REQUEST FOR SYNERGY TRANSLATIONAL PILOT PROJECT APPLICATIONS

RELEASE DATE: October 7, 2016

INFORMATIONAL MEETINGS: October 20 and November 1, 2016*
MANDATORY LETTER OF INTENT DUE: November 14, 2016
INVITATION FOR FULL APPLICATIONS: December 1, 2016
APPLICATIONS DUE: January 18, 2017

The Dartmouth SYNERGY Translational Pilot Program funds innovative, interdisciplinary research proposals that have clear potential for translation into patient-oriented care and improved population health. The program’s goal is to facilitate collaborative translational research studies within Dartmouth institutions and affiliated health centers. By providing support for translational pilot studies, SYNERGY aims to accelerate the process of translational research across the entire (T1 to T4) translational research spectrum.

Grants are available for projects that are at an early stage and need support to create pilot data and/or to develop research concepts that will advance translational research in five focus areas, including a new area of Translational Research Acceleration (see below). Successful proposals must have a high chance of leading to extramurally funded research and/or discoveries with the potential for commercialization. The total number of awards granted will depend on the quality of applications, independent of focus area.

* Times and Locations to be determined. See: https://synergy.dartmouth.edu/translational-pilot-grants

GUIDELINES

Eligibility

- Investigators at Dartmouth College; Geisel School of Medicine; Thayer School of Engineering; Tuck School of Business; and Dartmouth-Hitchcock and its affiliated sites, including the VA Medical Centers in White River Junction, VT, Manchester, NH, and Togus in Augusta, ME; who meet the requirements below are eligible to apply.
- To foster interdisciplinary and inter-institutional research, the application must list a PI and co-PI, each from a different discipline, department, or school.
- The contact PI must have a Dartmouth faculty appointment at the rank of instructor, assistant professor, associate professor, or professor.
- Should the contact PI be a junior faculty member at the rank of instructor or assistant professor, the applicant must identify his/her research mentor(s) in the Letter of Intent (LOI).
- Investigators are limited to a single application as the contact PI.

Pilot Project Focus Areas

To fulfill the translational expectation, SYNERGY seeks proposals that pursue either (1) the application of scientific discoveries to clinical practice or (2) the underlying mechanisms behind observations from patient care or public health. If the research is focused on testing a drug or medical device, the SYNERGY Pilot award is restricted to only early-phase clinical trials. See http://grants.nih.gov/grants/policy/hs/glossary.htm for a full definition of patient-oriented research and clinical trials.

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Pilot Project Focus Areas are as follows:

**Patient-oriented Translational Research:** Examples include (1) discoveries in the research laboratory or in preclinical studies that will impact human health and may lead to human studies; and (2) applying discoveries generated during laboratory research or preclinical studies to the development of human trials and studies.

**Methodology and Technology Innovations for Translational Research Awards (MITRA):** Examples include, but are not limited to: innovative use of imaging and/or biomarkers to assess treatment prognosis; genomics research methodology; design or implementation of assays in medium-throughput screening for drug discovery; innovative experimental design and development of statistical methodologies for clinical and translational research applications, including innovative clinical trial design; and technologies for clinical decision support.

**Population-based Translational Research:** Examples include, but are not limited to: analysis of administrative claims data such as Medicare that elucidate associations between drug exposures and outcomes in defined populations (e.g., pharmaco-epidemiologic studies); evaluation of hypotheses generated in the laboratory through claims analyses; comparative effectiveness studies involving claims-based analyses that compare outcomes of alternative healthcare approaches for defined populations (e.g., surgical vs. non-operative care for specific conditions, treatment with innovative technologies vs. established technologies); comparative effectiveness studies of alternative approaches to healthcare delivery, which may include both health and economic outcomes of care, and may involve analyses of patient-reported measures and/or registry-enriched claims data; and claims-based analyses that elucidate health and healthcare disparities.

**Reverse-translational Research:** A T1 or pilot T2-level research project motivated by observations from large population databases. The majority of the proposed work should involve testing the hypothesis via new primary data collection from human subjects. Examples include, but are not limited to: new use of an approved drug based on a pharmaco-epidemiologic association; a behavioral intervention study to test a previously observed association in a controlled setting; demonstrating certain biomarkers or characteristics that confer a beneficial/toxic response to an intervention; and a nested case-control study to identify specific molecular changes explaining an observed exposure-disease association. Preliminary data on the population observations used to generate the specific hypothesis is a strength. Use of locally held datasets is encouraged (e.g., Medicare claims, regional disease/screening registries, or large population-based studies).

