National Institute on Aging

NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Request for Applications

IMPACT Funding Opportunity Number: RFA-IMPACT-19-P01

Pilot Grants

Pilot pragmatic clinical trials for people living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their caregivers

KEY DATES:

Request for Applications Released	September 10, 2019
***Letters of Intent Due** – Required*	Rolling through October 11, 2019 @5pm ET
Letters of Intent – Notification	October 18, 2019 @5pm ET
***Full Proposals Due** – By invitation only*	December 6, 2019 @ 5pm EST
Scientific Merit Review	December 2019
Notification of Awards	January 2020
***sIRB & DSMP and Charter Submissions Due** – Required for awarded pilot studies*	January 2020
Earliest Project Start Date	March 2020
Award Cycle	March 2020 – February 2021

2019

Program Overview

The National Institute on Aging (NIA) Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory (U54AG063546) was established in 2019 to build the nation's capacity to conduct embedded pragmatic clinical trials (ePCTs) of non-pharmacologic interventions within health care systems to improve the care of people living with AD/ADRD and their caregivers. The NIA IMPACT Collaboratory provides guidance for investigators in the design, conduct, and dissemination of ePCTs through its **Core Groups and Teams**:

- Administration Core
- Pilot Studies Core
- Regulations & Ethics Core
- Technical & Data Core
- Design & Statistics Core
- Health Care Systems Core
- Patient & Caregiver Reported Outcomes Core
- Dissemination & Implementation Core
- Training Core
- Diversity & Inclusion Team
- Stakeholder Engagement Team

The IMPACT Collaboratory funds several one-year pilot studies annually. Pilot studies are meant to generate the preliminary data necessary to design and conduct a future full-scale ePCT for which funding would be sought from the National Institutes of Health (R01 or equivalent) or other sources. The IMPACT Collaboratory prioritizes applications that address dementia care for people of all backgrounds.

Learn more about the support provided by the Cores and Teams at http://www.impactcollaboratory.org.

Funding Opportunity Description

IMPACT Collaboratory will fund 3-4 one-year, non-renewable pilot studies.

Pilot studies must:

- Pilot test a non-pharmacological intervention targeting people living with AD/ADRD and/or their caregivers using a pragmatic trial design.
- Implement the intervention in two or more health care systems or sites within health care systems (e.g., ≥ 2 nursing homes, hospitals, healthcare provider practices).
- Be feasible within the one-year time frame.

Informational Webinars

Two optional informational webinars will be hosted to provide investigators with an overview of application details and support that the IMPACT Collaboratory can provide in assistance with proposal development (e.g., trial design, linkage to health care systems). Investigators will have the opportunity to ask questions. Pre-registration is required using the link listed below.

Thursday, September 26, 2019 at 1:00 PM ET

- https://hebrewseniorlife.zoom.us/meeting/register/6b9468a5e98bef768c34be5db4a05ad8

Wednesday, October 2, 2019 at 4:00 PM ET

- https://hebrewseniorlife.zoom.us/meeting/register/d62d9fabe3c17cf04ac87b605f06faf5

Informational webinars will be recorded and posted online at http://www.impactcollaboratory.org.

Frequently Asked Questions

A set of frequently asked questions (FAQ) regarding this award is available online at http://www.impactcollaboratory.org.

Award Information

Awards are for one year, up to $150,000 (total costs) and are non-renewable. No-cost extensions will be permitted with strong rationale. Only a single Principal Investigator (PI) is allowed, and only one application per individual PI is permitted per funding cycle.

Eligibility

Institution

- Eligible institutions include colleges, universities, medical or nursing schools, or other fiscally responsible organizations within the United States. No research may be performed outside of the United States.

Principal Investigator

- Applicants must hold a doctorate degree (MD, PhD, or equivalent)
- Applicants must hold a full-time faculty or research scientist position at an eligible institution by the start date of the award.
- Applicants must be citizens or permanent residents of the United States.
- Applicants from under-represented racial and ethnic groups as well as individuals with disabilities are strongly encouraged to apply for funding.

How to Apply

Interested applicants are required to submit a letter of intent through the Brown University UFunds online portal at: https://ufunds.brown.edu/ no later than October 11, 2019 at 5:00 PM ET.

