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

REQUEST FOR APPLICATIONS

Nexus Award for Innovations in Drug Delivery: Sponsored by the ICTR Drugs/Biologics/Vaccines/Devices Translational Research Community

Deadline: Wednesday, October 1, 2014 at 11:59 PM

Eligible: All Johns Hopkins University faculty

Budget: Up to $100,000

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

Application: Upload via the ICTR Connection Request website

GENERAL NEXUS GRANT PROGRAM OVERVIEW
The ICTR is has established three new Translational Research Communities:

1. Drugs/Biologics/Vaccines/Devices
2. Biomarkers and Diagnostic Testing
3. Behavioral, Social and Systems Science

All three communities are supporting Nexus grants which are designed to accomplish the following objectives and goals in their respective community areas:
- 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.
- 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 support investigators in the efficient attainment of translational milestones by providing guidance, resources, and feedback from the ICTR.

The Nexus funding mechanism distinguishes itself from other ICTR funding programs in that these grants can be used to develop technology and innovative methodologies that address specific problems or gaps along the translational pathway in the context of a specific project. The research carried out under these awards should also have broad applicability beyond the funded project, but must focus on a specific area of research within the specific Translational community.

The TRC Program Administrator will serve as the primary link between the Nexus Investigator and the ICTR. Progress and completion of all projects will be facilitated by the Program Administrator and ICTR Research Navigators.

NEXUS AWARD FOR INNOVATIONS IN DRUG DELIVERY PROGRAM OVERVIEW

Although modern biotechnology has produced extremely sophisticated and potent therapeutic drugs, many of these compounds cannot be effectively delivered. The intent of this RFA is to specifically address the drug delivery problem by encouraging applicants to develop innovative approaches, technologies, tools, and methods that will result in new drug delivery systems and devices. It is anticipated that solving problems of drug delivery will involve many scientific fields, including chemistry, pharmacology, biology, materials science, and biomedical engineering.

Potential applications may involve improving the safety to efficacy ratio of "old" drugs or the development of methods for the delivery of "new" therapeutics such as peptides, proteins, DNA, RNA or small molecules. Topics can range from the "macro" (e.g. device or materials development) to the "nano" (e.g. nanoparticle mediated delivery) but the topic should focus on the development of a drug delivery system that overcomes a current challenge.

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.

Any faculty member at Johns Hopkins University 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 but can be incorporated as team members into any proposal.

Awarded Nexus PIs are not eligible to apply for a new Nexus project in the following grant cycle.

Regulatory approval: A just-in-time period has been built into the grant review process, which will be a period of time when awardees must obtain necessary regulatory approvals. If applicable, investigators should initiate any regulatory approvals at the time of grant submission. Investigators with necessary regulatory approvals, internal and/or external to the institution (e.g. ACUC, IRB, FDA, or the NIH/OBA) pending or in-hand will receive higher feasibility scores for their projects than those with regulatory submissions that have not been prepared or submitted for review.

If awarded, the start date of the 12-month grant will be provided in the award notification letter, but will be approximately 90 days post the Nexus submission deadline. The start date may be revised as circumstances require.

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/).

Funding Restrictions, Terms and Conditions

- Requests must be no more than $100,000 in direct costs. **Requests exceeding $100,000 will not be reviewed.**

- Funding will be for 12 months only. **No-cost extensions will not be granted. No exceptions will be made.**

- Indirect costs should not be included in the budget, except in the case of subcontracts.

- Grants can be used only for support of projects conducted primarily at Johns Hopkins or by Johns Hopkins investigators. Subcontracts with outside institutions/facilities are permitted, but should be no more than 25% of total requested budget.

- Applicants with projects requiring subcontracts must provide a separate budget and justification detailing the total funds required for the sub-award including total direct costs AND total indirect costs of the outside facility.

- Nexus funds may be used for faculty salary, but excessive and unjustified faculty salary requests will be scored negatively.

- 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 be used for travel essential to the conduct of research, but not for travel to present results at established meetings or conferences without strong justification and the approval of a Navigator**.** Any foreseeable travel should be included in the budget.

- 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." All other equipment requests should be accompanied by a justification that includes why it is needed, whether it is available in either ICTR Cores or in elsewhere within JHU, and what would be used to carry out the project without the requested equipment.

- If awarded, failure to comply with terms and conditions of the Nexus program may result in termination of funding.

