NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE



Request For Applications – 2026
Overview of Pilot Grants Program



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



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

Penn | Palliative & Advanced Illness Research (PAIR) Center

Indiana University

Regenstrief Institute

Objectives

- Introduce IMPACT
- Learn about the Pilot Grant RFA
  - Determine if the grant mechanism fits your research
  - Scientific rationale and components
  - Administrative components
  - Application and review processes
- Questions

IMPACT Mission

NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

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



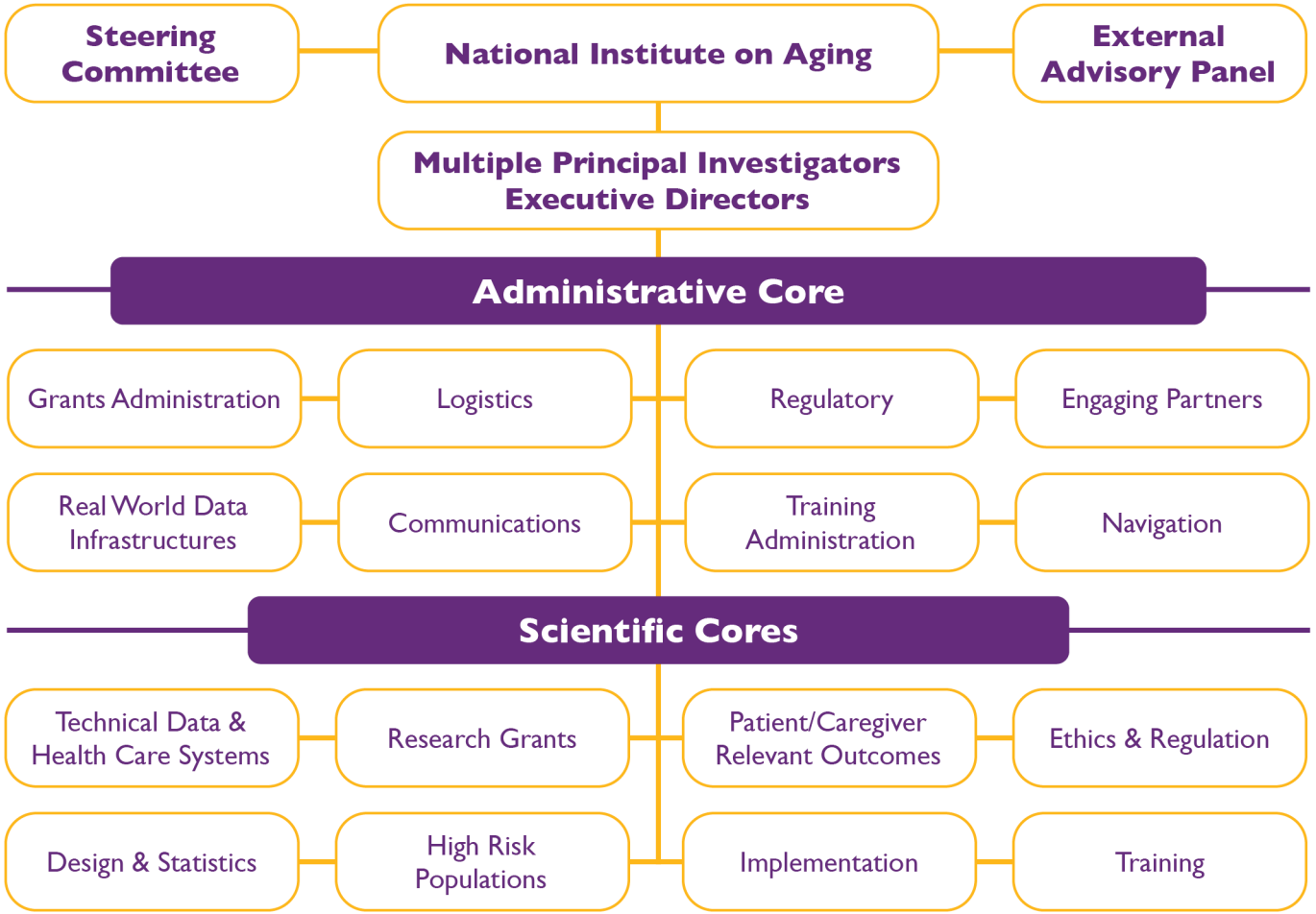
Ab Brody, PhD, RN, FAAN
Principal Investigator
Assistant Dean for Transformational Excellence in Aging
Mathy Mezey Professor of Geriatric Nursing
Professor of Nursing and Medicine
NYU Rory Meyers College of Nursing
Founder, Aliviado Health

Marcus Institute for Aging Research
Hebrew SeniorLife
HARVARD MEDICAL SCHOOL AFFILIATE

NYU RORY MEYERS COLLEGE OF NURSING

BROWN School of Public Health

Governance Structure



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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
Wake Forest School of Medicine



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



Quincy 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
Professor, Indiana University Department of Medicine,
Indiana University Center for Aging Research,
Regenstrief Institute