Access to UFunds: Applicants without a Brown University email address must FIRST request access to the UFunds system using a Gmail (Google) account at: https://tinyurl.com/UFundsAccess. You will receive an email at your Gmail address once access to the UFunds system has been granted. *Please note that the registration process can take up to 2 business days, so applicants are strongly encouraged to request access as early as possible.*

There is a competitive two-step application process:

STEP 1: Letter of Intent (LOI)

The LOI application includes the following main elements:

- Pilot study description not exceeding 2-pages (single spaced, 11 Arial font, 0.5” margins) including: Specific Aims specifying primary and secondary outcomes; Background/Rationale; Overview of Research Design (e.g., study population, setting (types and/or names of health care systems)); and Intervention Structure and Implementation Strategy.
- Anticipated total budget (maximum of $150,000 in total costs) and whether any subawards are anticipated. Subawards (cannot exceed 3) are allowed but must be issued by Brown University on behalf of the IMPACT Collaboratory. Whenever feasible, purchase of services and consulting agreements are strongly preferred to subawards.

How to Apply continued

- PI's NIH Biosketch (PDF upload)

LOIs will be accepted and reviewed on a rolling basis until October 11, 2019 at 5:00 PM ET. Applicants are strongly encouraged to submit their LOI early. LOI decisions will be provided on or before October 18, 2019. Possible decisions include: 1) invitation for full proposal for current cycle; 2) invitation for full proposal for a future cycle; and 3) no further consideration.

STEP 2: Full Proposals by Invitation Only

Applications selected for further consideration will be invited to submit a full proposal online that will be due no later than December 6, 2019 at 5:00 PM ET.

Full proposals must be submitted online through Brown University's UFunds system: https://ufunds.brown.edu.

Full Proposal Guidance

LOI applicants who are invited to submit a full proposal will be immediately connected to the IMPACT Collaboratory Investigator Navigation Team who will play an active role in linking applicants to the appropriate Core Groups and Teams for assistance generating a high-quality application.

Full Proposal Requirements

General Considerations:

Applicants are encouraged to consider the following components in their research plan: evidence base for the intervention, risks, feasibility, acceptability to the health care system partners, costs, alignment with external stakeholders' priorities, and impact. Applicants may find the Readiness Assessment for Pragmatic Trials (RAPT) model a useful tool to assess an intervention's readiness for ePCTs. A useful guideline for consideration of key issues pertaining to the evaluation of complex interventions in ePCTs can be found at https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Complex.

Proposals **are expected** to adhere to NIH policy and guidelines regarding inclusion of women and minorities in the design and conduct of their study as mandated by Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2**.** The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study.

Moreover, a description of how the pilot project considers issues related to diversity and inclusion must be integrated into each section of the Research Plan. Rationale should be provided about how aspects of the design (for example, selection of health care system location, target study population demographics, and/or tailoring of the intervention to different cultures) are and are not relevant to people from diverse backgrounds. While it may not be possible to address all issues within the limited scope of a pilot study, at minimum, a description should be provided about how the pilot project experience will inform the design of future larger ePCT in terms of its relevance to people from diverse backgrounds who are living with dementia and/or their caregivers.

Full Proposal Requirements continued

Proposal Content:

Those invited to apply for full proposals will be sent a detailed Application Guide. Full proposals will include applicable PHS 398 Forms. Full proposals will follow the general format of an NIH R21 with IMPACT Collaboratory-specific additions, including:

- Abstract (max 300 words)
- Specific Aims (1 page)
- Research Plan (6 pages)
  - **Background and Significance**
  - **Preliminary Studies** (if applicable)
  - **Research Design and Methods**: Include the following: 1) Study population, 2) Setting (sites/heath care systems), 3) Randomization scheme and masking when appropriate (not expected for all pilot studies), 4) Intervention structure, implementation protocol, and fidelity/adherence monitoring plan, 5) Data sources, elements, and collection protocol, and 6) Analytic plan.
  - **Milestones**: Specify quarterly milestones with which your progress can be measured.
  - **Future Directions and Next Steps**: Specify how the pilot study will directly inform the development of a full-scale ePCT application to the NIH or other funding sources and the anticipated timeline to apply for such funding.
- Bibliography and References Cited
- NIH Biosketch for PI and each additional Key Personnel (must not exceed 3 additional Key Personnel)
- sIRB Pre-Checklist (entered within online application)
- Letters of Support (required from participating health care systems).
- Appendices are NOT permitted

Budget Considerations:

A budget detailing research-related expenses and salary support is required along with an accompanying budget justification. All NIH rules and regulations regarding budgets for R-series grants will be enforced. The project period is for one year, and the budget may not exceed $150,000 in total costs.

