NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE



Request For Applications – 2026
Overview of Demonstration Projects Grants Program



Kate Courtright, MD, MS
Core Leader
Research Grants Core (RGC)
Steering Committee

Director of Palliative Care Research, Perelman School of Medicine
Faculty, Palliative and Advanced Illness Research (PAIR) Center



Quincy Samus, PhD
Executive Committee
Research Grants Core (RGC)

Director, Translational Aging Services Core
Associate Professor of Psychiatry and Behavioral Sciences

Objectives

- Introduce IMPACT
- Learn about the Demonstration Projects Grants RFA
  - Does the mechanism fit your research project
  - Scientific rationale and components
  - Administrative components
  - Application and review processes
- Questions

IMPACT Mission

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

IMPACT Leadership



Susan Mitchell, MD, MPH
Principal Investigator
Professor of Medicine, Harvard Medical School
Senior Scientist, Hebrew SeniorLife
Marcus Institute



Ellen McCarthy, PhD, MPH
Executive Director
Associate Professor of Medicine, Epidemiology
Harvard Medical School
Associate Scientist, Hebrew SeniorLife
Marcus Institute



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



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



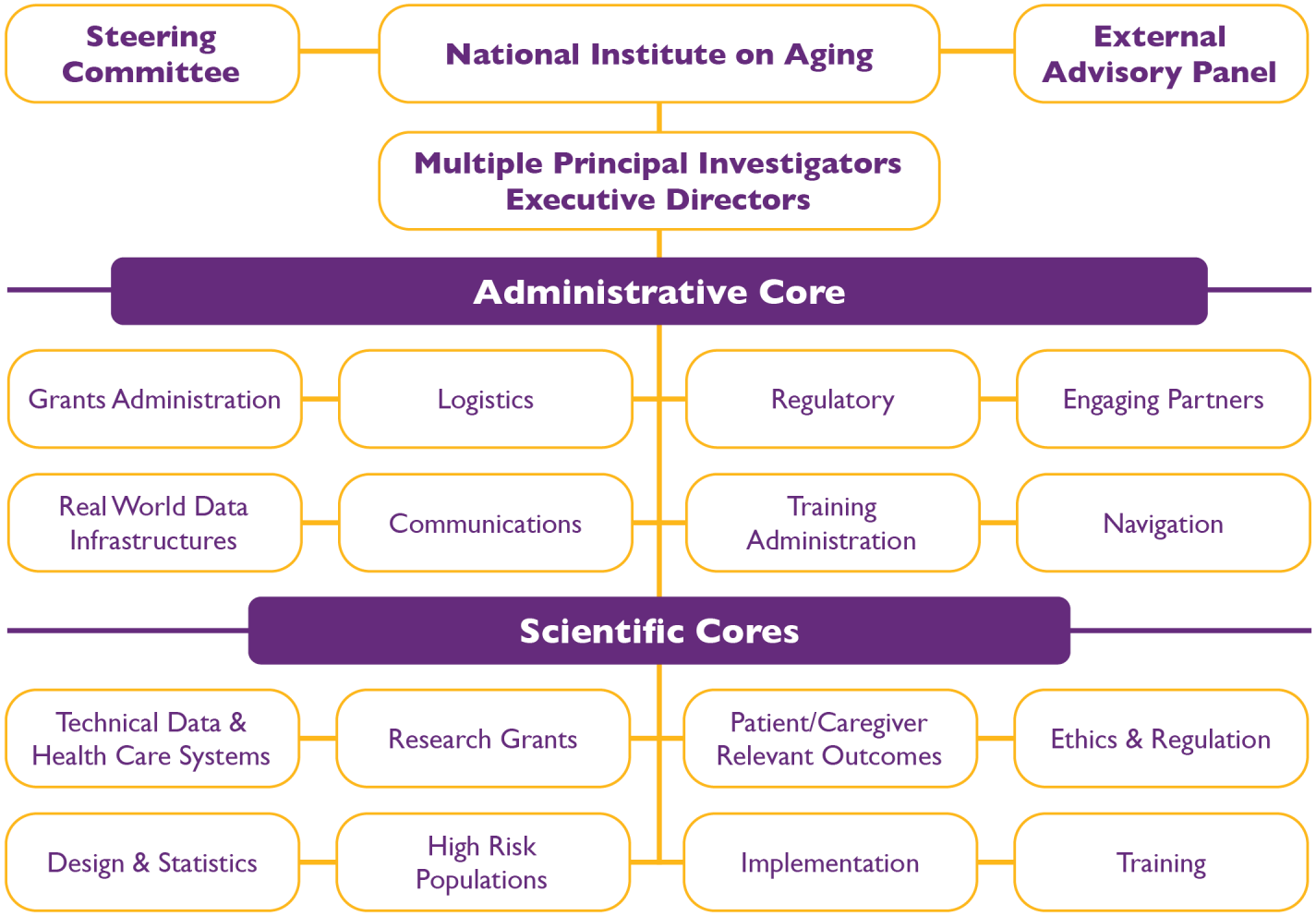
Ab Brody, PhD, RN, FAAN
Principal Investigator
Assistant Dean for Transformational Excellence in Aging
Mathy Mezey Professor of Geriatric Nursing
Professor of Nursing and Medicine
NYU Rory Meyers College of Nursing
Founder, Aliviado Health

Marcus Institute for Aging Research
Hebrew SeniorLife
HARVARD MEDICAL SCHOOL AFFILIATE

