2021 Demonstration Projects Overview

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

To build the nation’s capacity to conduct ePCTs of interventions within health care systems (HCS) for people living with dementia (PLWD) and their care partners (CPs)

Vision

To transform the delivery, quality, and outcomes of care provided to PLWD and their CPs by accelerating the testing and adoption of evidence-based interventions in HCS

Values

Be Collaborative
Be Generative
Be Inclusive
Be Excellent
Be Transformative
Be Sustainable
Scope

• NIA U54 grant

• 31 academic institutions

• 60 investigators

• 10 Core and Teams
Governance Structure
Leadership

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

Jill Harrison, PhD
Executive Director
Assistant Professor of Health Services, Policy and Practice
Brown University School of Public Health
Request for Applications

- Demonstration projects - designed as full-scale, Stage IV effectiveness ePCTs (based on NIH Stage Model)

- Test the effectiveness of a care delivery intervention program embedded in a health care system (HCS) targeting people living with AD/ADRD and/or care partners

- **Goal:** to generate evidence on effective care delivery practices that can be disseminated to other HCS

- Fund up to 2 awards for $500,000 (total direct costs) for maximum of 24 months

- Multiple Principal Investigators (MPI) allowed
Intervention

- **Must be** a non-pharmacological intervention

- Reflect (based upon) the needs of the health care system
Health Care System Partnership

• Requires at least one **HCS** as a **clinical or operational partner**

• Committed to testing a care intervention and applying the results in practice

• Facilitate investigator access to all relevant data sources (e.g., EHR, inpatient, outpatient, imaging, lab, pharmacy, assessment)

• **Ideally** applicants have established research partnerships with HCS & Leadership

• Effective and sustainable partnerships with health care delivery organizations and champions within systems are critical to implementation and testing of program interventions
Health Care Systems Interested in Collaboration

If you’re in a HCS that is interested in testing a care intervention, but do not have a researcher to serve as a principal investigator

– IMPACT Collaboratory may be able to act as a bridge to finding an appropriate investigational partner

– Email: IMPACTcollaboratory@hsl.harvard.edu

Let’s talk!
Demonstration Project Requirements

- Design features consistent with an ePCT (see PRECIS-2 framework)
  - Projects that do not reflect an ePCT cannot be considered

- Conducted within ≥1 HCS with clear commitment

- Intervention must be well-characterized, able to be delivered with high fidelity, reasonably simple, and should not require excessive personnel to support implementation
  - System-level interventions may be particularly suitable

- Intervention can be implemented with flexibility
Requirements ~ continued

• Leverage opportunities to identify study population, ascertain outcomes captured routinely by EHR and/or administrative data sources, and with minimal need for adjudication

• Enrollment based on broad eligibility criteria to maximize diversity, minimize intentional or unintentional exclusions based on risk, age, health literacy, demographics, expected adherence

• Primary outcome measure → clinically meaningful and important to stakeholders

• Specify implementation outcomes (e.g., fidelity, usability and acceptability)
• Trial design must incorporate a control arm, prospectively identified, preferably by randomization

• Proposed analytic plan addresses sample size and power estimates. Employs analytic strategies relevant for ePCT designs

• **Powered to detect a significant difference in primary outcome between trial arms**

• Detailed and definitive testing of validity of methods used for monitoring implementation and outcome assessment
Award Details

• Maximum 24-month project period; non-renewable
  – No-cost extensions are generally not allowed

• Up to $500,000 in total direct costs (over entire project period); indirect costs budgeted at your institutions’ negotiated F&A rate

• Follow NIH rules and regulations regarding allowable costs

• Multiple Principal Investigators are allowed

• Requires using the single IRB (sIRB) that oversees all IMPACT Collaboratory-funded research (Advarra) → requires Pis’ institution to cede

• Requires using the DSMB and/or Safety Officer that oversees all IMPACT Collaboratory-funded research
Eligibility

• U.S. institutions only – *all work must be performed within the United States*

• Eligible applicants
  – Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research
  – Hold a faculty or research scientist position at an eligible institution by the start date of the award or be otherwise eligible to serve as a PI as determined by their organization
  – Must be U.S. citizen or permanent resident
  – Applicants from under-represented racial and ethnic groups and individuals with disabilities are strongly encouraged
Application Process – Required Letter of Intent

• 500 word email to IMPACTcollaboratory@hsl.harvard.edu

• Must include:
  – PI(s) name and affiliation
  – Name of HCS(s) and partner(s)
  – Brief description of:
    ➢ intervention to be tested
    ➢ target study population
    ➢ control group (e.g. usual care)
    ➢ primary outcome

Due October 29, 2021 @5PM ET
Application Process

• Letters of intent will be reviewed and we may follow-up to discuss alignment with the funding mechanism

• Applications selected to submit a full proposal will be notified and provided an application guide detailing the application and submission process
Consultation from IMPACT Experts

- Offering a consult to all invited applicants
- Provide input on various aspects of study design and implementation
- Investigator Navigation Team will coordinate
Application Requirements

• Generally follow structure of **NIH R-series grant** plus **IMPACT-specific additions**

