iDAPT: Implementation & Informatics Developing Adaptable Processes and Technologies for Cancer Control Round 1 Implementation Pilot Studies Request for Applications (2020)

A. Release Date

March 25, 2020

B. Participating Organizations

Wake Forest University School of Medicine University of Massachusetts Medical School

C. Purpose

iDAPT (Implementation & Informatics: Developing Adaptable Processes and Technologies for Cancer Control) is one of six National Cancer Institute-funded Implementation Science Centers for Cancer Control funded to conduct a program of research in high-priority areas of cancer control implementation science and to advance the methods and measurement within implementation science. Implementation science includes testing strategies to support the adoption, implementation, and sustainability of evidence-based health interventions into clinical and community settings.

iDAPT pilot studies can be observational, experimental, and quasi-experimental studies, and are intended to be executed within the clinical systems associated with our participating organizations. Pilot studies can cross all phases of implementation including feasibility studies, pre-implementation evaluation or simulation, tests of study design components - each selected to inform iDAPT's emerging theme in technology-facilitated implementation science, and full pilot experiments. Pilot studies can also include: collecting process measures (e.g., implementation fidelity, adaptation, and engagement), or provide estimates of effect sizes for measures of implementation success, and/or implementation impact on quality, safety, and health outcomes in cancer control.

D. Anticipated Funding

Successful pilots will receive up to \$75,000, to be spent within a 12- to 24-month study period. Up to 2 studies will be funded from this Round 1 RFA (see section on Budget Guidelines for more details on allowable and non-allowable budget items).

E. Prioritization

Priority will be given to proposals that fulfill one or more of the following criteria: The pilot study:

- Addresses the concept of local adaptation across multiple healthcare teams or settings.
- Incorporates information and communication technologies.*
- Is innovative within the field of implementation science.
- Addresses a high-risk/high-reward concept in Implementation Research.
- Addresses health disparities.
- Integrates into collaborating healthcare settings.
- Describes resources needed for building technology.
- Describes resources needed for statistical, qualitative, measurement expertise.
- The study involves scholars (students, post-doctoral, K scholars).
- The Principal Investigator is a junior faculty who is supported by a senior faculty mentor.
- * Consistent with the iDAPT theme, pilot study proposals must use one or more information and communication technologies (e.g.: simulations, data mining, machine learning, electronic health record functions, patient portals, automated texting, mHealth, clinical data warehouse).

As required by the funding mechanism, pilot studies must focus on novel, adaptable approaches to implementation across the **cancer continuum**, including primary and secondary prevention, screening, implementation to support symptom control, and survivorship. Studies should consider how different components of the clinical systems (inpatient, outpatient, primary and subspecialty care, physician, and other provider), public health systems, and family systems could be more interconnected.

Successful proposals will clearly describe:

- A rationale for the proposed study, including the significance of the research being addressed and potential for generalizability of the strategy being proposed.
- Evidence for the innovation, and the implementation program (See INSPECT criteria below)
- A feasible study plan for the 12- to 24-month award period.
- Next steps for this study. (For example, will the study lead to larger, subsequent grant applications [be specific]? How will results be disseminated? Is the study scalable? Is the clinical system willing to adopt the program if successful?

F. Eligibility

The Principal Investigator must be a post-doctoral fellow or faculty at a participating organization. Applications should be collaborative and multi-disciplinary, crossing divisions, clinical and non-clinical departments, and organizations. Multi-departmental or cross-institutional teams are welcome to apply.

G. Key Dates

Date	Detail
Prior to application deadline	Two-page Letter of Intent*
7/31/2020, 5:00 pm EST	Application Due
9/1/2020, 5:00 pm EST	Notice of Intention to Fund
10/1/2020	Latest Study Start Date

^{*} Submitting a letter of intent is strongly recommended, but not required. The LOI is non-binding. The letter of intent will allow iDAPT program leadership to provide constructive feedback during the writing process.

