Overview of 2021 Pilot Grants Program Request For Applications 3B

Kathleen Unroe, MD, MHA
IMPACT Collaboratory Pilot Core Associate Lead
Associate Professor of Medicine, Geriatrics
Indiana University School of Medicine
Scientist, Regenstrief Institute
**Mission**
To build the nation’s capacity to conduct ePCTs of interventions within health care systems (HCS) for people living with dementia and their care partners (CPs)

**Values**
- Be Collaborative
- Be Generative
- Be Inclusive
- Be Excellent
- Be Transformative
- Be Sustainable

**Vision**
To transform the delivery, quality, and outcomes of care provided to Americans living with dementia and their CPs by accelerating the testing and adoption of evidence-based interventions within HCS
Governance Structure

NIA PROJECT OFFICE

STEERING COMMITTEE

EXTERNAL ADVISORY PANEL

ADMINISTRATIVE & MANAGEMENT CORE TEAMS

- Grants Administration
- Organization & Logistics
- Data Sharing & Standards
- Investigator Navigation
- Communication & Knowledge Dissemination
- Institutional Review Board & Regulation

WORKING GROUP CORES & TEAMS

- Technical Data
- Pilot Studies
- Patient/Caregiver Relevant Outcomes
- Ethics & Regulation
- Health Equity
- Design & Statistics
- Training
- Implementation
- Health Care Systems
- Stakeholder Engagement
Leadership

Susan Mitchell, MD, MPH
Principal Investigator
Professor of Medicine, Harvard Medical School
Senior Scientist, Hebrew SeniorLife’s Hinda and Arthur Marcus Institute for Aging Research

Vincent Mor, PhD
Principal Investigator
Florence Pirce Grant University Professor
Professor of Health Services, Policy and Practice
Brown University School of Public Health

Ellen McCarthy, PhD, MPH
Executive Director
Associate Professor of Medicine, Epidemiology
Harvard Medical School
Associate Scientist, Hebrew SeniorLife’s Hinda and Arthur Marcus Institute for Aging Research

Jill Harrison, PhD
Executive Director
Associate Professor of Health Services, Policy and Practice
Brown University School of Public Health
# Pilot Core

## Executive Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Position and Affiliation</th>
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| Ab Brody, PhD, RN, FAAN     | Associate Professor and Associate Director, Hartford Institute for Geriatric Nursing, NYU Rory Meyers College of Nursing  
**Lead** (Geriatric and Palliative Nursing) |
| Kathleen Unroe, MD, MHA     | Associate Professor, Indiana University Department of Medicine, Indiana University Center for Aging Research, Regenstrief Institute  
**Associate Lead** (Geriatrician) |
| Deborah Barnes, PhD, MPH    | Professor, Psychiatry, Epidemiology & Biostatistics, UCSF  
San Francisco VA Health Care System (Epidemiologist, Health Services) |
| Joshua Chodosh, MD, MSHS    | Professor of Medicine and Population Health, NYU School of Medicine (Geriatrician, Health Services) |
| James Galvin, MD, MPH       | Professor of Neurology, University of Miami Miller School of Medicine  
(Neurology) |
| Kenneth Hepburn, PhD        | Professor, Nell Hodgson Woodruff School of Nursing, Emory University  
(Social Scientist) |
| Nicholas Pajewski, PhD      | Associate Professor, Biostatistics and Data Science, Wake Forest School of Medicine  
(Biostatistician) |

## Adjunct Faculty

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<th>Name</th>
<th>Position and Affiliation</th>
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<tr>
<td>Fayron Epps, PhD, RN</td>
<td>Assistant Professor, Emory University Nell Hodgson Woodruff School of Nursing</td>
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2021 Pilot Grants Program
Request for Applications
Request For Applications - Cycle 3B

• Up to 5 pilot studies funded

• **Goal:** Generate preliminary data necessary for future full-scale ePCT of non-pharmacological interventions in health care systems (HCS) for people living with AD/ADRD and their care partners

• **Amount:** 1 year, up to $175,000 (direct costs), non-renewable

**Priority Areas:**

• Improve care through behavioral economics “nudge” interventions
• Reduce inequities in health care
• Reduce potentially inappropriate medications through de-prescribing
• Improve care in emergency departments
Requirements

Pilot Studies must:

- Test a non-pharmacological intervention for people living with AD/ADRD and/or their care partners using an ePCT design
- Have a reasonable evidence-base to demonstrate intervention’s efficacy *(as described in the RAPT Model paper)*
- Evaluate an intervention that can be implemented with a high level of fidelity

Readiness Assessment for Pragmatic Trials
(RAPT Model)
Requirements ~ continued

- Have no more than minimal risk to human subjects
- Qualify for a waiver or alteration of informed consent
- Have high alignment with stakeholder priorities
- Address biologic variable of sex as it relates to populations and outcomes