• **Project Summary and Relevance**

• **Specific Aims** (1 page)

• **Research Plan** (6 pages)
  – Background and Significance
  – Preliminary Studies (if applicable)
Research Plan ~ continued

• Research Design and Methods → must be an ePCT
  – Study population and identification strategy
  – Setting(s) and Health Care Partnership(s)
  – Randomization scheme and masking
  – Intervention structure, implementation protocol, and monitoring plan for fidelity and adherence
  – Data sources, elements, and collection protocol
  – Primary clinical outcome (must be pragmatic) and implementation outcomes
  – Analytic plan → Demonstration Project must be powered to detect a difference in primary outcome between trial arms
Research Plan ~ continued

• Milestones
  – Specify quarterly milestones that are specific & measurable, so progress can be reviewed

• Future Directions and Next Steps
  – Specify how the Demonstration Project will directly inform the scalability and sustainability of the intervention

• Important considerations in research plan
  – Health equity must be integrated in all aspects of the research design
    ➢ Online video providing a framework to integrate health equity into the design is posted on Demonstration Projects webpage
  – NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting
Pragmatic Design Worksheet

– Complete a worksheet based on the PRECIS-2 Framework: http://www.precis-2.org/

– Intent is to work through study design elements to ensure the design is as pragmatic as possible along the continuum of explanatory to pragmatic

– Worksheet is available on the website
Letter of Support from Heath Care System[s]

• Letters of support are essential for this funding opportunity!

• Letters from health system partners must clearly state their commitment to the research and address the following 5 elements:
  
  – Describe how the project fits with organizational priorities and directly impact delivery of health care within the organization
  
  – Describe how the intervention could be feasibly integrated and adopted into the clinical workflow by frontline providers
  
  – Describe quality of the proposed data systems (e.g., EHR) for subject identification and outcome ascertainment
  
  – Describe how essential data can be extracted and applied for the planned investigation and in subsequent clinical care
  
  – State the commitment of information technology (IT) staff to the project
Budget Considerations

• Up to $500,000 in total direct costs for up to 24 months
  – Indirect costs at your institution’s negotiated F&A rate

• Up to 2 subawards are allowed
  – Whenever feasible, purchase of services/consulting agreements are strongly preferred over subawards

• Up to $30,000 in direct costs are allowed toward primary data collection
  – Encouraged to use administrative data sources and/or low- to no-cost smartphone/tablet or web interventions that could feasibly become part of routine care delivery
  – Primary data collection needs to be fully justified
Budget Considerations ~ continued

• Appropriate mix of junior and senior investigators
  – **must** include a biostatistician

• Appropriate personnel from partnering health care system(s)
  – Think carefully about which costs derive from – and directly support – the research project, as opposed to those costs that would otherwise be incurred in the course of providing clinical care
    - intervention should be integrated into clinical workflow and be sustainable without research funding
  – Examples of relevant personnel might include informaticists, clinical investigators, staff with expertise in administrative aspects of clinical trials oversight

• Do not need to include costs of sIRB; IMPACT supports sIRB costs
Application Templates & Relevant Videos on IMPACT Website

Demonstration Projects Required Materials and Resources

Application Resources and Templates

- Application Guide
- DSMB Charter for the NIA IMPACT Collaboratory Omnibus
- IMPACT Collaboratory Resource and Data Sharing Plan
- Template - Acknowledgment Letter from IRB/HRPP Official
- Template - Single IRB Plan
- Template - Clinical Trial Milestone Plan
- Template - Data and Safety Monitoring Plan
- Template - Dissemination Plan
- Template - Demonstration Project Pragmatic Design Worksheet
- Template - Study Record: PHS Human Subjects and Clinical Trials Information Form
  (NIH Form Requires Adobe Reader 8 or higher to open)

Relevant Resources

https://impactcollaboratory.org/demo-required-materials-and-resources/
Scientific Merit Review

• Reviewed by non-conflicted scientific reviewers

• Review criteria are specified with more detail in RFA; encourage you to review these criteria since they differ from traditional NIH grants
  – Fit with mission of IMPACT Collaboratory
  – Significance
  – Alignment with stakeholder priorities
  – Investigative team qualifications
  – Intervention readiness for embedding into a health care system
  – Design including scientific validity and pragmatism
  – Scientific milestones
  – Integration of health equity in the design
  – Future directions and next steps
<table>
<thead>
<tr>
<th>Event</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for Applications - Released</td>
<td>October 4, 2021</td>
</tr>
<tr>
<td>Informational Webinar</td>
<td>October 19, 2021 @ 1pm ET</td>
</tr>
<tr>
<td>Letter of Intent by Email Due - Required</td>
<td>October 29, 2021 @ 5pm ET</td>
</tr>
<tr>
<td>Letter of Intent Notifications</td>
<td>Rolling basis</td>
</tr>
<tr>
<td>Full Applications Due – By Invitation Only</td>
<td>January 14, 2022 @ 5pm ET</td>
</tr>
<tr>
<td>Notifications</td>
<td>June 2022</td>
</tr>
</tbody>
</table>
Questions?

Send us an email: IMPACTcollaboratory@hsl.harvard.edu