

REQUEST FOR SYNERGY TRANSLATIONAL PILOT PROJECT APPLICATIONS RELEASE DATE: January 17, 2014 MANDATORY LETTER OF INTENT DUE: February 28, 2014 **Invitation for Full Applications: March 14, 2014 APPLICATIONS DUE: April 18, 2014**

This announcement from the Dartmouth SYNERGY Translational Pilot Program seeks to fund innovative, interdisciplinary research proposals that have clear potential for translation into patientoriented care and for improving population health. The goal of the SYNERGY Pilot Projects Program is to facilitate collaborative translational research studies within all our institutions and affiliated health centers. By providing support for clinical and translational pilot studies, SYNERGY aims to accelerate the process of clinical, community-based, and translational research.

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 any of four focus areas: 1) methodology and technical innovation for translational research (MITRA); 2) population-based translational research; 3) community-based translational research; or 4) reverse-translational research.

Successful proposals must have a high chance of leading to extramurally funded research and/or to discoveries with the potential for commercialization. A total of up to \$400,000 will be used to fund SYNERGY Pilot Projects in 2014. The total number of awards granted under this RFA will depend on the quality of applications independent of focus area.

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 White River Junction, Manchester and Togus VAs, who meet the requirements below are eligible to apply.
- To foster interdisciplinary and inter-institutional research, the application must list two co-PIs, each from a different discipline, department, or school.
- The contact PI must have a faculty appointment. ▶
- Should the contact PI be a junior faculty member, his/her research mentor(s) must be identified ▶ in the letter of intent (LOI).
- Investigators are limited to a single application as the *contact* PI. ▶
- Only Investigators who complete the required LOI and are invited to submit a full ▶ application will be eligible for an award.

Pilot Project Focus Areas: To fulfill the translational expectation of SYNERGY, proposals are sought that pursue either (1) application of scientific discoveries to clinical practice or community interventions or (2) 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 in the following focus areas:

Methodology and Technology Innovations for Translational Research Awards (MITRA): Examples of pilot projects that would be viewed as responsive under this category 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 of population-based translational research 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 or hypotheses generated from other population-based data sources that are further explored in the laboratory; comparative effectiveness studies involving claims-based analyses designed to compare outcomes of alternative approaches to health care 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 health care 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; claims-based analyses that elucidate health and health care disparities.

Community-based Translational Research: Examples include, but are not limited to, applying findings from basic research or clinical trials to design and implement innovative interventions or models of care in community-based settings; innovative applications of technology and informatics to improve health behaviors or disease management; application of findings from decision science or use of innovative mobile health delivery systems to provide decision support or practical implementation of shared decision making in community-based settings; implementation science research in the evolving health care reform arena; the analysis of observational studies using community samples to model underlying mechanisms of health determinants or to identify and develop innovative approaches to addressing health disparities. Community-based participatory research is encouraged within this pilot project focus area.

*Reverse-translational research**: Laboratory or clinical research exploring hypotheses motivated by observations from large population databases using model systems or new primary data collection from human subjects. Examples include, but are not limited to, demonstrating certain biomarkers or characteristics that confer a beneficial / toxic response to an pharmacological exposure, device or other intervention; a nested case-control study to identify specific molecular changes explaining an observed exposure-disease association.

*Investigators with questions on pilot development in these areas should contact Sheila Noone at <u>sheila.b.noone@dartmouth.edu</u>.

Budget. Applicants should prepare a budget that is appropriate for the resources necessary to carry out the proposed research. Most successful pilot project applications are completed with budgets of \$25,000 to \$50,000, although some studies may be more costly to undertake. Award amounts may range up to a limit of \$100,000, depending on the scope of the proposed work, its scientific merit, feasibility, and relevance to the SYNERGY mission. All project work must be completed within 24 months.

Human Subjects: Investigators submitting proposals involving human subjects must obtain approval from the Committee for the Protection of Human Subjects 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.

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 http://synergy.dartmouth.edu/research_landing.html. Successful applicants may also utilize the SYNERGY Clinical Research Unit (CRU) at DHMC for study visit support. Requests for CRU services may be made through http://synergy.dartmouth.edu/cru.html.

Submission procedures:

- Letter of Intent (LOI): A two-page LOI, accompanied by Biosketch(s) (NIH format) for the PIs and, if applicable, mentor, must be submitted to <u>synergy@dartmouth.edu</u> by 5:00pm, February 28, 2014. Candidates must follow the SYNERGY Pilot Instructions and Template for Letter of Intent available at <u>http://synergy.dartmouth.edu/funding_landing.html</u>.
- 2. <u>LOI Review</u>: Receipt of your LOI will be acknowledged within one business day by SYNERGY administrative staff. The Pilot LOI Review Committee will review all LOIs within two weeks of receipt, and those who have submitted LOIs will be notified by March 14, 2014 whether they have been selected to submit a detailed full proposal.
- 3. <u>Invited Pilot Project Full Proposals</u>: Applicants must use the SYNERGY Pilot Project Instructions and Template for Full Proposal at (<u>http://synergy.dartmouth.edu/funding_landing.html_Note</u> that the scientific section of each proposal (Specific Aims, Significance, Innovation, and Approach) is limited to 6 pages. Applications must be submitted by email as a single PDF file in standard format to <u>synergy@dartmouth.edu</u>. The absolute final submission deadline for invited Pilot Project applicants is 5:00 PM, April 18, 2014.
- 4. <u>Review of Invited Full Proposals</u>: Full Proposals will be reviewed by the SYNERGY Pilot Application Review Committee. Review criteria applied by the multidisciplinary Pilot Application Review Committee include innovation, interdisciplinary engagement, approach, significance, community impact, translational character, investigator qualifications, and strength of mentoring environment. Funding decisions will be announced on or before May 30, 2014. All 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:

- Progress reports SYNERGY Pilot Awardees are required to submit written progress reports every six months during the award period detailing progress towards research project aims, as well as the status of publications and grant submissions. Each Awardee and his/her Mentors must attend an annual meeting to discuss progress with the SYNERGY Pilot Project Committee.
- Awardees must provide, upon request, written updates on the Awardee's academic career accomplishments and feedback on the program, both during the program and throughout the Awardee's career.
- Awardees must work with administrators in their home departments as well as SYNERGY administrators to ensure successful management of SYNERGY Pilot Project funds.
- Awardees must be willing to serve on future SYNERGY Pilot Application Review panels.