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



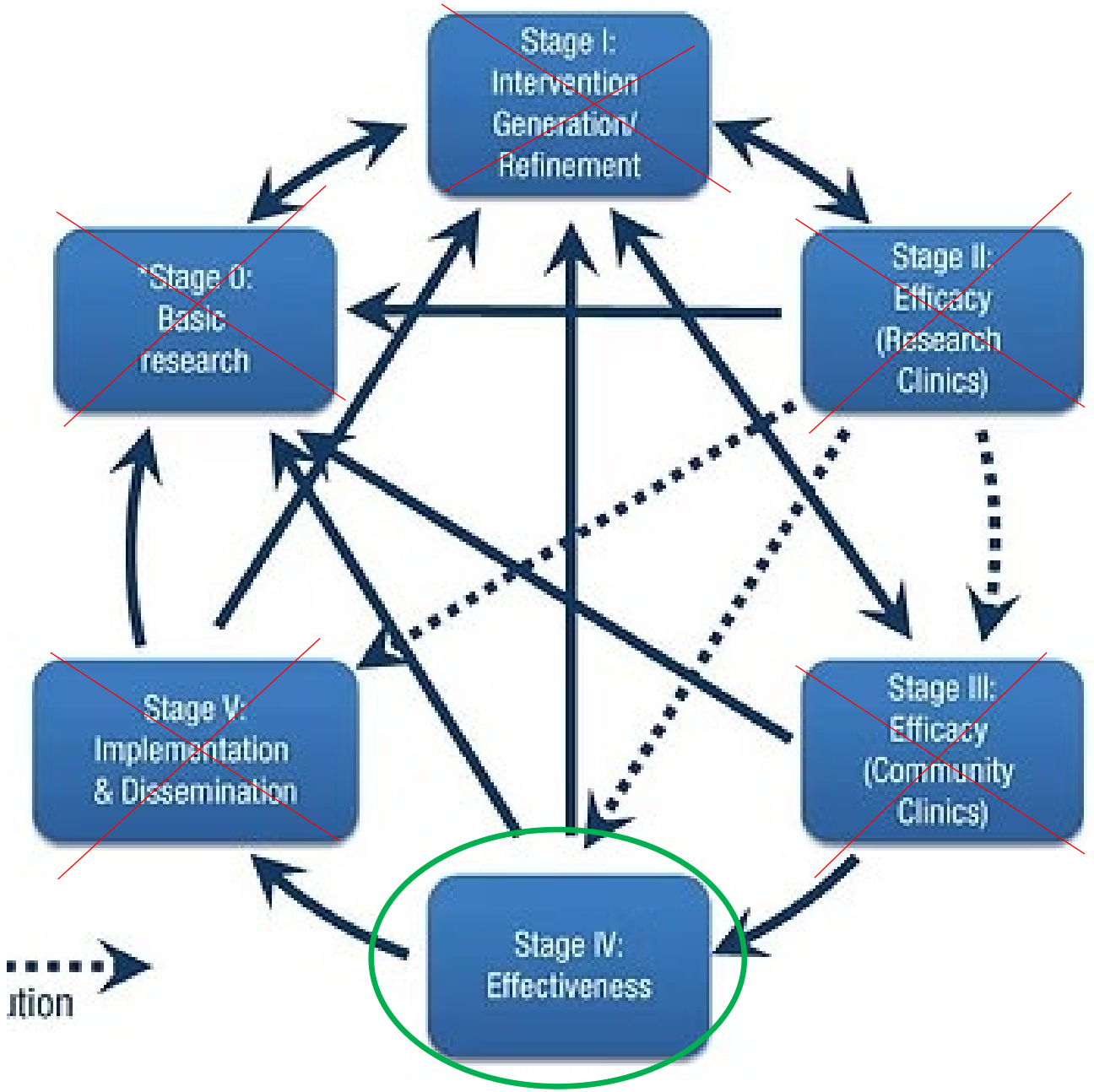
Sarah Berry, MD, MPH
Senior Scientist
Associate Professor of Medicine, Harvard Medical School and Beth Israel Deaconess Medical Center
Chief, Division of Gerontology, Beth Israel Deaconess Medical Center