NYU RORY MEYERS COLLEGE OF NURSING

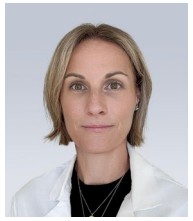
BROWN School of Public Health

Governance Structure



NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Research Grants Core (RGC)



Kate Courtright, MD, MSHP | RGC Lead
Assistant Professor, Medicine,
Perelman School of Medicine
University of Pennsylvania



Jennifer Gabbard, MD
Associate Professor of Internal Medicine, Section on Gerontology, Geriatric & Palliative Medicine
Serious Illness and Palliative Medicine Research Director
Wake Forest University School of Medicine



Huong Q. Nguyen, PhD, RN
Interim Director
Division of Health Services Research & Implementation Science
Kaiser Permanente



Quincy M. Samus, PhD
Professor
Associate Director for Innovation, Center for Health Equity in Aging, Johns Hopkins School of Nursing
Director, Memory and Aging Services Innovation Center, Johns Hopkins School of Medicine



Kathleen Unroe, MD, MHA, MS | RGC Associate Lead
Cornelius and Yvonne Pettinga Professor of Medicine
Indiana University Center for Aging Research, Regenstrief Institute



Nicholas Pajewski, PhD
Associate Professor, Biostatistics and Data Science,
Wake Forest School of Medicine



Sarah Berry, MD, MPH
Senior Scientist
Associate Professor of Medicine, Harvard Medical School and Beth Israel Deaconess Medical Center
Chief, Division of Gerontology, Beth Israel Deaconess Medical Center

High Risk Populations Core Representative



Fayron Epps, PhD, RN, FGSA, FAAN
Professor
Karen and Ron Herman Endowed Chair in Caregiver Research
The University of Texas Health Science Center at San Antonio

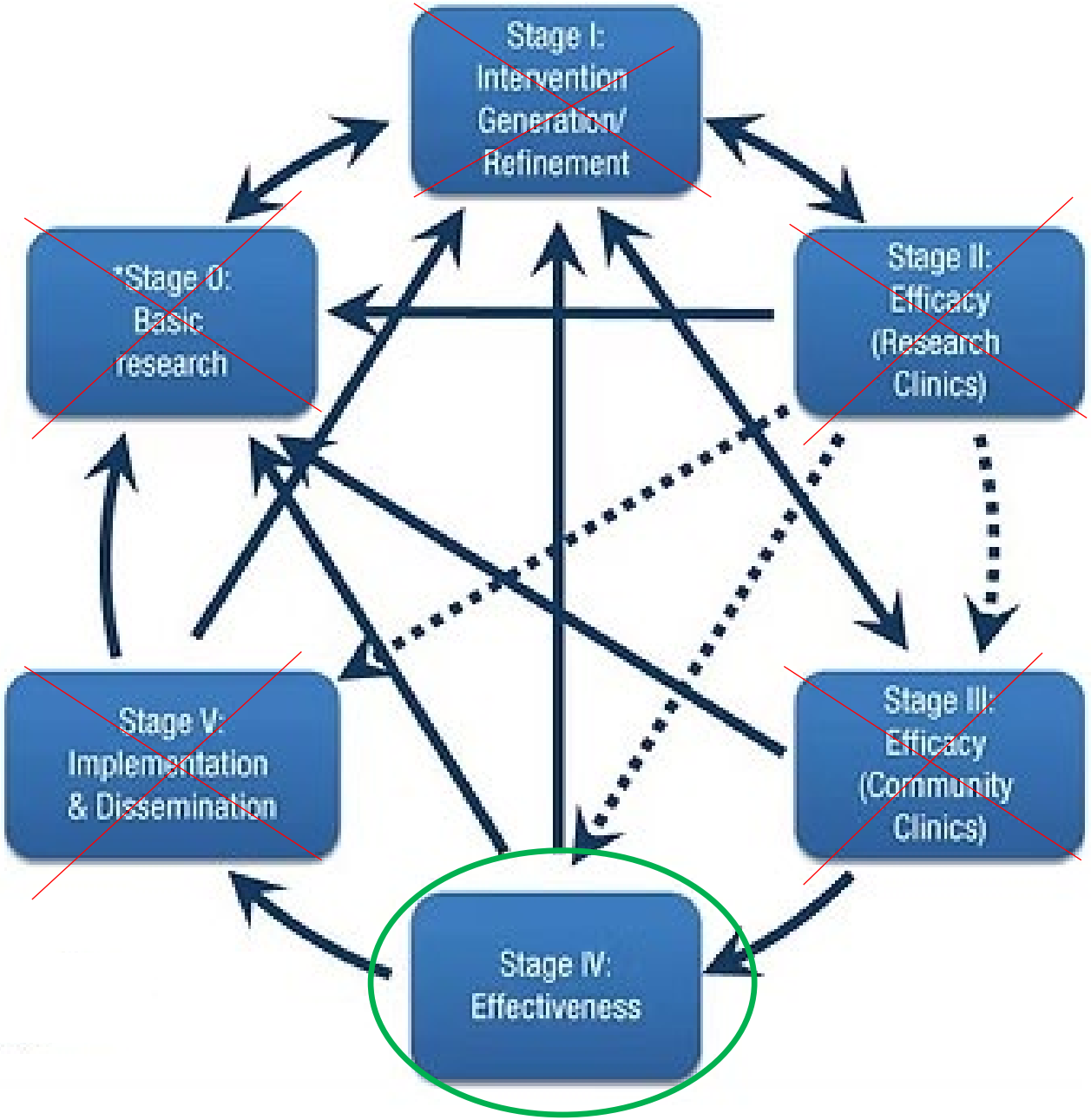
Demonstration Projects Grants Program

Goal: Test the effectiveness of a care delivery intervention embedded in a health care system (HCS) targeting people living with dementia (PLWD) and/or their care partners