Dissemination Plan

Nexus grant proposals will be accepted once a year, with submission deadlines 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 website and sent upon posting to individuals who opt in for ICTR updates via email or newsfeed. 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, 2014. All application materials must be received **by 11:59 PM on October 1, 2014**.

APPLICATION PROCESS

Applications must be submitted through the Nexus Grant Program ICTR Connection Request form, located on the ICTR website: https://ictrweb.johnshopkins.edu/ictr/connection/. The personnel information, abstract, specific aims, research plan, project schedule and optional references described below, should be uploaded as separate documents through the application form in either Adobe PDF or Microsoft Word format. Budgets may be provided in Microsoft Excel format.

Questions about the application process should be directed to program administrator, Kelly Crowley, (kelly.crowley@jhmu.edu). Please <u>CC:</u> the ICTR Navigators (ICTR_Navigators@jhmi.edu).

<u>**Materials required to be submitted via the online application include:**</u>

- A short C.V. or biographical sketch (NIH-format or similar) for the PI (4-page limit total)
- Biographical description of all study team personnel (4-page limit total)
- Abstract (250 words)
- Specific Aims (1-page limit)
- Research Plan (5-page limit, content and format described below in "Research Plan Guidelines")
- Reference list of up to 30 references (optional)
- Completed Project Schedule, which can be found here: link
    - Use the Project Schedule template to list project **milestones** encompassing all significant **events**, **activities**, and/or **deliverables** that are crucial to the successful completion of the overall project. The milestones can be portions of the Specific Aims of the project, critical events such as regulatory approvals, acquisition of necessary supplies/equipment, and completion of critical experiments and portions of a study. Each milestone identified should be broken down into quantifiable components or steps required to achieve the particular milestone, as well as he time required to complete each individual task.
- A comprehensive, itemized budget. The budget must also include an explanation of other funding sources that will be used to cover costs not covered by Nexus. Budgets may be submitted in Microsoft Excel format.
    - A detailed justification is required and should include salary, supplies, equipment, travel, etc., and any other expenses required to complete the study. The justification should be provided down to $1,000.
    - If the budget includes a subcontract, the total requested funds (including sub-site INDIRECT costs, if applicable) 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.

RESEARCH PLAN GUIDELINES

Presentation and Formatting: The Specific Aims are limited to 1 page and 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 short abstract

should follow the same formatting. **References are not included in the total plan page limit**. 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:

Abstract (not more than 250 words – text only): Succinctly describe the importance and relevance of your research project with enough detail to clearly convey the promise of your approach.

Specific Aims (not more than 1 page): The purpose of the specific aims page is to concisely and realistically describe the project goals of the proposed research project. The expected outcome(s) should be summarized, including long-term goals and the expected impact of the proposed research on the field(s).

Research Plan (not more than 5 pages):

- **Project Milestones and Timeline:** In the research plan, 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.

- **NOTE:** In contrast to the milestone/timeline summary presented in the research plan, the Project Schedule document that is required with the application MUST include the milestones described in the research plan AND a breakdown of all activities necessary to complete the milestone and the time required for each activity.

- **Background (including Preliminary Results, if available) and Significance**: In addition to scientific background and significance, this section should indicate how success of the grant will affect subsequent research. 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 and should also discuss the project's potential for clinical and public health impact.

- **Design**: Method description should be sufficiently detailed to convince reviewers of feasibility and validity. Explain how the data will be collected, analyzed and interpreted. Statistical approaches to data analysis should be outlined. A brief section outlining any collaborative links to biostatistical, clinical or laboratory cores is necessary, as are details for outside contractual services.

- **Anticipated Problems and Possible Solutions**: Any anticipated experimental or interpretive problems should be addressed, with alternative approaches described when possible.

REVIEW PROCESS

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

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project demonstrate both technical and operational feasibility?

(3) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed project take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

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

Administrative Triage: The TRC Co-Leaders will review applications for compliance with budgetary, content, eligibility, and other submission guidelines as described in this document and the Nexus Grant Program Connection Request form. **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 and Feedback: All applicants will be notified of funding decisions approximately three months after the submission deadline. **The 12-month award period will be included in the notification of award.**

For this round of Nexus grants, applications will not receive pink sheets. Resubmission of denied grants is not allowed.

Questions about the Nexus application, as well as feedback regarding the Nexus Program, should be directed to Kelly Crowley, (kelly.crowley@jhmu.edu). Please CC: the ICTR Navigators (ICTR_Navigators@jhmi.edu).