<u>High Risk Populations Core Representative</u>

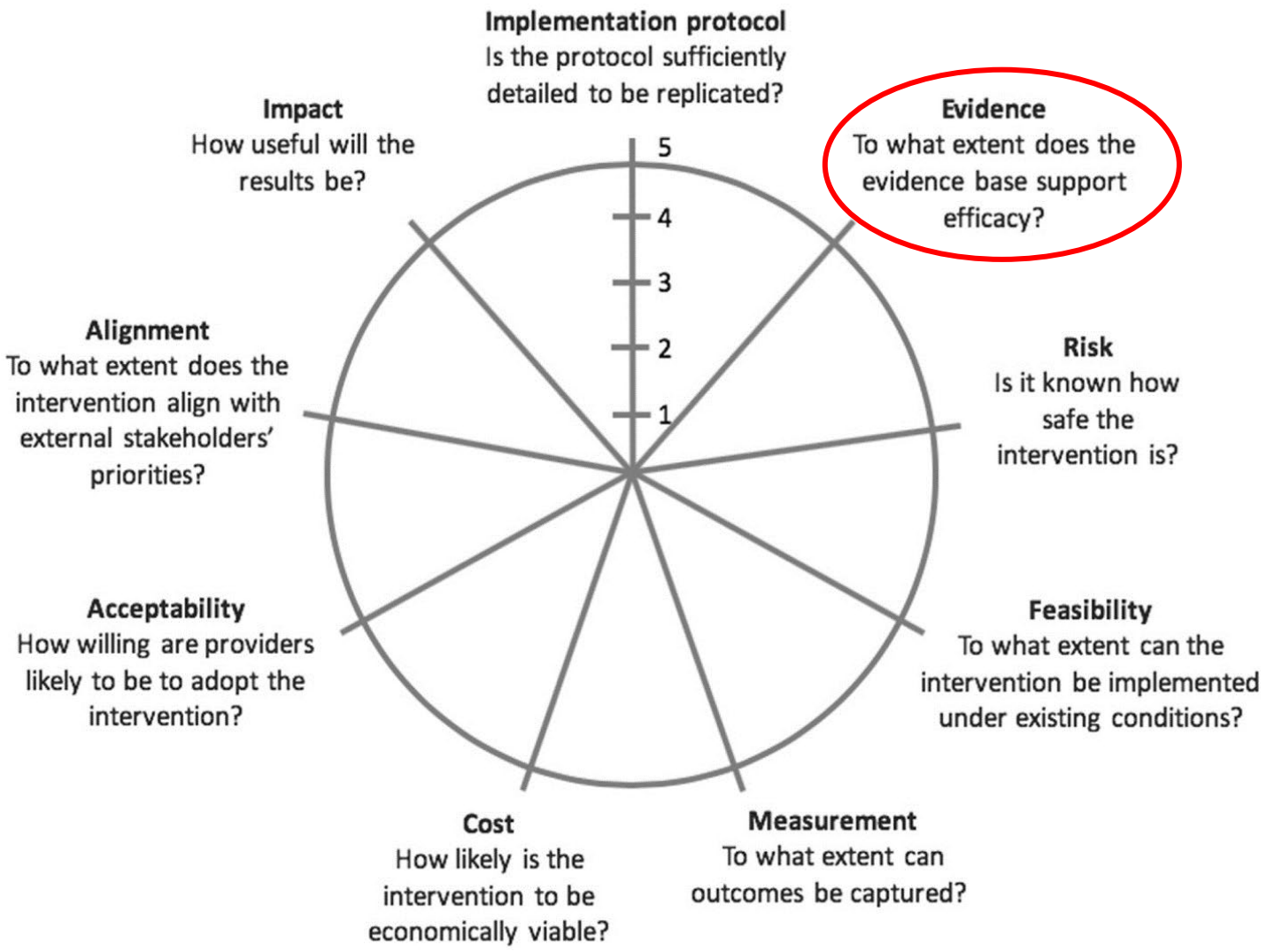


Fayron Epps, PhD, RN, FGSA, FAAN
Professor
Karen and Ron Herman Endowed Chair in Caregiver Research
The University of Texas Health Science Center at San Antonio

NIH Stage Model for Behavioral Interventions



Is the intervention ready for an ePCT?