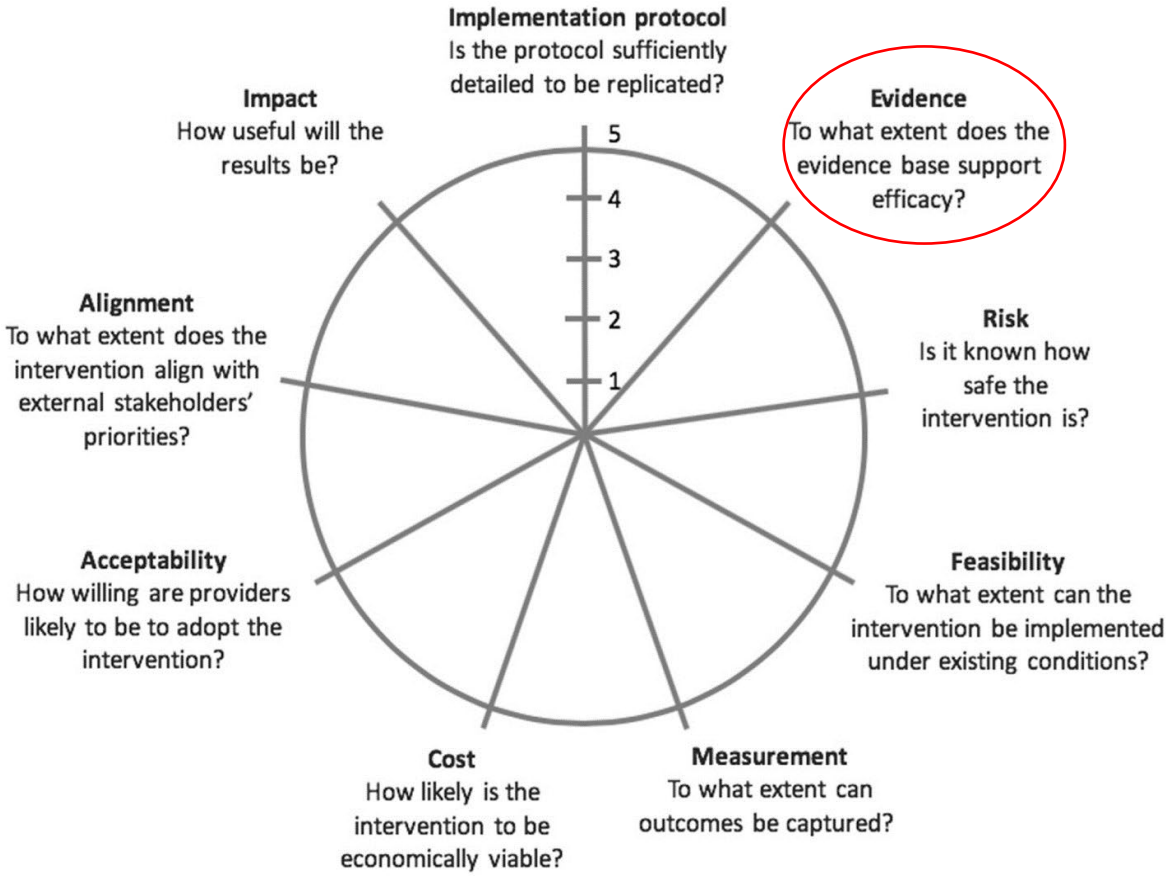
- Full-scale, Stage IV effectiveness ePCTs (based on NIH Stage Model)
- Randomized with intervention and control/comparator arms
- Powered to test a significant difference in the primary clinical outcome between trial arms

Award: 24 months, up to $800,000 (total direct costs), non-renewable
Fund up 2 per RFA cycle

