



# NIA IMPACT

## COLLABORATORY

TRANSFORMING DEMENTIA CARE

### *Request for Applications*

***IMPACT Funding Opportunity Number: RFA-IMPACT-21-CDA-02***

## Career Development Award

#### KEY DATES:

<i>Request for Applications Released</i>	January 7, 2021
<i>Informational Webinars</i>	January 19, 2021 @ 2pm ET February 3, 2021 @ 3pm ET
<i>Application Period Opens</i>	January 18, 2021
<i>Proposals Due</i>	April 2, 2021 @ 5pm ET
<i>Scientific Merit Review</i>	May 2021
<i>Notifications</i>	May 2021
<i>Earliest Project Start Date</i>	June 2021

Career Development Award for scientists pursuing careers in embedded pragmatic clinical trials for people living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their care partners

2021

## Program Overview and Rationale

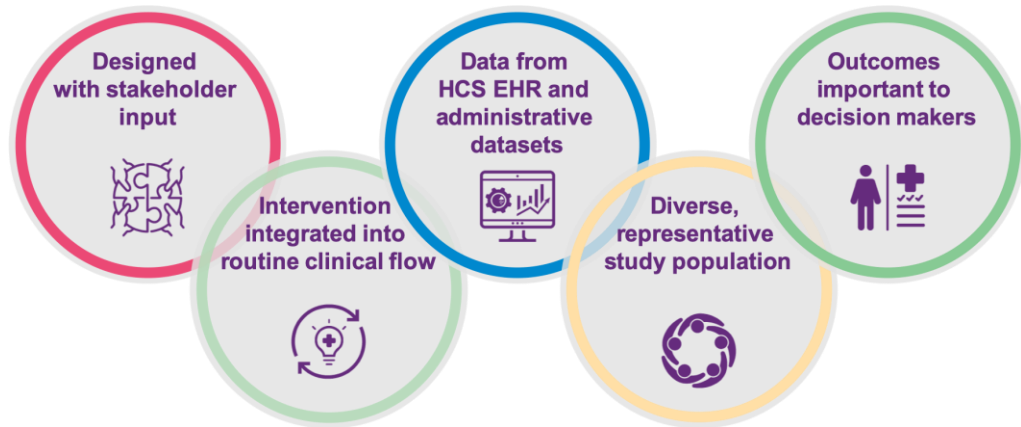
The National Institute on Aging (NIA) Imbedded Pragmatic Alzheimer’s Disease and Alzheimer’s Disease-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (U54AG063546) was established in 2019 to build the nation’s capacity to conduct embedded [pragmatic clinical trials](#) of non-pharmacologic interventions within healthcare systems (HCS) to improve the care of people living with AD/ADRD and their care partners. Learn more about the NIA IMPACT Collaboratory at <http://www.impactcollaboratory.org>.

Close to 6 million Americans have Alzheimer’s disease and AD related dementia. These high-need, high-cost patients are vulnerable to receiving poor quality, uncoordinated care, ultimately leading to adverse health outcomes, poor quality of life, and misuse of resources. Improving the care of people living with dementia (PLWD) and their care partners is an urgent public health challenge that must be informed by high quality evidence. While prior research has elucidated opportunities to improve AD/ADRD care, the adoption of promising interventions has been stymied by the lack of research evaluating their effectiveness when implemented under “real-world” conditions. Pragmatic clinical trials embedded (ePCTs) in healthcare systems have the potential to accelerate the translation of evidence-based interventions into clinical practice.

Conducting ePCTs in AD/ADRD within HCS requires unique research skills, yet the field is relatively nascent. The number of investigators capable of rigorously designing and executing ePCTs in partnership with HCS and other key stakeholders remains limited, and those that have intersecting expertise in AD/ADRD populations are even fewer. Thus, a critical objective of the IMPACT Collaboratory is to build the nation’s capacity to conduct impactful ePCTs in AD/ADRD by training a workforce of investigators prepared to carry on this work well into the future.