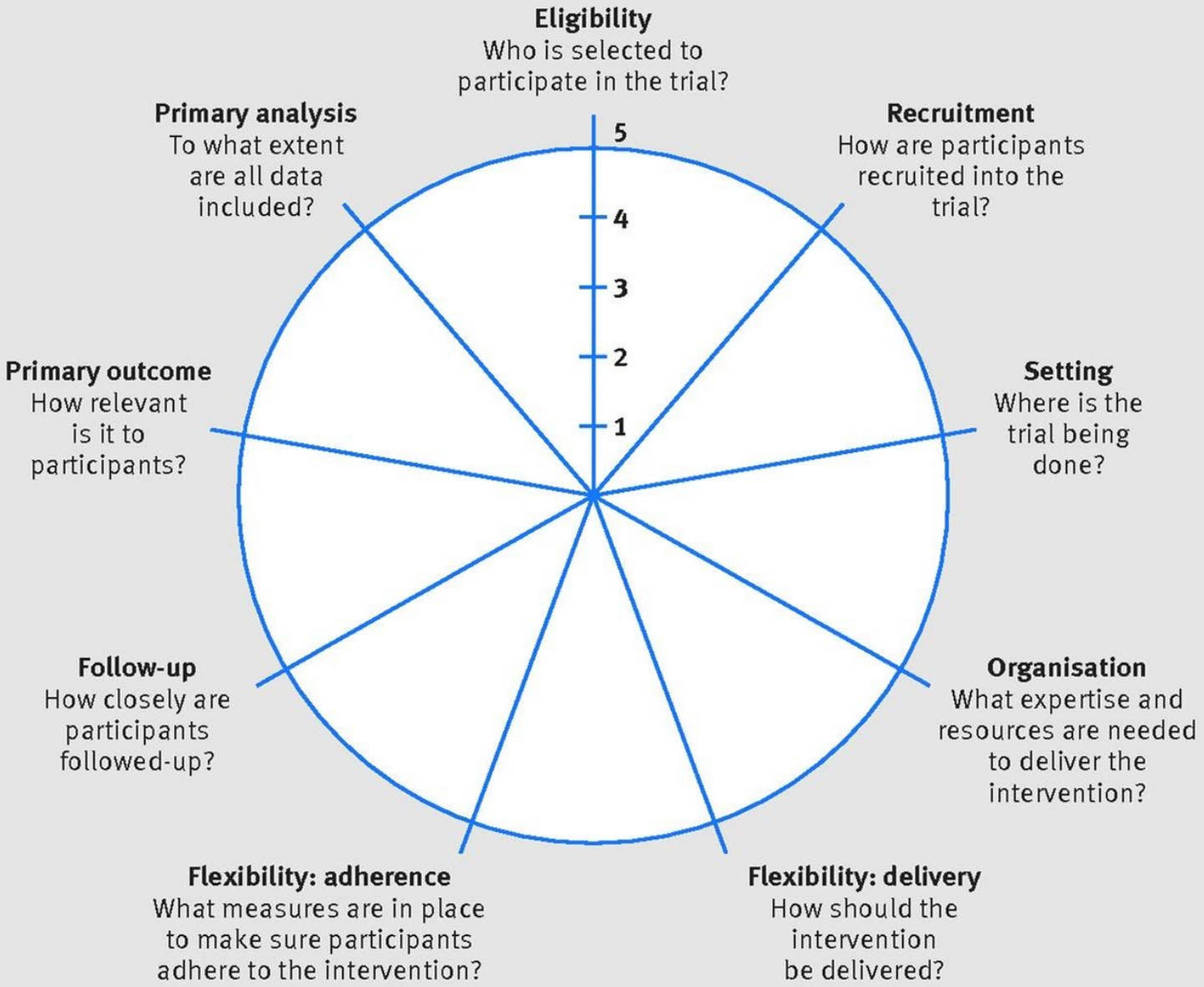


- Readiness Assessment for Pragmatic Trials (RAPT Model)
- Consider all domains
- Reasonable **evidence-base** demonstrating intervention's **efficacy** from prior RTCs (Stage II/III).
    - *Level of evidence of efficacy is less stringent for simple or "nudge" (versus complex) interventions.*

What is an ePCT?

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

PRagmatic Explanatory Continuum Indicator Summary 2 (PRECIS-2)



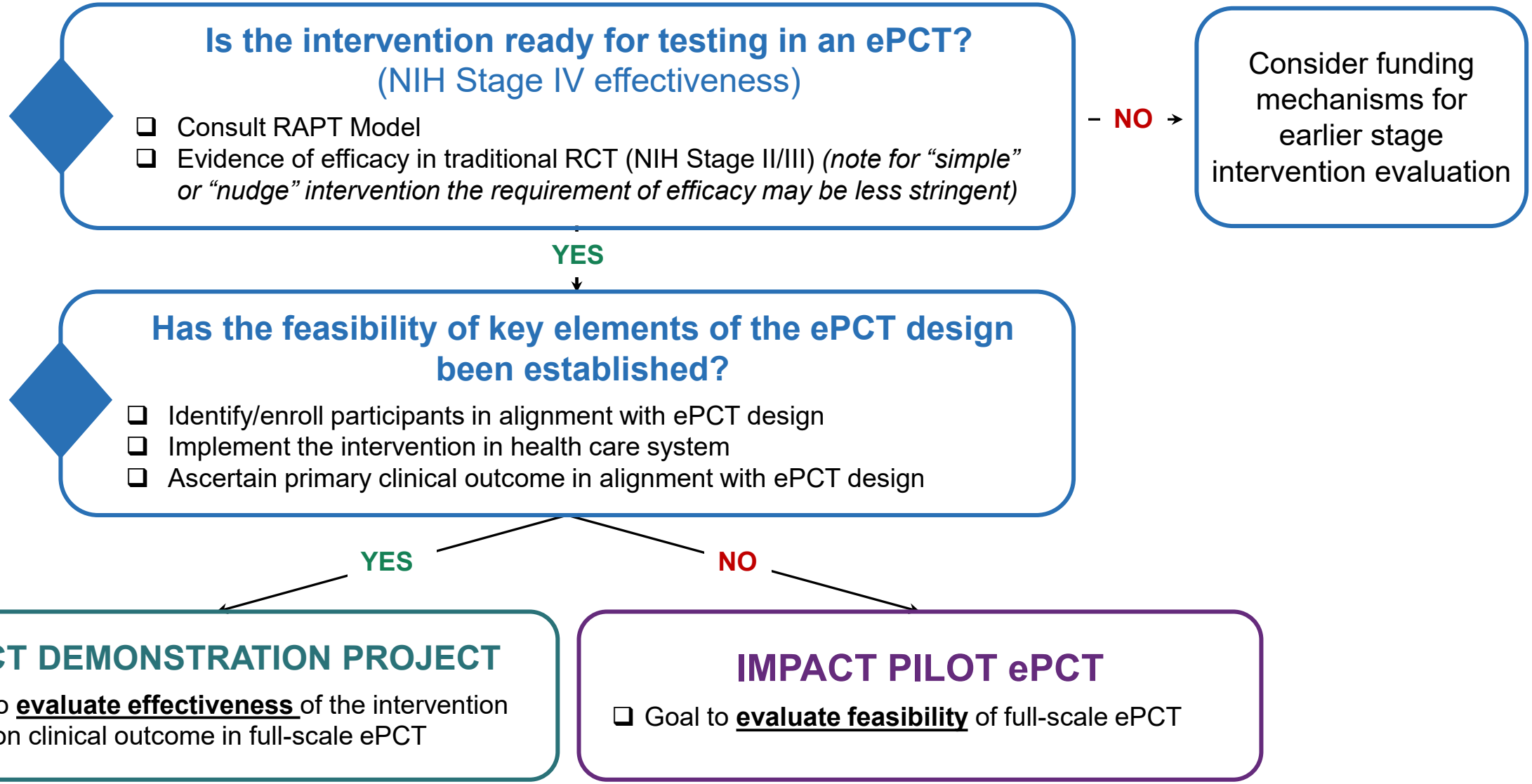
Pilot Grants Program

- Goal: Demonstrate **feasibility** and **inform** the design of a full-scale ePCT (Stage IV effectiveness) evaluating a non-pharmacological intervention for PLWD and/or their care partners embedded in a health care system. Focus on feasibility of three key design elements in alignment with an ePCT design:

  - ❑ Identify and enroll participants
  - ❑ Implement the intervention
  - ❑ Collect primary (and secondary) clinical outcomes

- Goal is NOT to demonstrate effectiveness of intervention on a clinical outcome
- Earlier stage (i.e., efficacy) will not be accepted.

Which IMPACT Research Grant do I Apply for?