H. Application Procedure

Letter of Intent

Submission Deadline: Prior to Application Deadline

A letter of intent (LOI) is strongly recommended, but not required. The LOI is non-binding. Letters of intent should be submitted before the application deadline to:

Thomas K. Houston, MD, MPH (tkhousto@wakehealth.edu)

iDAPT Research Program Director

and copy:

Jessica Wijesundara, MPH, CHES (<u>jessica.wijesundara@umassmed.edu</u>) iDAPT Navigator

The LOI should identify the title of the study, the principal investigator and their contact information, the research team, and the clinical units, teams, or leaders involved in the application. Briefly, the investigators should describe the goals of the research and anticipated next steps. Providing how the proposed study relates to the priorities listed above will be helpful as well. Further, the investigators should identify if they seek additional guidance from the iDAPT pilot program team and/or connection with participating organizations.

Full Application

Submission Deadline: 7/31/2020, 5:00 pm EST

Full applications must be submitted by 7/31/2020, 5PM EST. The link to the application can be found at: https://redcap.wakehealth.edu/redcap/surveys/?s=RJF434DH9M. Application instructions are summarized below.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information

- Study Title
- Submitting Principal Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max)

Research Plan (4 pages max)

- Specific Aims
- Significance Explain how the study addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice.
- Investigator(s) Describe how each member of the team will contribute to the study. Include their expertise and experience that will be utilized on this study.
- *Innovation* Explain how this study uses novel concepts, approaches or methodologies, instrumentation or interventions.
- Alignment with iDAPT Explain how the study is related to iDAPT's theme, how it relates to the
 concept of cancer control implementation science, and list the clinical units, services, and leaders
 supporting the study.
- Approach Describe the overall strategy for this study, including potential problems, alternative strategies, and benchmarks for success. Specifically describe the:
 - Patient (and/or provider) population that will be studied
 - Data sources and data elements
 - Data collection strategies
 - Any interventions or innovative healthcare delivery strategies that will be used
 - Analytic and statistical approaches
- Quarterly Milestones (refer to Appendix I)

References (2-page limit)

Budget and Justification (budget template plus 1-page justification)

 Complete the pilot budget form, provided in the application link, along with a brief justification for the funds requested for this RFA. Please include explanation of other resources that may be leveraged to support the study.

Biosketch

• Provide the submitting Principal Investigator's biosketch.

I. Budget Guidelines

The budget period is up to 24 months. Up to \$75,000 in direct costs may be requested.

Funds may be budgeted for:

- Faculty or other investigator effort
- Support for iDAPT methods core effort

- Research support personnel (including undergraduate and graduate students)
- Travel necessary to perform the research
- Small equipment or research supplies
- Other purposes deemed necessary for the successful execution of the proposed study

Funds may **not** be budgeted for:

- Meals or travel, including to conferences*, except as required to collect data
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Indirect costs

Awarded funds must be used to conduct the work proposed. The iDAPT Developing Center reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol.

J. Review Criteria and Process

Proposals are competitive and peer reviewed. Studies will be initially evaluated on 1) Scientific merit and feasibility, 2) Relevance to iDAPT theme; and 3) Potential to lead to successful extramural funding. Proposals will also be evaluated based on the INSPECT criteria¹ (see below and Reference).

Reviewers will first consider study alignment with priorities listed above in Section E, and score applications based on these priorities and the following:

- 1. Significance of the research to be conducted:
- 2. Innovation in the proposed solutions;
- 3. Strength and breadth of the investigative team;
- 4. Methodological rigor and feasibility with clear milestones;
- 5. Likelihood the innovation will be broadly applicable and have impact on cancer control implementation science;
- 6. A dissemination plan, regardless of whether the study yields positive or negative results, including a plan for applying for additional funds;