NIH Stage Model for Behavioral Interventions



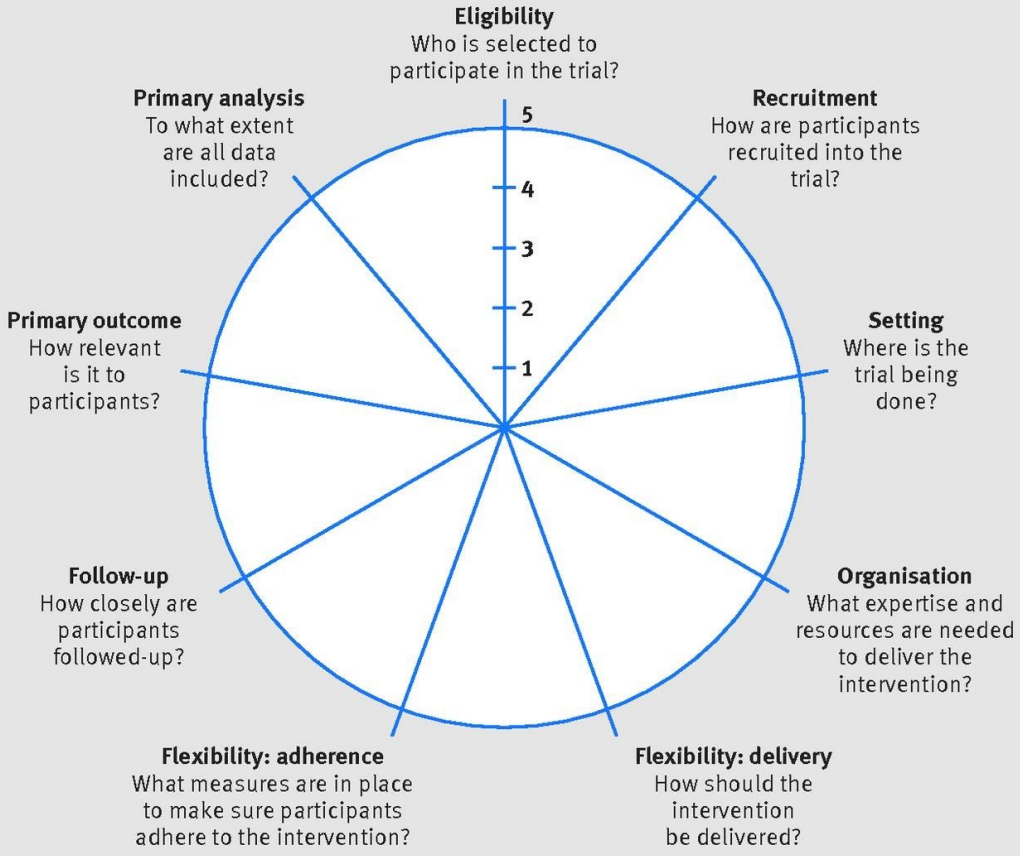
Is the intervention ready for an ePCT?



- Readiness Assessment for Pragmatic Trials (RAPT Model)
- Consider all domains
- Have a reasonable **evidence-base** to demonstrate intervention's **efficacy** from prior RCTs (Stage II/III). *The level of evidence of efficacy is less stringent for simple or "nudge" (versus complex) interventions.*

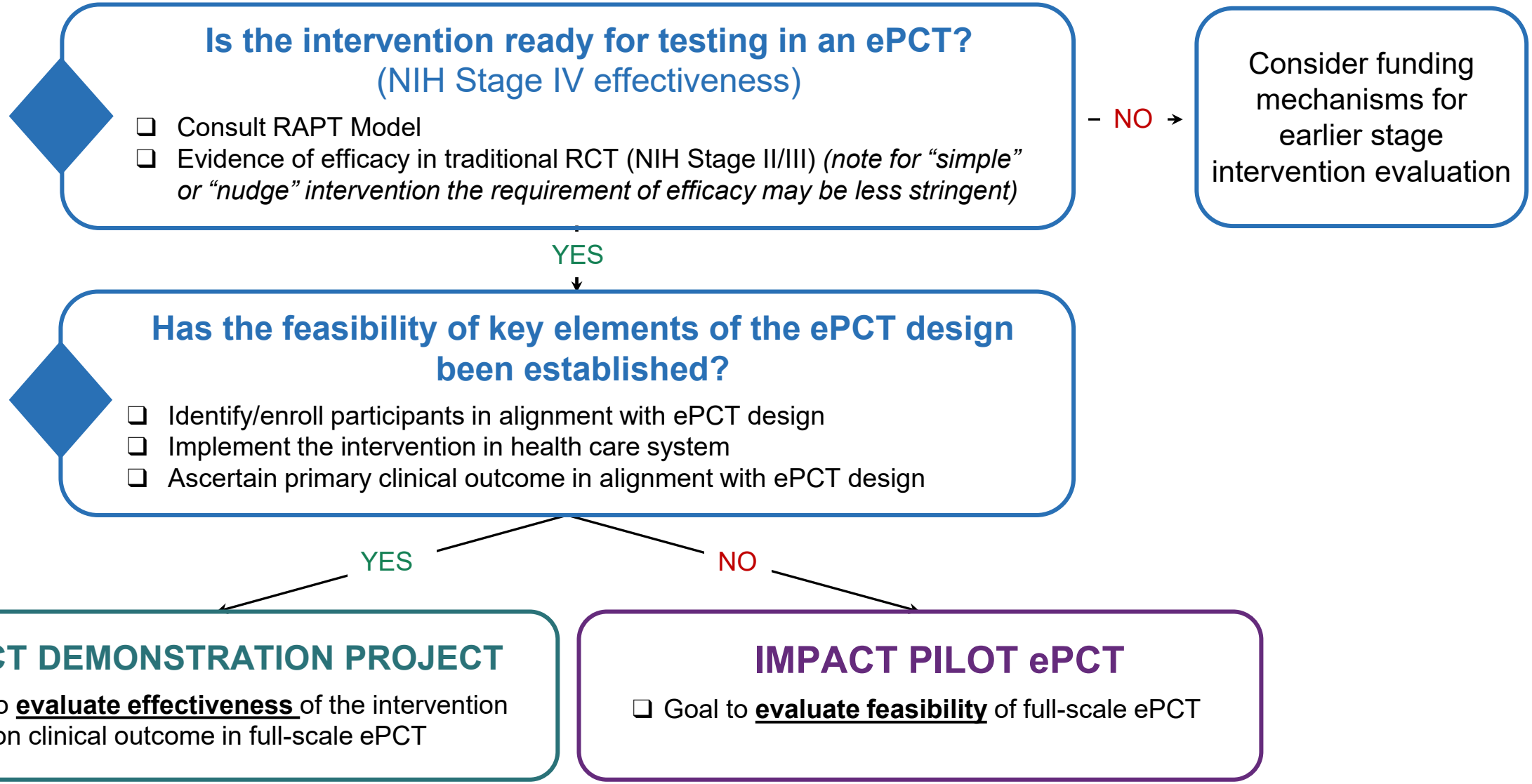
What is an ePCT?

