DATE: November 23, 2015
TO: UMCCTS Members with an Interest in Clinical & Translational Science
FROM: Katherine Luzuriaga, MD, Director, UMass Center for Clinical & Translational Science
Mark Klempner, MD, Executive Vice Chancellor, MassBiologics of UMMS
RE: NEW FUNDING OPPORTUNITY: The “Next Hundred Million” Pilot Projects (NHMPP) 2016

INTRODUCTION
The University of Massachusetts Center for Clinical and Translational Science (UMCCTS) and MassBiologics of the University of Massachusetts Medical School are pleased to announce a funding call for “The Next Hundred Million” Pilot Projects (NHMPP). The NHMPP will serve as a dedicated pool of funding to spur innovative collaborations between UMMS, MassBiologics of UMMS and investigators across the UMass System with the goal of enhancing the translation of discoveries for clinical use.

PURPOSES
For over 120 years, MassBiologics of UMMS (www.umassmed.edu/massbiologics) has discovered, manufactured and delivered over 100 million doses of vaccines and immunotherapeutics to people all over the world. We are looking for pilot projects that will contribute to the discovery, preclinical and clinical research, manufacture and delivery of the “next hundred million doses” of products to improve public health. MassBiologics of UMMS is the only FDA licensed biologics production facility owned and operated by a University in the United States. It has unique discovery, preclinical, clinical, regulatory, quality assessment and GMP manufacturing expertise. The academic affiliation of MassBiologics of UMMS also allows it to serve as an incubator to innovate and improve the process of vaccine and biological and immunologic therapeutics development.

With the addition of the Vector Manufacturing Center (VMC) at MassBiologics SouthCoast in 2015, proposals that use viral vectors, such as rAAV, for delivery of therapies are especially encouraged.

Proposed projects must include at least one investigator from MassBiologics of UMMS (see below and www.umassmed.edu/massbiologics) and a faculty investigator from at least one UMass campus. Inclusion of collaborators from UMMS is highly encouraged but not required. The following Division Leaders (all are UMMS faculty) should serve as initial points of contact for expertise at MassBiologics:

- For discovery research related to vaccines and monoclonal antibodies, Dr. Keith Reimann, keith.reimann@umassmed.edu
- For in vivo pre-clinical research, Dr. Keith Reimann, keith.reimann@umassmed.edu
- For vectoring biologicals research, Dr. Yang Wang, yang.wang@umassmed.edu
- For vector process development and manufacturing, Dr. Joshua Merritt, joshua.merritt@umassmed.edu
- For clinical research, Dr. Deb Molrine, deborah.molrine@umassmed.edu
- For process development research, Dr. Sadettin Ozturk, sadettin.ozturk@umassmed.edu
- For manufacturing research, Frank Fazio, frank.fazio@umassmed.edu
For quality assessment proposals, Dr. Mark Leney, mark.leney@umassmed.edu
For regulatory affairs proposals, Michaele Williamson, michaele.williamson@umassmed.edu

Current and future projects supported by this fund are envisioned to develop into larger initiatives that attract substantial funding from extramural sources, including the Federal Government, the Commonwealth, industry, foundations and others.

ELIGIBILITY

1. UMCCTS member faculty from any of the five UMass campuses are eligible to participate. Investigators must hold UMass faculty status at the time that the award is made. UMCCTS membership is free, easy, and entails completion of an on-line membership form on the UMCCTS website at http://umassmed.edu/ccts/footer/membership
2. Projects must include at least one investigator from MassBiologics of UMMS and a faculty investigator from at least one UMass campus.

ALLOWABLE USE OF FUNDS – RESEARCH AREAS OF INTEREST

Individual project awards (up to $75,000 for 1 year, up to $125,000 for 2 years) will be made on a competitive basis to enable investigators to accelerate the translation of innovative, cutting edge research into:

- Discovery research to develop novel therapeutics and vaccines for the prevention and/or treatment of disease;
- Clinical studies of novel or approved therapeutics or vaccines for the prevention and/or treatment of disease;
- Ways to improve currently available therapeutics/vaccines or product platforms – improved PK/PD, efficacy, stability, convenience, or manufacturing methods; reduced cost of goods;
- Improvements in any part of the product development process that lead to more efficient therapeutic development;
- Research diagnostics or other research tools;
- Innovation related to quality assessment, quality control, or regulatory science;
- Innovation related to the process of therapeutic/vaccine development or production for human use.