Pilot Grant Program: Scientific Components

- Broad Design Considerations
- *Suggested* Specific Aims Organization
- Sample Size Estimates

Highly simplified example of pilot ePCT

- Assess feasibility of full-scale ePCT evaluating effectiveness of MEDLESS intervention
  - ➢ *Clinical pharmacist in a health care system reviews participants' EHRs, including out-patient medications, then sends their primary care physicians (PCPs) deprescribing considerations*

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Design Considerations: ≥2 Arms & Randomization

- Include at least **two trial arms**
  - Intervention arm
  - Comparator arm – Justify choice and its relevance to routine practice
    - *e.g., routine care, enhanced routine care, other appropriate comparison condition*
- Randomization is required
  - Level of randomization (e.g., individual, cluster)
  - Randomization scheme (e.g., parallel, stepped wedge, crossover, etc.)
  - Approach to balancing key characteristics between arms (e.g., stratified, matched, constrained)

Design Considerations: Setting

- **Must have two or more HCS or sites** that care for PLWD
  - e.g., hospitals, nursing homes, clinics, adult day centers, community-based organizations
- Should be same or similar to future ePCT
- Must address HCS priority for caring for PLWD
- Health care system must support pilot ePCT
  - Buy-in, data Infrastructure, integration of intervention into clinical care
- Engage key persons/groups in pilot ePCT design & conduct
- Helpful if you have established collaboration
- IMPACT may be able to help match with health care system



Example: Featuring Design Considerations

- Two-armed parallel cluster design with primary care practice as cluster intervention and control (e.g., routine care) groups
- Work with a known HCS with 50 primary care practices
- Randomize 4 practices: 2 to MEDLESS and 2 to routine care
- Practices must have > 1000 patient panel with 40% > 65 years
- Allows assessment of:
  - Randomization scheme
  - Identify/enroll participants & collect outcomes in control/comparator arm(s)

Specific Aims: "*Suggested*" organization

- Organized around evaluating **feasibility of approach to 3 key design elements**
  - AIM 1. Identify and enroll participants
  - AIM 2. Implement the intervention
  - AIM 3. Collect primary (and secondary) clinical outcomes
- Set feasibility endpoints for each design element
- Hypotheses focused on achieving feasibility endpoint progression thresholds
- Consider traffic light approach to set progression thresholds**



RED = NOT feasible

AMBER = Maybe feasible with adjustments

GREEN = Feasible

**Lewis M, et al. Pilot Feasibility Stud. 2021 Feb 3;7(1):40. doi: 10.1186/s40814-021-00770-x.

Aim 1: Identify and enroll participants

- ***Assess feasibility of participant identification/enrollment strategy***
- Typically involves real-world data with **minimal to no** active screening/recruitment by research personnel
- **Identical methods** must be used for intervention and comparator arms
- Defines the cohort “denominator” for the primary outcome analysis in a full-scale ePCT
- Consider the need a waiver or alteration of informed consent
- Specify quantitative key **feasibility endpoints** and **thresholds** indicating success of identification/enrollment strategy
- Include plan for monitoring accuracy and success of strategy towards target goals

Example Aim 1:

Identify & enroll participants

Aim 1. To assess the feasibility of identifying eligible participants in the primary care practices using the EHR.

Eligibility criteria: ≥ 65y, diagnosis of dementia, ≥ 8 daily medications at baseline

Feasibility endpoint: % of all patients in the practices who meet eligibility criteria

Hypothesis: ≥ 25% of patients will be eligible

- Progression thresholds

  ≤ 15% not feasible RED

  15%–25% adjustments needed AMBER

  ≥ 25% feasible GREEN



Aim 2: Intervention Implementation

- ***Assess the feasibility of the intervention implementation strategy***
- Typically implemented in course of routine care (e.g., by providers) with **minimal to no** involvement by research personnel
- Plan to **evaluate** implementation strategy using established framework (e.g., RE-AIM, CFIR, PRISM)
- Specify quantitative key **feasibility endpoints** and **thresholds** indicating success
- May include qualitative methods (e.g., participant interviews)
- Document intervention adaptions using a framework (e.g., FRAME)

Example Aim 2:

Intervention Implementation

Aim 2. To assess the feasibility of implementing MEDLESS using RE-AIM framework, quantitative endpoints and qualitative semi-structured exit interviews with pharmacists.

Feasibility endpoint: % enrolled patients for whom pharmacist sends deprescribing recommendations to primary care physician.

Hypothesis: Recommendation will be sent for > 75% of enrolled patients

- Progression thresholds

  < 50% not feasible RED

  51%-74% adjustments needed AMBER

  > 75% feasible GREEN



Aim 3: Primary and Secondary Clinical Outcomes

- ***Assess feasibility of collecting clinical outcomes to evaluate intervention's effectiveness in full-scale ePCT***
- Clinical outcomes for ePCTs should be:
  - Relevant to PLWD, care partners, providers and decision-making
  - Captured with **minimal** additional follow up, resources, or impact on routine care
- Identify a **single** primary clinical outcome *i.e., used to estimate sample size in full-scale ePCT*
- Specify secondary clinical outcomes (e.g., 1-3)
- **Identical methods** must be used to ascertain the clinical outcomes in all trial arms
- Specify quantitative key **feasibility endpoints** and **thresholds** indicating success
- Consider the need for a waiver or alteration of informed consent

Example Aim 3:

Outcome Ascertainment

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Aim 3. To assess the feasibility of ascertaining clinical outcomes to evaluate the effectiveness of MEDLESS from the EHR. Primary outcome is % eligible patients ≥ 2 baseline medications discontinued at 6 months. Secondary outcomes are…

Feasibility endpoint: % enrolled patients for whom primary outcome is ascertained.