In contrast to traditional, highly controlled efficacy trials, ePCTs aim to evaluate the effectiveness of interventions implemented under real world conditions. ePCTs commonly randomize and deliver the intervention at the level of the unit of care (e.g., nursing home, physician practice), rather than at the individual level. In addition, the intervention is implemented by providers during the course of clinical care, rather than by researchers under artificial circumstances. Instead of enrolling highly selective participants, ePCTs minimize restrictive eligibility criteria and attempt to expand recruitment to all individuals receiving care in a particular setting. ePCTs also aim to leverage existing administrative or electronic health records to identify participants and ascertain outcomes, avoiding the need for a special research infrastructure to collect data. Intervention delivery, participant follow-up, and adherence are typically more flexible and closely align with usual care. The [PRECIS-2 framework](#) describes how pragmatic and efficacy trials differ along 9 domains. Key features and design principles of ePCTs are shown in Figure 1.

Figure 1. Design principles of ePCTs among PLWD



The IMPACT Collaboratory is motivated by the recognition that conducting ePCTs among PLWD and their care partners merits special focus. PLWD are served by a variety of unique healthcare systems (HCS) that employ distinct electronic health records (EHRs), registries, and administrative datasets. Novel approaches and standards are needed to identify PLWD and capture relevant outcomes using these data sources. There are also distinct ethical and regulatory considerations for involving vulnerable PLWD in ePCTs and their care partners, an array of particular stakeholders that must be engaged, and the need to address health equity in all aspects of ePCTs conducted.

The IMPACT Collaboratory funds up to four career development awards (CDAs) annually. These CDAs seek to support the development of early-stage MD, PhD, or equivalent researchers who seek careers conducting ePCTs for people living with AD/ABD and their care partners. The IMPACT Collaboratory prioritizes applications that address dementia care for people of all backgrounds and promote health equity.

CDA applicants must:

- Be no more than 7 years out of their post-doctoral training program at the time of application. With prior approval, rare exceptions may be made for investigators more than 7 years from postdoctoral training who are seeking to change their career path to pursue research on ePCTs among PLWD.
- Demonstrate a commitment to pursuing a career in conducting ePCTs for PLWD and their care partners. This is best demonstrated by current or prior training, clinical work, publications, or research projects focused on improving care for PLWD and their care partners.
- Demonstrate basic training (post-graduate) in fundamental clinical research methods and have completed training in the ethical conduct of clinical research.
- Provide evidence of prior research productivity in seeking to improve outcomes of PLWD.

- Identify a mentoring team that includes expertise in: (a) conducting ePCTs for PLWD and their care partners; (b) organizational change within healthcare systems; and (c) professional development of clinical researchers.
- Describe a two-year training plan in collaboration with their mentoring team focused on training in the conduct of ePCTs for PLWD and their care partners.
- Propose a research project focused on: (a) building competency and experience in ePCTs among PLWD; and (b) generating preliminary, publishable data that will build a foundation for ongoing research focusing on ePCTs for PLWD. Projects may employ a variety of research methods, such as primary or secondary data analysis, intervention development, outcome measure development, feasibility of implementation, pilot ePCTs, or qualitative methods.
- Exceptional candidates will also demonstrate access to, and collaboration with, organizational leadership within a targeted HCS. This may be demonstrated by a current or planned relationship with health system leadership at the site where the research will be conducted or other evidence of engagement with health system leadership.
- Attend the annual 2-day IMPACT Collaboratory national Training Workshop and Retreat with your mentor in both years of the CDA, which will be held in scheduled for April 2022. When available, these dates can be found at <https://impactcollaboratory.org/cda/>.
- Participate in quarterly mentoring meetings with one or more representatives from the IMPACT Collaboratory Core Groups and Teams in addition to regular meetings with their local mentor(s).

### Informational Webinars

Two optional informational webinars will be hosted to provide investigators with an overview of application details. Investigators will have the opportunity to ask questions. Pre-registration is required using the links below.

- **Tuesday, January 19, 2021 at 2:00 PM ET: [Register here](#)** for webinar.
- **Wednesday, February 3, 2021 at 3:00 PM ET: [Register here](#)** for webinar.