7. INSPECT Criteria:

- a. Care or quality gap: Quality gap clearly supported by national and local setting data.
- b. Strength of evidence-base: Prior efficacy studies discussed, evidence-based (not evidence-informed).
- Conceptual model and theory justification: Implementation conceptual framework or model described is used to frame all aspects including study questions, processes, and outcome measures.
- d. Stakeholder priorities/engagement: Detailed description of how stakeholders were involved in the conceptual design of the intervention.
- e. Setting's readiness to adopt new services/program: Evidence of support from the study setting that addresses how the proposed study aligns with the organization's priorities.
- f. Implementation strategy/process: Theoretically justified implementation strategies & link to study aims.
- g. Team experience with setting and Implementation process: Clearly describes strengths of research environment including resources and infrastructure.
- h. Feasibility of design and methods: Potential barriers to implementation & remediation strategies are defined.
- i. Measurement and analysis: Outcomes are clearly linked to the proposed study aims.
- j. Policy/funding environment and support for sustaining change: Potential impact is explicitly

^{*}Note: Requests for supplemental funds for travel to disseminate main findings as presentations at national meetings will be considered only after successful completion of the study.

linked to relevant policies and funding issues associated with clinical settings.

8. Other elements to be considered in the review include: early-career faculty involvement; race/gender inclusiveness of the research team; and inclusion of women, minorities, and individuals across the lifespan (from children to older adults) as potential participants.

The top proposals (e.g.: three to four best scoring proposals) may be invited to present a virtual "chalk talk" to the iDAPT leadership and faculty, describing their research plan, expected results, and future directions. Individuals that are not on the iDAPT Executive Committee will score this presentation.

Final decision will be made by an external reviewer or reviewers. The iDAPT Navigator will synthesize this information and produce a ranked list. Any required IRB protocols must be approved prior to funding of the approved pilot.

K. Program Expectations

The study team will be required to work with the iDAPT team to define milestones for the study to be successfully completed (or in rare cases, terminated). This may include a 5-day SPRINT (http://www.gv.com/sprint/) to prototype the proposed technology.

L. Other Guidelines

- 1. Prior to receiving funds, research involving human subjects must have appropriate approvals from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the iDAPT team prior to funds being released. Human subjects must be reviewed in accordance with the awarding institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the award period.
- 2. iDAPT staff will work closely with funded teams throughout the award period to monitor progress and, when necessary, provide assistance. A final progress report will be required. We expect PIs to report over the lifetime of iDAPT, the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.
- 3. Any awardee who intends to leave his or her position should contact Dr. Thomas Houston as soon as feasible to discuss future plans for the study.
- 4. Pilot principal investigators and mentors from Round 1 are expected to be available for conference calls and meetings with new potential principal investigators across the five years of the iDAPT program.

M. Pilot Award Administration

The Corresponding Principal Investigator is responsible for the administration of pilot award funds. Studies will be for a 12- to 24-month period of time.

N. Pilot Program Contacts

Questions about your proposed research study should be directed to:

Thomas K. Houston, MD MPH (<u>tkhousto@wakehealth.edu</u>), iDAPT Research Program Director and copy:

Jessica Wijesundara, MPH, CHES (jessica.wijesundara@umassmed.edu), iDAPT Navigator

Additional Contacts:

Kristie Foley, PhD, Corresponding Principal Investigator, iDAPT Developing Center Sarah Cutrona, MD, MPH, Multi-PI, and UMMS Principal Investigator Milena Duque, MD, BA, Program Manager, iDAPT Developing Center

Appendix I

Below are examples that show different methods of providing study milestones, outcomes, and timeline. However, these formats are not required.

Example 1:

- Milestone 1 (0-1.5 months): Milestone 1 Details Outcome: Outcome 1 Details
- Milestone 2 (1.5- 4 months): Milestone 2 Details Outcome: Outcome 2 Details
- ...

Example 2:

Timeline and Milestones							
Quarters	1	2	3	4			
Activity/Aim/Milestone 1	Χ	Х	Χ				
Activity/Aim/Milestone 2	Х	Х					
Activity/Aim/Milestone 3		Х	Х	Х			