Hypothesis: 1^0 outcome will be ascertained in 90% of enrolled patients

- Progression thresholds:

  ≤ 75% not feasible RED

  76%-89% adjustments needed AMBER

  ≥ 90% feasible GREEN



Sample Size Estimates

- Calculated to ensure a high degree of **confidence** that thresholds for key **feasibility endpoints** are met in a full-scale ePCT
- NOT calculated to demonstrate effect of intervention or estimate effect size
- Calculate using **progression thresholds** for 1-3 key endpoints*
- Larger sample allows **greater precision** around estimates of thresholds for progression
- Preliminary sample size calculations for full-scale ePCT useful in pilot phase
- Consider approaches that account for cluster design when appropriate

*Lewis M, et al. Pilot Feasibility Stud. 2021 Feb 3;7(1):40. doi: 10.1186/s40814-021-00770-x.

Example: Sample Size Estimates

Feasibility endpoint: % of all patients in the practices meeting eligibility criteria.

Hypothesis: ≥ 25% of patients will be eligible.

- Progression thresholds: ≤ 15% not feasible, RED ; 15%-25% AMBER; 25% feasible, GREEN
- Powered to reject null hypothesis that true eligibility rate is < 15% (RED)
- Assume 5% alpha and 90% power
- **Need 140 patients in both arms**

- Can achieve with only 2 practices, but will enroll 4 for greater precision
- Doesn't account for clustering or consider multiple endpoints

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**Lewis M, et al. Pilot Feasibility Stud. 2021 Feb 3;7(1):40. doi: 10.1186/s40814-021-00770-x.*

Key Dates

June 2, 2026	***RFA Release Date***
June 8, 2026	*Letter of Intent Application – Opens*
June 11, 2026 @ 2:00pm ET	*Informational webinar*
July 23, 2026 @ 11:59pm ET	*Letters of Intent Due Date – Required*
August 2026	*Letters of Intent – Notification*
November 19, 2026 @ 11:59pm ET	*Full Proposal Application Due Date – By Invitation Only*
February 15, 2027	*Earliest Start and Budget Date*

Applicant Eligibility

- **Must be citizens or permanent residents of the United States**
- **Faculty or research scientist at an eligible institution or otherwise, eligible to serve as Principal Investigator**
- **No research may be conducted outside of the United States**

Application Process

Competitive two-step application process:

STEP 1: Letter of Intent – *due **Thursday, July 23, 2026** at 11:59pm ET*

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

- One Principal Investigator allowed
- One LOI 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)

1. Pilot ePCT Description* (2 pages):
   - Rationale
   - Design overview (intervention, comparator, randomization)
   - Specific aims
   - Setting(s) (types, names of HCS or sites)
   - Participants (eligibility criteria, identification and enrollment strategy)
   - Intervention structure and content
   - Intervention implementation strategy
   - Clinical outcome definitions and collection strategy

Review based on:

✓ Responsiveness to RFA and IMPACT Collaboratory mission

✓ Scientific impact and potential for full-scale ePCT

✓ Feasible within grant period

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**Required template linked in RFA and located on https://impactcollaboratory.org/research-grants-overview/pilot-grants-program/pilot-required-materials-and-resources/*

Step 1: Letter of Intent ~ continued

2. Attestation in UFunds that PI has:
   - Read the *RAPT Model paper**
   - Read the *PRECIS-2 Framework paper**
3. NIH Biosketch for PI
4. Bibliography and References Cited (≤1-page; not included in 2-page limit)



**Resources for #2 linked in RFA and located on https://impactcollaboratory.org/research-grants-overview/pilot-grants-program/pilot-required-materials-and-resources/*

LOI to Full Proposal Stage

LOI applicants invited to submit a full proposal will:



Be granted access to the application in UFunds

Meet **twice** with an IMPACT Consultation Team to align and strengthen proposal



- **Meeting 1:** Structured feedback and facilitated discussion around design elements for Pilot ePCT to shape Specific Aims
- **Meeting 2:** Feedback and refinement of Specific Aims

Pilot ePCT Consultation Process



Targeted one-on-one consultation w/ experts from Cores as needed

Step 2: Full Proposal (by invitation only)

Due: Thursday, **November 19, 2026**, at 11:59PM ET

Submitted online through Brown University's UFunds system: https://ufunds.brown.edu

Applicants will receive an application guide with required components of the grant.

Full Proposal Requirements

1. General Audience Summary (max 500 words)
2. Specific Aims (1 page)
3. **Research Plan - 6 pages**, with IMPACT-specific instructions
4. Bibliography and References Cited
5. PHS Human Subjects and Clinical Trial Information Form*
6. Clinical Trial Milestone Plan*
7. Data Management and Sharing Plan*
8. Acknowledgment Letter from IRB/HRPP Official*



*Form/template will be provided

Research Plan - detailed in RFA Appendix 2

- Background/Significance
- Preliminary Studies (if applicable)
- Research Design and Methods
  - Study population
  - Setting
  - Randomization scheme
  - Intervention structure, implementation protocol and evaluation plan
  - Clearly specify the Comparator arm(s)
  - Data sources, elements, and collection protocol
  - Analytic plan, including sample sizes
- Milestones (specific, measurable for progress review)
- Future Directions and Next Steps (e.g., full scale ePCT)