Readiness Assessment for Pragmatic Trials (RAPT Model)
Requirements ~ continued

• Implement intervention in ≥ 2 HCS or sites (e.g., nursing homes, hospitals, healthcare provider practices, adult day)

• Maximize number of sites and subjects

• Include qualified biostatistician on research team

• Be feasible within the 1-year time-frame

Randomization is NOT required
Stage of Research and Outcomes

Stage of Research

Pilot studies should enable researchers to receive funding for and carry out, a Stage IV effectiveness ePCT aligned with the NIH Stage Model for Behavioral Intervention Development

Primary and Secondary Outcome Requirements

• Primary clinical outcome, collected pragmatically

• Secondary feasibility endpoints evaluating implementation fidelity, usability, acceptability, or additional target metrics (e.g., > 80% adherence)

• Pilot study is NOT expected to be powered to demonstrate an effect of the intervention
Additional Key Methodologic Considerations of a Pilot for an ePCT

To prepare for a full-scale ePCT, the following may be appropriate:

- Refine approach to implementation of prior developed intervention
- Develop pragmatic approach to identification and enrollment of participants
Eligibility

Eligible Applicants:

- Must be citizens or permanent residents
- Hold faculty or research scientist position at an eligible institution by the award’s start date or be otherwise eligible to serve as Principal Investigator as determined by their organization
- Individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research may also work with their organization to develop an application

Applicants from under-represented racial and ethnic groups and individuals with disabilities are strongly encouraged to apply
Application Process

Two Step Application Process:

STEP 1: Letter of Intent – *due September 17, 2021 at 5pm ET*

STEP 2: Full Proposal Application – *by Invitation Only*

- One Principal Investigator allowed
- One LOI per PI per cycle
Step 1: Letter of Intent

Main Elements:

1. Pilot Study Description (2 pages), with:
   - Background/rationale
   - Specific aims
   - Design overview
   - Setting (types, names of HCS)
   - Participants, participant identification strategy
   - Intervention structure, implementation strategy
   - Outcome definitions, collection methods

Review based on:

- Responsiveness to RFA and IMPACT Collaboratory mission
- Scientific impact and potential for full-scale ePCT
- Feasible within one-year
Step 1: Letter of Intent ~ continued

2. Pilot Study Pragmatic Design Worksheet (not included in 2-page)

3. Attestation in UFunds that PI has:
   - Viewed “Pragmatic clinical trials: How do I start?” video
   - Read the RAPT Model paper OR viewed “Are you ready for a pragmatic trial? The RAPT Model and implementation considerations”
   - Read the PRECIS-2 paper

4. PI’s NIH Biosketch

5. Bibliography and References Cited (≤1-page; not included in 2-page)

6. Anticipated total direct costs (≤ $175,000), subawards (if anticipated)

*Resources for #2-3 linked in RFA and located on impactcollaboratory.org/pilot-required-materials-and-resources/
Online Submission & Access to UFunds

• LOIs must be submitted **online via UFunds** grant application system

• Applicants **without** a Brown University email address **must FIRST request access** to the UFunds system using a Gmail (Google) account
  
  – Request process takes up to 2 business days ➔ If you are thinking of applying, PLEASE REQUEST ACCESS NOW

  – LOIs will not be accepted after deadline because an applicant did not request access in a timely fashion

• Applicants will be notified by email once access has been granted
LOI to Full Proposal Stage

LOI Notification:

• Notification by October 22, 2021

• Applicants invited to submit a full proposal will:

  - Be granted access to application in UFunds
  - Meet with a Consultation Team twice for guidance and advice on developing the specific aims and full proposal
    – Composed of IMPACT experts to help develop the strongest proposal possible
Step 2: Full Proposal (by invitation only)

General Considerations:

- Applications without **substantially pragmatic designs** will not be reviewed
  - Pilot studies for efficacy trials (e.g., Stage III on NIH Stage Model) will NOT be considered
- Applications must adhere to NIH policy and guidelines regarding inclusion of women and minorities and inclusion across the life span
- Scientific review focuses on the degree to which health equity considerations are addressed in preparation for the full-scale ePCT
  - Provide rationale about how aspects of the design address the needs of people from diverse backgrounds
Full Proposal Requirements

1. General Audience Summary (max 500 words)
2. Specific Aims (1 page)
3. Research Plan - follow NIH R21 format (6 pages)
4. Letters of Support from each participating HCS / site
5. PHS Human Subjects and Clinical Trial Information
6. Pilot Study Pragmatic Design Worksheet
7. Clinical Trial Milestones Plan

