



DATE: November 13, 2017

TO: All UMMS Faculty

FROM: Katherine Luzuriaga, MD, Director UMCCTS
Brendan O’Leary, PhD, Executive Vice Chancellor, Office of Innovation and Business Development
Mark Klempner, MD, Executive Vice Chancellor, MassBiologics

RE: 2017-2018 IND/IDE LAUNCH Awards

The UMass Center for Clinical and Translational Science, UMMS Office of Innovation and Business Development, and Mass Biologics are pleased to announce a new funding opportunity to support IND/IDE-Enabling Studies. The purpose of this program is to assist faculty with the commercial development of UMass discoveries; specifically, to facilitate additional research and development work directed at enabling first in human studies. Individual project awards (**up to \$50,000 for 1 year**) will be made on a competitive basis to enable investigators to move innovative, cutting edge research toward commercialization. Funds will typically be used to support additional experimentation and other services (PK/PD, animal toxicology studies, project management, business plan development, product profile development, regulatory filing, etc) that are necessary steps in filing an IND/IDE. **Indirect costs are not allowed.**

Thank you for your interest in this program. We look forward to your ideas.

Application Instructions

Please email your application as a single document (Word or PDF) to: ccts@umassmed.edu by 5:00 PM (EST) on Monday, December 18th, 2017.

Applications should include the following:

- Cover page with the name of the PI, other key personnel, contact information, title of project, and a 1 paragraph abstract (1 page)
- Project plan which includes a description of the technology and its competitive advantage, commercial potential, work proposed, a description of how this work will help to result in IND/IDE filing, and future plans (2 pages).
- Budget (use PHS 398 form page 4 as a template, 1 page) and budget justification (1 page)
- NIH biosketch of Principal Investigator (5 pages)

Applicants will receive added consideration from the reviewers if they plan to use one or more of the research resources available through the Center for Clinical and Translational Science <http://www.umassmed.edu/ccts> , MassBiologics <http://www.umassmed.edu/massbiologics/> , or the Office of Innovation and Business Development <http://www.umassmed.edu/ibd/> .

While the Principal Investigator must be a UMMS Worcester faculty member, collaborations with external collaborators, including those from other UMass campuses that facilitate work towards an IND/IDE filing are encouraged.

All faculty applicants must be UMCCTS members. Membership entails completion of an on-line membership form on the UMCCTS website at <https://umassmed.edu/ccts/about/membership/>.

Oversight and Review Criteria

The LAUNCH program is overseen and administered by the UMMS Strategic Product Development Committee. The Review Panel will make funding decisions based upon the scientific merit and potential impact of the proposals. Proposals may focus on drug, device, or biologics development but those that capitalize on MassBiologics' significant infrastructure for biologics development and vectored gene therapy are particularly sought. Reviewers will give a strong preference to projects with a significant commercial potential. Strong preference will also be given to projects that demonstrate ability to combine LAUNCH funds with funds from other sources to complete the proposed work. Work completed under this award should move the project significantly towards IND/IDE filing.

Previous Awards

Prior awardees have used IND Launch funds to develop 1) a diagnostic radiopharmaceutical to assess functional activity of biological processes, 2) a GMP master cell bank, 3) a strategy for preclinical toxicology evaluation and clinical development plan for a novel monoclonal antibody. More information is available here:

<https://umassmed.edu/globalassets/ccts/ccts-media/funding/current-and-past-awardees/ind-enabling-funding-awardees.pdf>

Timeline:

Request for Application Announced	November 13, 2017
Proposals Due	December 18, 2017
Project Start Date	No later than January 31, 2018

Partial List of CCTS Resources Available for Applicants

More information about these resources can be found at <http://www.umassmed.edu/ccts> or by contacting Nate Hafer at nathaniel.hafer@umassmed.edu

- Massachusetts Integrated Clinical Academic Research Database (MICARD)
- REDCap (Research Electronic Data Capture)
- Informatics Core
- Quantitative Methods Core
- Regulatory Consultation
- Clinical Research Center
- Investigational Drug Service (Pharmacy)
- Conquering Diseases Biorepository
- Conquering Diseases Volunteer Recruitment Core
- Community Engagement resources and consultation services
- Special Population Resource Center
- Small Molecule Screening Core