Budget Considerations



- 18-month study period, non-renewable
- Up to $300,000 (total direct costs)
  - Indirect costs at your institution's negotiated facilities/administrative rate
  - Do **not** budget oversight costs for Advarra, (IMPACT sIRB) but…
  - Translation costs required by Advarra should be included
  - Include PI's travel and accommodation to annual 2.5-day IMPACT meeting in Bethesda, MD
  - Include publication costs
- Follow NIH rules and regulations regarding allowable costs
- Up to 2 Subawards allowed
  - Whenever appropriate, purchase of services and consulting agreements are encouraged

Scientific Merit Review

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Detailed Criteria in RFA Appendix 3

Elements considered in review process:

1. Alignment with IMPACT Pilot Grants Program
2. Significance
3. Approach: Overall Design
4. Approach: Participants
5. Approach: Intervention Structure and Implementation Strategy and Evaluation Plan
6. Approach: Clinical Outcomes
7. Human Subjects
8. Timeline and Milestones
9. Future Directions



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 people living with dementia, 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

Pilot Grant Awardees



Cycle 1

Brent Forester, MD, MSc
McLean Hospital,
Mass General Brigham

Implementation of the Care Ecosystem training model for individuals with dementia in a high risk, integrated care management program



Cycle 1

Ula Hwang, MD, MPH
Yale School of Medicine

Pathway to Detection & Differentiation of Delirium & Dementia in the Emergency Department



Cycle 2A

Joan Carpenter, PhD, CRNP
University of Maryland
School of Nursing

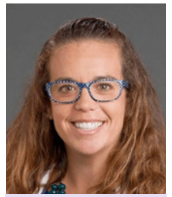
Implementation of a Telehealth Palliative Care Model for Persons with Dementia



Cycle 2A

Richard Fortinsky, PhD
Wake University of Connecticut
Health Center

Pilot Pragmatic Clinical Trial to Embed Tele-Savvy into Health Care Systems



Cycle 2A

Jennifer Gabbard, MD
Wake Forest School of Medicine

Using Telemedicine to Improve Engagement in Advance Care Planning in Patients with Cognitive Impairment / Unrecognized Dementia



Cycle 2A

Ariel Green, MD, MPH, PhD
Johns Hopkins University
School of Medicine

ALIGN: Aligning Medications with What Matters Most



Cycle 2B

Michael Lepore, PhD
University of Maryland
School of Nursing

Cognitive Stimulation Therapy for Mild to Moderate Dementia



Cycle 2B

Medha Munshi, MD
Joslin Diabetes Center,
Harvard Medical School

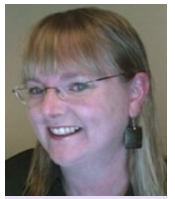
Deprescribing of Diabetes Treatment Regimens in Long Term Care Residents with ADRD



Cycle 2B

Aanand Naik, MD
Baylor College of Medicine

Patient Priorities Care for Hispanics with Dementia (PPC-HD)



Cycle 2B

Annette Totten, PhD
Oregon Health & Science
University

ADVANCE-PC: Testing Critical Components for a Trial of Advance Care Planning in Primary Care for Dementia



Cycle 3A

Elizabeth Ciemins, PhD
AMGA

Implementation of MIND at Home Program in Primary Care for PLWD



Cycle 3A

Leah Hanson, PhD
HealthPartners Institute

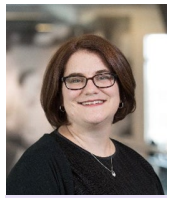
Mindfulness-Based Dementia Care Partner Program to Reduce Depressive Symptoms



Cycle 3A

Magaly Ramirez, PhD, MS
University of Washington

Virtual Training for Latino Caregivers to Manage Symptoms of Dementia



Cycle 3B

Jennifer Carnahan, MD, MPH, MA
Indiana University School of Medicine

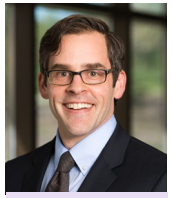
Patient Priorities Care among Persons Living with Mild Cognitive Impairment / Dementia



Cycle 3B

Helen Kales, MD
University of California, Davis

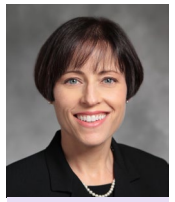
Reducing Inappropriate Medication use for Behavioral and Psychological Symptom of Dementia and Improving Health Outcomes in PLWD



Cycle 3B

Donovan Maust, MD, MS
University of Michigan

A Patient-Facing Tool to Reduce Opioid, Psychotropic Polypharmacy in PLWD



Cycle 3B

Elizabeth Phelan, MD, MS
University of Washington

Deprescribing to Reduce Injurious Falls among Older Adults with Dementia (STOP-FALLS-D)