- All applications must align with an embedded pragmatic clinical (ePCT) trial design
- Be familiar with the PRECIS-2 framework



PRagmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2)

Which IMPACT Research Grant do I Apply for?



Preliminary data/requirements

- Intervention
  - Non-pharmacological
  - Address area relevant to PLWD, care partners, health care providers, and/or clinical decision-making
  - Simple or complex
    - complex must have mature protocol, pilot testing, efficacy data (including for training)
  - Evidence of efficacy from traditional RCTs (NIH Stage Model II/III)
    - relaxed for simple or “nudge” (versus complex) interventions
- Pilot Data
  - Demonstrated feasibility of participant enrollment, intervention implementation, outcome collection

Setting

- HCS or setting caring for PLWD
- Intervention addresses a priority for the HCS
- Ideally investigator has an established partnership with the HCS
- HCS committed to integrating the intervention into care flow with buy-in at all levels from c-suite to front line providers
- Has required infrastructure: electronic data platforms, informaticists etc,
- Includes advisory group from HCS for ePCT design and conduct (administrator, PLWD/CP, providers, informaticist)

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!

Identifying and Enrolling Participants

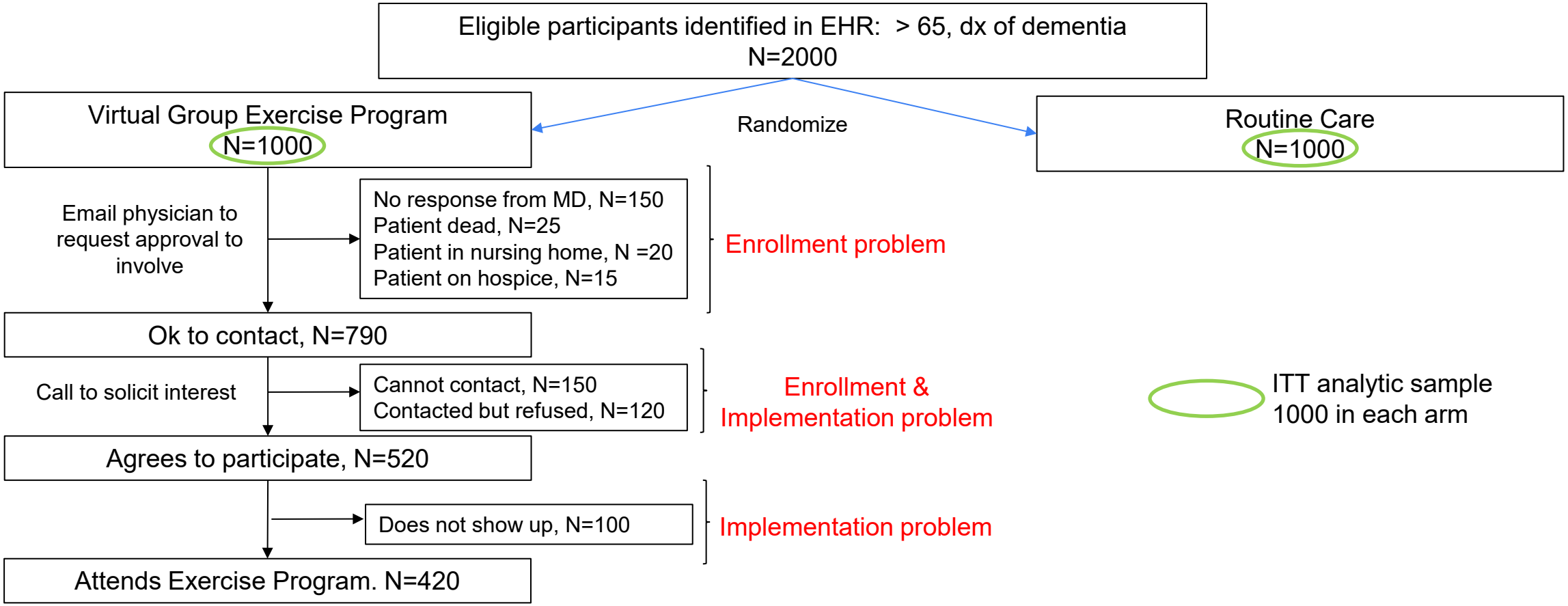
Example

Intervention: Virtual Exercise Program for Community Dwelling PLWD

Primary outcome: Injurious fall presenting to ER from EHR data



Participant flow (with waiver of consent):



Intervention Implementation

- Typically implemented in the course of routine care (e.g. by providers) with no involvement by research personnel
- Should include ongoing strategy to evaluate the success of the implementation strategy using an established framework (e.g. RE-AIM, CFIR, PRISM) and intervene where not meeting implementation goals
- Implementation strategy should have defined parameters indicating success

Clinical Outcomes

- Evaluate a single primary clinical outcome measure that is:
  1) Relevant to PLWD, care partners, providers or decision makers
  2) efficiently captured with minimal need for additional follow up, resources, or impact on routine care
- Power for the ePCT based in the primary clinical outcome
- Specify secondary clinical outcomes
- Must be captured in the exact same way in intervention and comparator group
- Consider eligibility for waiver/alteration of consent to collect outcomes