The intent of the funding is to speed the translation of basic research, a clinical finding or other discovery into a broader network of activities, while maximizing the breadth of interdisciplinary skills applied to the research question. Faculty support up to 10% of the NIH salary cap is allowable. Indirect costs are not allowed. We are particularly interested in proposals which feature a clinical scientist working with a basic scientist. Proposals that include a significant training opportunity in clinical/translational research for students, trainees, fellows, or junior faculty will be given priority.

Thank you for your interest in clinical and translational science. We look forward to your ideas.

OVERSIGHT

The UMass NHMPP is overseen and administered by a subgroup of the Steering Committee of the University of Massachusetts Center for Clinical and Translational Science (http://www.umassmed.edu/globalassets/center-for-clinical-translational-science/funding/rfa-funding-announcements/next-hundred-million-pilot-project-programs-nhmpp/nhmpp_review_committee.pdf) which includes reviewers from MassBiologics. The NHMPP Review Committee makes funding decisions based upon the scientific merits, potential for future funding, and potential impact of the proposals.
CRITERIA FOR AWARDS

The evaluation criteria that are used to review proposals include the following:

- **Intellectual Merit** – Projects that include innovative efforts to enhance the impact of scholarly endeavors on benefiting the human condition, which for the purposes of this fund will include enabling technologies, will be considered for funding.
- **Inter-Campus Collaboration** – Projects that are multi-campus in orientation and involve at least one collaborator from the MassBiologics of the University of Massachusetts Medical School and one investigator from a UMass campus will be considered for funding.
- **Training Opportunity** – Projects that provide a training opportunity broadly related to clinical and translational research for students, trainees, fellows, or junior faculty will be prioritized for funding.
- **Growth Opportunity** – Projects must describe the path to attract and secure outside funding from federal, state, industry, foundation and other sources.
- **Use of UMCCTS Resources** - Applicants will receive added consideration from the reviewers if they plan to use one or more of the research resources (http://www.umassmed.edu/ccts/resources/) available through the UMCCTS.

APPLICATION SUBMISSION AND REVIEW PROCESS

Send Letter of Intent (LOI) as an attachment (Word or PDF format) on or before: **Friday, January 8, 2016 by 5:00 pm EST** to ccts@umassmed.edu

Complete information is also available at: http://www.umassmed.edu/ccts/funding/NHMPP/

**Application Instructions:**

- Describe in two (2) pages or less the work that has motivated you to apply for this particular fund.
- The collaborating PI’s and the role of each in the project.
- A brief discussion of the training plan, and the importance of the collaboration.
- References are not required and do not count towards the 2 page limit.

**Review Process:**

Letters of Intent (LOI) will be reviewed by the NHMPP Review Committee (described above) to determine which projects are inter-campus in orientation and significantly linked to the Research Areas of Interest listed above. Based on this review, the most promising projects will be selected for full proposal submission. Full proposals will be subject to a standard NIH-type study section assessment.

Investigators will be notified of the selection of LOI finalists by late January 2016. Full proposal instructions will be provided at the time of notification. Full proposals will be due on February 29, 2016 for those selected finalists.

**Application Timeline:**

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Partial List of CCTS Resources Available for NHMPP Applicants

More information about these resources can be found at [http://www.umassmed.edu/ccts/resources](http://www.umassmed.edu/ccts/resources) or by contacting Nate Hafer at [nathaniel.hafer@umassmed.edu](mailto:nathaniel.hafer@umassmed.edu)

- Massachusetts Integrated Clinical Academic Research Database (MICARD)
- REDCap (Research Electronic Data Capture)
- Biomedical Research Informatics Consulting and Knowledge Service (BRICKS)
- Biomedical Research Development Group (BRIDG)
- Quantitative Methods Core
- Regulatory Consultation
- Clinical Research Center
- Investigational Drug Service (Pharmacy)
- Conquering Diseases Biorepository
- Conquering Diseases Volunteer Recruitment Core
- Bioinformatics Core
- Deep Sequencing Core
- Proteomics and Mass Spectrometry Core
- Community Engagement resources and consultation services
- Special Population Resource Center