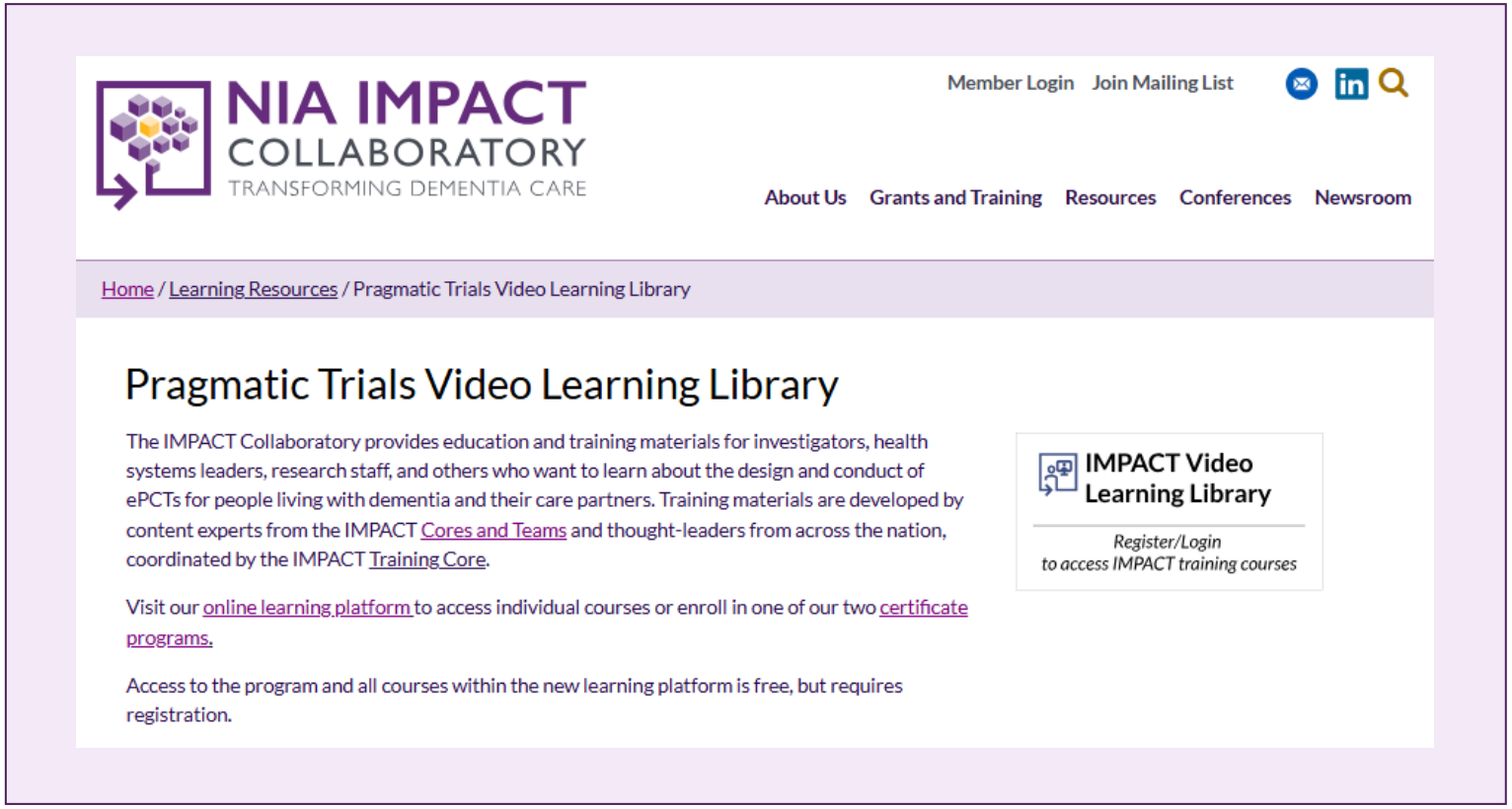
Cycle 4A

Katherine Abbott, PhD, MGS
Miami University
Scripps Gerontology Center

Testing Feasibility of the Individualized Positive Psychological Intervention

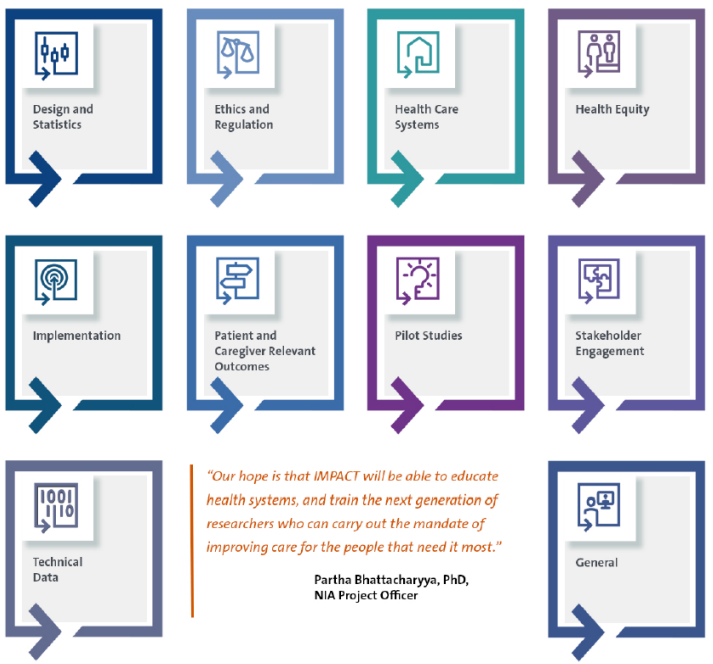
IMPACT Online Training

- Free online ePCT Training Resources
- 2 Certificate programs
- Topic-specific content





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For answers to Frequently Asked Questions, visit our website:

https://impactcollaboratory.org/research-grants-overview/pilot-grants-program/pilot-grant-faq/

Contact Us:
IMPACTcollaboratory@hsl.harvard.edu

Is it permissible to use primary data collection to ascertain clinical outcomes?

- Using methods that align with a pragmatic trial design are encouraged, which includes selecting outcomes that are relevant to PLWD, their care partners and/or their healthcare providers and that can be ascertained with as little interruption as possible to routine care and minimal follow up.
- Generally, this implies using minimal to no involvement of research personnel. However, in ePCTs for which the optimal outcomes to demonstrate intervention effectiveness are not attainable from existing data sources, primary data collection will be allowable. Issues relating to the need for informed consent should be considered.