Key Dates – IMPACT Collaboratory Demonstration Projects 2026

Request for Applications - Released	September 9, 2026
Letter of Intent Application Opens	September 11, 2026
Informational Webinar – Recording available	September 16, 2026
Letter of Intent Due - Required	October 15, 2026 @ 11:59pm ET
Full Applications Due – By Invitation Only	January 14, 2027 @ 11:59pm ET

Eligibility

- US 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 US citizen or permanent resident
  - Multiple Principal Investigators (MPIs) are allowed
    - Only one application per PI/MPI is permitted in a single funding cycle

Application Process

Competitive two-step application process:

STEP 1: Letter of Intent – *due **Thursday, October 15, 2026** at 11:59pm ET*

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

- Multiple Principal Investigators allowed
- One application per PI



Online Submission & Access to UFunds



- LOIs must be submitted **online via UFunds** grant application system
- Applicants <u>without</u> 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

Step 1: Letter of Intent (Main Elements)

Template is linked in RFA, must include:

- Objective and Rationale
- Preliminary Data
- Overview of ePCT Design
- Specific Aims
- Setting(s)
- Participants and the Identification and Enrollment Strategy
- Intervention Structure and Content
- Intervention Implementation Strategy
- Clinical Outcome Definitions and Collection Strategy

2 pages

Due October 15, 2026
11:59pm ET

LOI to Full Proposal

- Letters of intent will be reviewed
- LOI decisions will be provided on a rolling basis
- Applicants invited to submit a full proposal will:
  - Receive an application guide detailing submission forms and process
  - Have a Consultation Team assembled from IMPACT experts to strengthen the proposal