**NEW AREA** **Translational Science Acceleration:** This area supports the development of new methods, processes or workflow to achieve efficiency in the implementation of clinical and translational research, including development of technologies, methods, data, analytics and resources that change the way translational scientists approach their work. Examples include: development of biostatistical and epidemiological methods that enhance the validity and accuracy, scope or speed of clinical and translational research; development of novel methods for clinical study design; and harnessing of informatics tools and electronic health records (EHR) in innovative ways to assess cohort exploration, participant recruitment, data management and study oversight.

**Budget:** Applicants should prepare a budget appropriate for the resources necessary to carry out the proposed research beginning on May 1, 2017 and ending April 30, 2018. The pilot project must be completed within 12 months with a budget of $25,000 to $50,000. Award amounts will vary depending on the scope of the proposed work, its scientific merit, feasibility, and relevance to the SYNERGY mission.

**Human Subjects:** Investigators submitting proposals involving human subjects must obtain approval from the Committee for the Protection of Human Subjects (CPHS) at Dartmouth College. Release of
funds will be contingent upon CPHS approval, but it is not necessary to obtain approval prior to submitting a proposal. If investigators are relying on an existing CPHS approval, they must delineate what is novel about the proposed work and give a timeline for amending the existing CPHS protocol.

Animal Use: Projects involving animals must obtain approval from the Institutional Animal Care and Use Committee (IACUC). Release of funds will be contingent upon approval, but it is not necessary to obtain approval prior to submitting a proposal.

Study Design: All applicants are encouraged to use SYNERGY-supported research consultation cores and services. To arrange for consultations, see: https://synergy.dartmouth.edu/research-resources. Successful applicants may also use the SYNERGY Clinical Research Unit (CRU) at DHMC for study visit support. Requests for CRU services may be made through https://synergy.dartmouth.edu/clinical-research-unit. Please contact synergy.pilots@dartmouth.edu with any additional questions.

Submission Procedures:

1. **Letter of Intent (LOI):** A fully completed LOI, including Biosketch(es) (NIH format) for the PIs and, if applicable, mentor, must be combined into one PDF and submitted via email to synergy.pilots@dartmouth.edu no later than 5:00 pm, November 14, 2016. Applicants must follow the SYNERGY Pilot Instructions and Template for Letter of Intent available at https://synergy.dartmouth.edu/translational-pilot-grants.

2. **Review of LOI:** SYNERGY staff will acknowledge LOI receipt within one business day. The SYNERGY Pilot LOI Review Committee will review all LOIs and SYNERGY staff will notify all PIs no later than December 1, 2016 regarding whether or not they are invited to submit a Full Proposal.

3. **Invited Pilot Project Full Proposals:** Invited applicants must use the SYNERGY Pilot Project Instructions and Template for Full Proposal, which will be emailed to them. The final submission deadline for invited Pilot Project applicants will be 5:00 PM, January 18, 2017.

4. **Review of Full Proposals:** The SYNERGY Pilot Application Review Committee (PARC) will review Full Proposals. Review criteria include innovation, interdisciplinary engagement, approach, significance, community impact, translational character, investigator qualifications, and—for junior faculty at the rank of instructor or assistant professor—strength of mentoring environment. Funding decisions will be announced in February 2017 with awards starting on May 1, 2017. All invited applicants will receive a summary of reviewer comments and may also request to meet with a review committee representative for further guidance.

Post-Award Conditions. To activate a SYNERGY Pilot Project Award, Co-Principal Investigators and their Mentors (if applicable) must sign a SYNERGY Award Compact, indicating their agreement to all Award requirements and expectations, including the following:

- Project award management – SYNERGY Pilot Awardees must work with administrators in their home departments and SYNERGY administrators to ensure successful Pilot funds management.
- Progress reports, presentations, publications, and grant applications – SYNERGY Pilot Awardees are required to submit written progress reports every six months during the award period detailing progress towards research project aims. Awardees are expected to present their research, submit papers to peer-reviewed journal(s) for publication, and seek follow-on grants—all of these being key indicators of research success. PIs must list this activity in their progress reports.
- Pilot Awardees are expected to participate in SYNERGY functions convened for Pilot Awardees and to provide additional written updates beyond the Pilot Award period when requested.
- Pilot Awardees are expected to serve on future SYNERGY Pilot Application Review panels and to provide feedback on the SYNERGY Pilot Program.

For questions on the SYNERGY Pilot Program or application process, please contact synergy.pilots@dartmouth.edu at any time.

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