Nexus Award for JHU-UMB Collaborations in Medical Device Development (Drug/Device Combinations are allowed)

Request for Applications
Sponsored by the ICTR Drugs/Biologics/Vaccines/Devices Translational Research Community

Deadline: July 1, 2021 at 5:00 PM

Eligible: All JHU faculty with a UMB faculty collaborator

Budget: Up to $75,000

Grant Period: Twelve months; No-Cost-Extension (NCE) will not be permitted

Application: Online at: https://redcap.link/nexusdevice
NEXUS GRANT PROGRAM OVERVIEW

The ICTR has 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.

Given the current partnerships between the respective Institutes for Clinical and Translational Research at Johns Hopkins and UMB, this specific Nexus award will be used to fund medical device development activities on projects that represent a collaboration between UMB and JHU translational scientists.

PROGRAM DETAILS

Eligibility
• Eligible submissions must be translational projects with clear endpoints and a realistic timeline for completion within the twelve-month funding period.
• Any faculty member at Johns Hopkins University collaborating with UMB faculty on a translational project is eligible to apply for a Nexus grant.
• Undergraduates, graduate students, and postdoctoral fellows are not eligible to apply as Principal or Co-Investigators for pilot grants.
• Awarded Nexus PIs are not eligible to apply for a new Nexus project in the following grant cycle.
• If awarded, the start date of the 12-month grant will be approximately 30 days post the Nexus submission deadline, after all applicable institutional and external regulatory requirements (i.e. FDA IND/IDE and NCATS) have been satisfied.
• All spending must be completed 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 each investigator’s ICTR and the institutional office responsible for managing conflicts of interest (i.e. the Office of Policy Coordination at Johns Hopkins and the Conflict of Interest Officer at UMB). 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 $75,000 in direct costs. Requests exceeding $75,000 will not be reviewed.
• No-cost extensions will not be granted. No exceptions will be made.
• Indirect costs should not be included in the budget.
• Grants can be used only for support of projects conducted at Johns Hopkins with sub-agreements of up to 50% for UMB faculty collaborators.
• Nexus funds may be used for faculty salary.
• Nexus funds may be used for fellow and staff salary support, as well as for stipends paid to undergraduate or
graduate students at Johns Hopkins.

- Nexus funds may not be used for travel to present results at established meetings or conferences.
- Nexus funds may not be used for 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.”
- If awarded, failure to comply with terms and conditions of the Nexus program may result in termination of funding.

APPLICATION PROCESS
Applications must be submitted through the Nexus Grant Program ICTR REDCap form, located here: https://redcap.link/nexusdevice

The grant application includes the following seven mandatory components:

- Specific Aims (1-page limit).
- Research Plan (3-page limit) which includes a proposed project timeline and specifies what work will be conducted at JHU versus UMB.
- An itemized budget, with line item detail to the $1000 level, which contains the budget requirements for both the JHU and UMB scopes of work (direct costs only) and must be created using the Microsoft Excel template provided in the application. The complete budget, which includes a statement of work for the UMB site, is not included in the total plan page limit.
- Budget justification
- Biographical sketch (NIH-format) for the JHU PI.
- Biographical sketch (NIH-format) for the UMB Faculty Collaborator.
- “Other Support” for the PI, and if applicable, a list of other funding sources that will be used to cover other costs associated with this project

* NOTE: A reference list of up to 30 references may be included but is optional

All application materials including the study budget should be saved into a zip file* named: PI Last name_DDMMYY and uploaded into the REDCap application.

[*To create a zip file, right click the folder and select "Send to", then select "Compressed (zipped) folder". A new zipped folder with the same name is then created in the same location.]*
REVIEW PROCESS

Review Criteria
Priority for funding will be given to JHU-UMB collaborative projects that demonstrate how the results will lead to direct translation or future grant funding (R01 or similar). Applications demonstrating new collaborative partnerships will be given preference. In addition, standard NIH review criteria will be used in scoring all applications:

(1) Scientific Merit
(2) Significance
(3) Approach
(4) Innovation
(5) Investigator

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

Administrative Triage: The Research Navigators will 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: Members of each TRC advisory board will assess applications in terms of the fit, feasibility, and translational nature of the proposed project. If necessary, TRC advisory board members will solicit feedback from secondary reviewers both internal and external to the Institution. If external to JHU, applicants may be asked by TRC Administration to initiate a non-disclosure agreement in order to protect intellectual property.

Notification: All applicants will be notified of funding decisions approximately 4-6 weeks after the submission deadline. No reviewer feedback will be provided for unfunded applications.

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