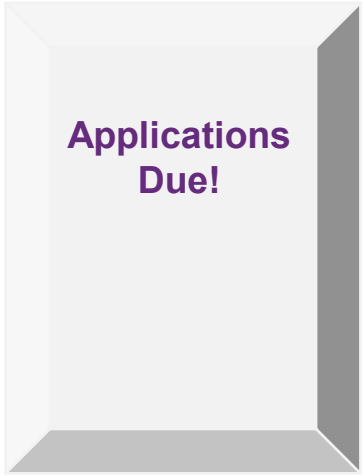
Demonstration Project Consultation



**Nov 30-
Dec 18**

PI + Biostatistician

**Review Aims
Provide Feedback
Answer questions**



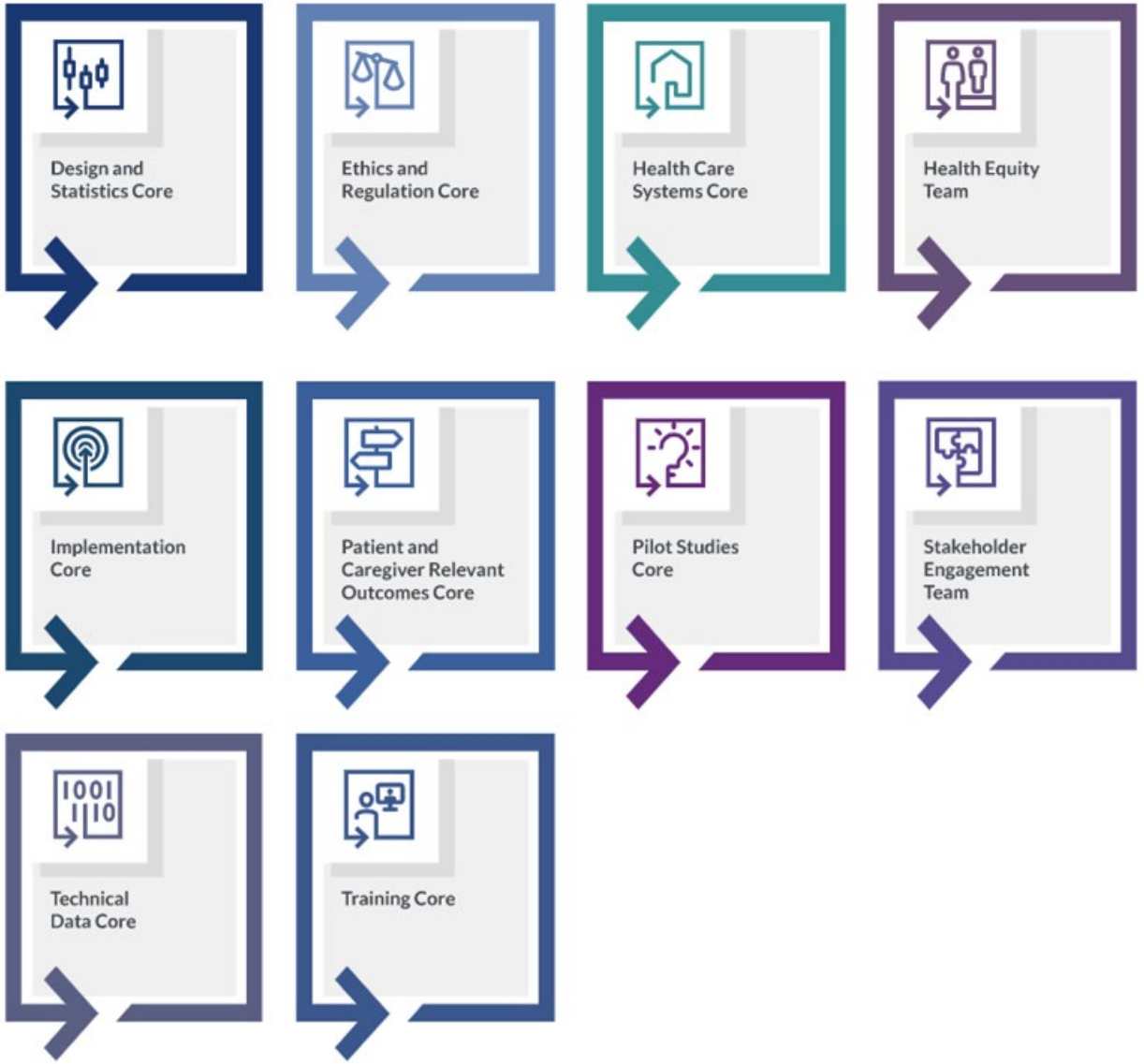
Jan 14, 2027

**Full proposals
submitted**

Targeted consultation w/Cores available

Consultation from IMPACT Experts

- Coordinated by Investigator Navigation Team
- Led by an MPI and experts from Cores
- Provide guidance on elements of study design and implementation to strengthen proposals
- Attended by PI and biostatistician
- Facilitate additional consults with Cores for targeted areas



Step 2: Full Proposal (by invitation only)

Full proposals due: **Thursday, January 14, 2027 @ 11:59pm ET**

Submitted online through Brown University's UFunds system:

https://ufunds.brown.edu

Note: *Application decisions are anticipated in April 2027. Actual award start dates will be later and may vary depending on the timing of NIA approval and completion of required risk assessments.*

Full Proposal | Required Sections

- General Audience Summary (max 500 words)
- Specific Aims (1 page)
- Research Plan (6 pages) - with IMPACT specific instructions
- Bibliography and References Cited
- PI/PD Leadership Plan (*only required for Multiple Principal Investigators*)
- Consort diagram, when applicable (*consultation process will determine when one is required*)
- PHS Human Subjects and Clinical Trial Information Form*
- Clinical Trial Milestone Plan*
- Data Management and Sharing Plan*
- NIH Biosketch Form and Supplement for the PI/MPIs and Key Personnel including the biostatistician.
  ~Note: The research team must include a qualified biostatistician as co-investigator or consultant.
- Acknowledgment Letters from IRB/HRPP Official
- Letters of Support

*Form/template and instructions will be provided by IMPACT.

Research Plan ~ detailed in RFA Appendix 1

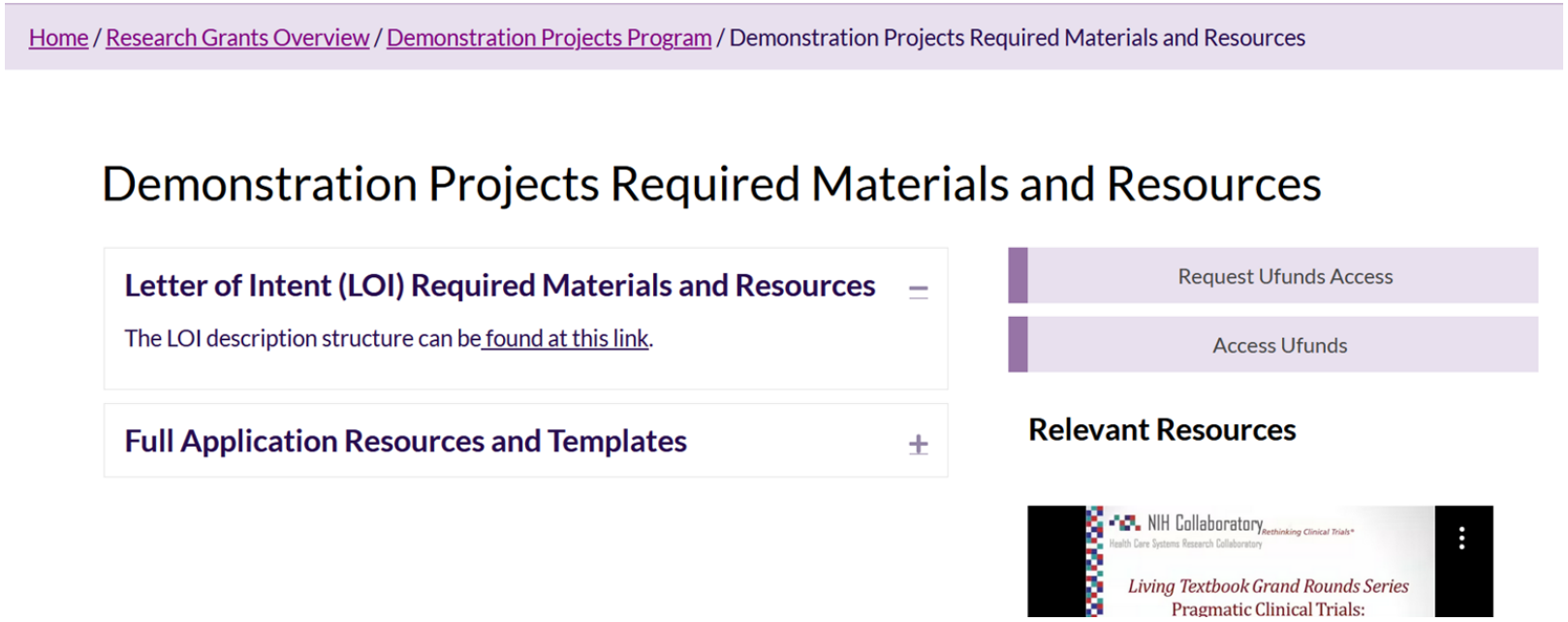
6-page Research Plan with the following sections:

