients of early career grants such as NIH K series awards.

Budget: Up to $37,500

Grant Period: Twelve-month project. Awardee must receive funds by June 30, 2021.

Application: Accepted beginning April 20, 2021

NEXUS GRANT PROGRAM OVERVIEW

The ICTR is has established three Translational Research Communities at JHU:
1. Drugs/Biologics/Vaccines/Devices
2. Biomarkers and Diagnostic Testing
3. Behavioral, Social and Systems Science

All three communities are supporting pilot Nexus grants which are designed to accelerate research by providing rapid, targeted funding to address critical gaps in clinical and translational research, be it taking a clinical observation into the lab, testing a technology or intervention in the clinical setting, or using funding to obtain data required to apply for a translationally focused R01.

The focus of this NEXUS award will be for the funding of new projects or expansion of existing projects in the development or evaluation of biomarkers. The biomarkers can be *in vitro* diagnostics or *in vivo* imaging diagnostics for any aspect of pathophysiology. Examples include but are not limited to biomarkers for early detection of diseases of the cardiovascular system, immune system, cancer, metabolism, or the central nervous system. We encourage Johns Hopkins faculty who have been awarded early career grants. Preference will be given to projects focusing on biomarkers with potential for clinical translation.

PROGRAM DETAILS

Eligibility
- Eligible submissions must be translational projects with clear endpoints and a realistic timeline for completion within a 12-month project period.

- Any faculty member or post-doctoral fellow with a faculty mentor at Johns Hopkins University
- We encourage current recipients of early career grants such as NIH K series awards or other Career Development Awards (e.g. American Heart Association, American Diabetes Association, Radiological Society of North America) to apply.
- If awarded, the start date of the 12 -month grant period will be approximately 30 days post the Nexus submission deadline, after all applicable institutional (e.g. Data Use Agreement) and external regulatory requirements (i.e., NCATS) have been satisfied.
- **All first-year funds must be paid out by ICTR by June 30,2022**

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 to each investigator's institutional office responsible for managing conflicts of interest (i.e. the Office of Policy Coordination at Johns Hopkins). 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 responsible institutional entity. Failure of any member of the study team to disclose all such conflicts could result in the termination of this award and the disallowance of all study costs. Applicants should refer to their institutional conflict of interest policies for more information about what constitutes a conflict and associated reporting responsibilities.

Funding Restrictions, Terms and Conditions

- Requests must be no more than $37,500 in direct costs. **Requests exceeding $37,500 will not be reviewed.**
- All funding must be accepted and spent by the awardee before June 30, 2022. There can be no extensions of this time frame for award payout.
- Indirect costs should not be included in the budget.
- Nexus funds may be used to support the salaries of any faculty, postdoctoral fellows, or other staff working on the awarded project; as well as well as for stipends paid to undergraduate or graduate students at Johns Hopkins.
- Pending approval by Nexus leadership, funds may be used for travel that is essential to the project or research conferences to present the results of the project.
- Nexus funds **may not** be used to purchase **capital** equipment defined as "an article of nonexpendable, tangible property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit."
- 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 NEXUS Executive Committee. Funding may be withdrawn if the project no longer meets the criteria for this award.
- All funded PIs will be required to submit a written progress report 6 months after the funding period starts and either a final close-out report or product at the termination of this grant.
- If awarded, failure to comply with terms and conditions of the Nexus program may result in termination of funding.

APPLICATION PROCESS
Grant applications will be accepted beginning on April 20, 2021. All applications must be submitted through the Nexus Grant Program ICTR Connection Request form, located

on the ICTR website: .

The grant application includes the following **eight mandatory components**:

- **Abstract** (**20-line limit**)
- **Research Plan** (**1-page limit**) which includes: Brief introduction; Study aims and design (study population including sample size, measurements); Significance/Implications
- **Anticipated Problems/Possible Solutions and Timeline/Milestones** (**1-page limit combined**)
- Reference list of up to 30 references**.** *(Not included in Research Plan page limit)*
- An itemized budget, with line item detail to the $1000 level, which contains the budget requirements for scope of work (direct costs only) and **must be created using the Microsoft Excel template provided in the application**.
- Detailed but brief budget justification including all requested expenditures
- Biographical sketch (NIH-format) for the JHU PI (or post-doc+faculty mentor pair)
- Other Support (PI), and if applicable, a list of other funding sources that will be used to cover other costs associated with this project.

<u>**All application materials including the study budget should be compiled into a single Adobe pdf,**</u> in the order specified above, and uploaded into the online application interface. The non-pdf'ed Excel template containing the study budget must also be uploaded as a separate document into the online application.

APPLICATIONS THAT DO NOT ADHERE TO THE PAGE LIMITS [RESEARCH PLAN (**1-page**) and PROBLEMS/SOLUTIONS/TIMELINE (**1-page**)] WILL NOT BE REVIEWED.

REVIEW PROCESS
Review Criteria
<u>**Priority for funding will be given to projects that expand an existing career development award or pilot projects that clearly demonstrate how the results will lead to future grant funding (R01 or similar).**</u> Standard NIH review criteria will be used to determine the overall impact of the application. Scoring will be based on:
1) Significance
2) Innovation
3) Approach
4) Investigator(s)

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

Administrative Triage: The ICTR Navigators will first review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in this document. **Incomplete or noncompliant applications will be returned without scientific review.**

Review Process: TRC Co-Leaders Drs. Martin Pomper and Elizabeth Selvin will recruit appropriate reviewers and each application will be reviewed by a committee and scored. All reviewers will be asked to disclose any relationships to the grant applicant and conflicted reviewers will not be allowed to vote on those applications. Top scoring applications will be further reviewed by the TRC co-leaders and up to 2 awards will be made.

Notification: All applicants will be notified of funding decisions approximately 2-3 weeks after the submission deadline. Award letters will explain the terms of the award, as well as descriptive information about regulatory approvals, agreements and other aspects of project start-up that should be completed immediately.

Questions about the application process should be directed to the ICTR Navigators who can be reached by email at: ICTRnexus@jhmi.edu