8. Health Equity (1 page)
   – Describe how health equity is addressed in the proposed study and will be considered in the future ePCT

9. NIH Biosketch for the PI and Key Personnel
   – Must include qualified biostatistician as co-investigator or consultant

10. Acknowledgment Letter from IRB/HRPP Official

11. Bibliography and References Cited

Appendices are NOT permitted
Research Plan

- Background/Significance
- Preliminary Studies (if applicable)
- Milestones (specific, measurable for progress review)
- Future Directions and Next Steps
  - How the pilot study will directly inform the development of a full-scale, Stage IV effectiveness ePCT

- Research Design and Methods, including:
  - Study population
  - Setting (HCS / Sites)
  - Randomization scheme and masking when appropriate (not expected for all pilot studies)
  - Intervention structure, implementation protocol, and fidelity/adherence monitoring plan
  - Data sources, elements, and collection protocol
  - Analytic plan

Health equity considerations must be integrated in the research design and methods
Research Design and Methods

The following additional design features are required:

• Feasible approach to participant identification/enrollment using existing electronic HCS data sources or infrastructures

• Address biologic variable of sex as it relates to populations and outcomes
Addressing Health Equity

Health equity (1 page)

This section should address how equity principles are applied to:

• Selection of health care system(s)
• Targeting study population demographics
• Tailoring intervention to different backgrounds, languages, cultures
• Monitoring differential implementation, adherence, attrition/retention
• Assessing outcomes
Budget

- 1-year study period, non-renewable
- Up to $175,000 (direct costs)
  - Indirect costs budgeted at your institution’s negotiated facilities/administrative rate
  - Extensive primary data collection (i.e., direct cost > $30,000) is NOT permissible
  - Applicants do not have to budget for the costs of using Advarra, the independent sIRB that oversees IMPACT-funded research
  - Applicants should budget for PI’s travel and accommodation to one in-person 2.5-day IMPACT Collaboratory meeting in Bethesda, MD
- Follow NIH rules and regulations regarding allowable costs
- Up to 2 Subawards allowed
  - When feasible, purchase of services/consulting agreements are strongly preferred to subawards
Scientific Merit Review Criteria

Scientific merit will consider:

1. Fit within IMPACT Collaboratory mission
2. Significance
3. Alignment with Stakeholder Priorities
4. Investigative Team Qualifications
5. Intervention readiness for a pilot ePCT based on the RAPT Model
6. Design (pragmatism, scientific validity) based on PRECIS-2 Framework
7. Health equity integration in research plan
8. Consent and risk of human subjects
9. Milestones that are specific, measurable, achievable and aligned with the project
10. Likelihood that the pilot study will lead to successful future extramural grant funding for a full ePCT
Stakeholder Review Criteria

Stakeholders will consider the following:

1. Importance and relevance of intervention
2. Does proposal address a weakness or need that is experienced in health care systems?
3. Does this study fill an important gap in dementia care and/or make a difference in the real-world for people living with dementia, care partners, and health care systems?
## Requirements for Funded Applications

<table>
<thead>
<tr>
<th>Category</th>
<th>Resource</th>
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<tbody>
<tr>
<td>IRB, Data &amp; Safety Monitoring, and Data &amp; Resource Sharing Policies</td>
<td>Reports Tracking Standardized Data Elements</td>
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<tr>
<td>Financial Conflict of Interest Assurance/Training</td>
<td>Invoicing Guidelines</td>
</tr>
<tr>
<td>Registration with ClinicalTrials.gov</td>
<td>Budget Reports</td>
</tr>
<tr>
<td>Pilot Core Advisor Meetings</td>
<td>Publication Policy, Sponsorship Acknowledgement</td>
</tr>
<tr>
<td>IMPACT Collaboratory’s Scientific Community</td>
<td>Queries post project</td>
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<td>NIH policy regarding inclusion of women and minorities and inclusion across the life span</td>
<td>NIA Clinical Research Operations Management System (CROMS)</td>
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Key Dates

- August 16, 2021
- August 23, 2021
- August 23, 2021 @ 2:00pm ET
- September 17, 2021 @ 5:00pm ET
- October 22, 2021
- January 14, 2022 @ 5:00pm ET

- RFA Release Date
- Letter of Intent Application – Opens
- Informational webinar
- Letters of Intent Due Date – Required
- Letters of Intent – Notification
- Full Proposal Application Due Date – By Invitation Only
For answers to Frequently Asked Questions, visit our website: [https://impactcollaboratory.org/pilot-grant-faq/](https://impactcollaboratory.org/pilot-grant-faq/)

Contact Us: [IMPACTcollaboratory@hsl.harvard.edu](mailto:IMPACTcollaboratory@hsl.harvard.edu)