Subawards are allowed (cannot exceed 3) but must be issued by Brown University on behalf of the IMPACT Collaboratory. Each subaward must have a separate budget and budget justification and at least one Key Personnel.

Whenever feasible, purchase of services/consulting agreements are strongly preferred to subawards.

Further Requirements for Proposals Recommended for Funding

Human subjects research cannot commence without approval by the IMPACT Collaboratory's overseeing single Institutional Review Board (sIRB) and Data and Safety Monitoring Board (DSMB). Within 2 weeks of notification of funding recommendation, applicants must submit:

- Human Subjects and Clinical Trial Information (e.g., Forms Version E)
- **sIRB Application**: The IMPACT Collaboratory adheres to the NIH sIRB Policy for Multi-Site Research. Thus, all awarded grants must be approved by the IMPACT Collaboratory's sIRB; PIs do not need to budget funds for the sIRB. The PI's home institution must agree to cede to the IMPACT Collaboratory's sIRB.
- **Data and Safety Monitoring (DSM)**: Pilot Studies will strictly follow NIA DSM policies. The IMPACT Collaboratory DSMB will oversee all pilot studies. A common template for the Data and Safety Monitoring Plan (DSMP) and Charter will be provided. PIs of pilot study awards recommended for funding will be required to submit a full study-specific DSMP and Charter.

The IMPACT Collaboratory Administration Core will assist the PI with the sIRB application and DSM materials.

Review Criteria and Process

Full proposals will be reviewed by three non-conflicted reviewers external to the IMPACT Collaboratory and will be rated based on scientific merit following NIH scoring criteria: Significance, Innovation, Investigators, Approach, and Environment. In addition, reviewers will evaluate the pilot study's fit with the IMPACT Collaboratory's mission and the likelihood that the pilot study will lead to successful future extramural grant funding for a full ePCT. The application's approach to integrating diversity and inclusion into each aspect of the Research Plan will be considered in the review process. Appropriateness of the budget, human subjects protections, and data and resource sharing plans will also be considered.

Pilot Grant Recipient Award Requirements

Award recipients of the IMPACT Collaboratory Pilot Grants Program are expected to adhere to the following requirements:

1. Pilot studies must adhere to sIRB, Data and Safety Monitoring, and Data and Resource Sharing policies.
2. Complete Financial Conflict of Interest assurance and training as detailed under their respective organization's policy.
3. Register with ClinicalTrials.gov in accordance with NIA guidelines. Maintain system record and complete all reporting requirements, including uploading results.
4. The PI will meet with an assigned Pilot Study Core Executive Committee member for one hour every month throughout the lifecycle of the pilot. The assigned Executive Committee member will be available to help strategize and navigate challenges. To help ensure successful progress,

Pilot Grant Recipient Award Requirements

the IMPACT Collaboratory's Investigator Navigation Team will link PIs and their research team members with the IMPACT Collaboratory Cores and Teams, according to their pilot study's needs.

5. Engage in the IMPACT Collaboratory's scientific community, including:
    a. Participating in the academic activities of the Core Groups and Teams (e.g., writing methods articles, developing guidance documents)
    b. Attending and presenting at the first in-person IMPACT Collaboratory Scientific Meeting in Bethesda, MD (travel and accommodations will be supported by the IMPACT Collaboratory; PIs do not need to budget for these funds)
    c. Attending webinar-based IMPACT Collaboratory grand rounds.
6. Submit required reports for study tracking and standardized data elements on a quarterly basis, as well as final report at the end of the pilot study year.
7. Follow IMPACT Collaboratory invoicing guidelines.
8. Provide budget reports upon request and at the end of the pilot study year.
9. Adhere to the IMPACT Collaboratory publication policy and acknowledge sponsorship in all presentations, publications, and subsequent grants stemming from this pilot project. This information is required for reporting to NIA.
10. Respond to IMPACT Collaboratory queries for information after project ends.

Questions?

For eligibility and research-related questions, please contact Ab Brody, PhD, RN, FAAN, Pilot Core Leader at IMPACTcollaboratory@hsl.harvard.edu.

For questions related to access or use of the UFunds system please contact Faye Dvorchak at Faye_Dvorchak@brown.edu.