- Background and Significance
- Preliminary Data
  - Evidence supporting the intervention's readiness for testing in an ePCT
  - Preliminary data supporting the feasibility of the key elements of the ePCT design, including strategies to:
    1. Identify/enroll participants
    2. Implement the intervention with fidelity
    3. Collect the primary and secondary clinical outcomes

Research Plan ~ Continued

- Research Design and Methods | must be an ePCT
  - Population and identification/enrollment strategy
  - Setting(s) and Health Care Partnership(s)
  - Randomization scheme and masking
  - Intervention structure, implementation protocol, and implementation evaluation plan
  - Data sources, elements, and collection protocol
  - Analytic plan → must include a section on ***Sample Size and Power Calculation***
- Milestones (specific, achievable, measurable for progress review)
- Future Directions and Next Steps

Application Templates & Relevant Videos on IMPACT Website



Direct link in the chat.

Letter of Support from Health Care System[s]

- Letters of support are essential for this funding opportunity!
- Letters from health system partners must clearly state their commitment to the proposed project and address the following 5 elements:
  - How the project fits with organizational priorities for PLWD or care partners
  - How the intervention program could be feasibly integrated and adopted into the clinical workflow
  - Readiness and quality of the proposed data systems (e.g., electronic health records) that may be required for participant identification/enrollment and outcome ascertainment
  - Description of how essential data can be extracted and applied for the planned investigation
  - Commitment of information technology (IT) staff from the HCS partner to support the relevant needs of the Demonstration Project

Award Details

- Maximum 24-month project period; non-renewable
- $800,000 in total direct costs (over entire project period), plus indirect costs at your institution's negotiated F&A rate
- Follow NIH rules and regulations regarding allowable costs
- Multiple Principal Investigators are allowed
- Requires using Advarra, the single IRB (sIRB) that oversees all IMPACT Collaboratory-funded research
- Requires using the DSMB and/or Safety Officer that oversees all IMPACT Collaboratory-funded research

Budget Considerations

- Up to 2 subawards are allowed
  - Whenever feasible, purchase of services/consulting agreements are strongly preferred over subawards
- Include costs for
  - PI travel and accommodation to the annual 2.5-day IMPACT Collaboratory Business Meeting and Scientific Conference in Bethesda in both years
  - Publication to support dissemination of project results
- Do **not include oversight** costs related to sIRB. However, research related costs, such as certified translations of consent or other materials should be budgeted.
- Key Personnel – Team must include a **biostatistician**

Budget Considerations ~ continued

- Consider whether to include support for health system personnel (local champion, informaticists) or other infrastructure elements
  - Think carefully about which costs should be supported by the research funds and those that would ordinarily be borne by health care system as part of clinical care
  - Ultimately the intervention should be sustainable without research funding
  - Examples of relevant personnel might include informaticists, clinical investigators, staff with expertise in administrative aspects of clinical trials oversight

sIRB Oversight for Demonstration Projects

- Advarra, Inc. is designated as the single Institutional Review Board (sIRB) of record for all Demonstration Projects
- Applicants invited for full proposals must submit a letter of acknowledgment from their institution's IRB or Human Research Protection Program official stating that, if funded, the institution will cede IRB oversight to Advarra

Scientific Review

Appendix 2

Criteria detailed in Appendix 2 of RFA

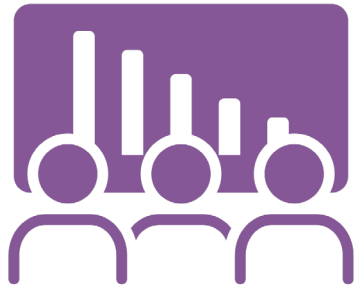
Reviewed by interdisciplinary reviewers, includes statistical review

- Follow NIH COI rules for reviewers

Elements considered in review process:

- Alignment with the Demonstration Projects Grants Program
- Significance
- Investigative team and environment
- Preliminary data
- Approach
  - Overall Design
  - Participants
  - Intervention structure, content, and implementation strategy
  - Clinical Outcomes
- Future Directions
- Human Subjects

Community Partner Review



Partners will consider the following:

- Importance and relevance of intervention
- Does proposal address a weakness or need that is experienced in health care systems?
- Does this study fill an important gap in dementia care and/or make a difference in the real-world for PLWD, care partners, and health care systems?

General Requirements for Funded Applications

- Usual NIH Regulatory & Reporting Requirements
- sIRB, Data & Safety Monitoring, and Data Management & Sharing Policies
- ClinicalTrials.gov & NIA Clinical Research Operations Management System (CROMS)
- Financial Conflict of Interest Assurance/Training
- Adhere to IRB-approved protocol
- Monthly Meetings with Advisor from Research Grants Core
- Engage in IMPACT's Scientific Community
- Publication Policy and Sponsorship Acknowledgement
- Invoicing Guidelines and Budget Reports
- Annual Progress Report and Final Report

NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Questions?

Please raise your hand or put your question in the chat box.

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

FAQs on impactcollaboratory.org