Informational webinars will be recorded and posted online at <https://impactcollaboratory.org/cda/>.

### Frequently Asked Questions

A set of frequently asked questions (FAQ) regarding this award is available online at <https://impactcollaboratory.org/CDA-grant-faq/>

### Award Information

CDAs are funded for two years. Each award will provide \$100,000 annually in direct costs with an indirect cost rate capped at 8%. Awardees are required to devote a minimum of 75% effort toward the goals of the award.

### Eligible Individuals

Eligible applicants include an MD, PhD, or equivalent researchers who seek careers conducting ePCTs for people living with AD/ABR and their care partners. Applicants must be no more than 7 years out of their post-doctoral training program at the time of application.

With prior approval, rare exceptions may be made investigators with more than 7 years who are seeking to change their career path to pursue research on ePCTs

among PLWD. Such applicants should request prior approval by emailing the rationale for the request to **Christopher Callahan, MD, Training Core Leader**, at [IMPACTcollaboratory@hsl.harvard.edu](mailto:IMPACTcollaboratory@hsl.harvard.edu). The request should be submitted well in advance of the application deadline.

Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply. Multiple PDs/PIs are not allowed for CDAs.

By the time of award, the candidate must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status). Candidates must have or be eligible for faculty appointments at academic institutions at the time of funding. Candidates and their home institutions must also agree to cede IRB oversight for all research funded by the IMPACT Collaboratory's IRB (currently Advarra).

The IMPACT Collaboratory views the CDA as a preparatory award, ultimately leading to a NIH K award, pilot funding, or R-series award. This CDA is focused on early career development. Current and former PDs/PIs on NIH research project (R01), program project (P01), center grants (P50), sub-projects of program project (P01), sub-projects of center grants (P50), other major individual career development awards (e.g., K-series awards), or the equivalent are generally not eligible. Exceptions may be made for later stage investigators seeking to change their career to pursue research on ePCTs among people living with AD/ADRD but require prior approval from **Christopher Callahan, MD, Training Core Leader**. Current and former PDs/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible, as do PD/PIs of Transition Scholar (K38) awards and individuals appointed to institutional K programs (K12, KL2).

To better understand the basic concepts of ePCTs, applicants are required to view and read the following materials prior to preparing an application. Applicants must attest to completing and understanding these materials in their application:

- View the video "[Pragmatic Clinical Trials: How Do I Start?](#)"
- Read the [RAPT Model](#) paper **OR** view the IMPACT Collaboratory Grand Rounds on "[Are you ready for a pragmatic trial? The RAPT Model and implementation considerations](#)"
- Read the [PRECIS-2](#) paper

## Level of Effort

At the time of award, the candidate must have a "full-time" appointment at the academic institution. Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9 person-months) to their program of career development activities during this award.

Candidates may engage in other duties as part of the remaining 25% of their full-time professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program. Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full-time requirement at the applicant institution.

Candidates must also participate in an annual two-day IMPACT Collaboratory Training Workshop and Retreat in both years of the CDA in Bethesda, Maryland.

## Mentor(s)

Before submitting the application, the candidate must identify a primary mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the area of ePCTs for PLWD and their care partners and be committed to the candidate's career development and research. The mentor must document the availability of sufficient research support and facilities for high-quality research and mentoring. Candidates may identify a secondary mentor, if deemed advantageous for providing expert advice in a specific content area. The candidate must work with their mentor(s) in preparing the application. The primary mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage.

The mentor(s) must demonstrate appropriate expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed research. Because this CDA focuses on ePCTs for PLWD and their care partners, mentors should include expertise in leadership, organizational change, conducting research and/or participating in the administration of HCS.

## How to Apply

Applications must be submitted online through the Brown University UFunds system at: <https://ufunds.brown.edu/>. The online grant application will be opened on January 18, 2021 at 9:00 am. Applications may be submitted no later than April 2, 2021 at 5:00 pm ET.

**Access to UFunds:** UFunds can be accessed using a Brown University email address or can be requested using a Gmail address ending in @gmail. The PI may request access, or someone else may request access to submit on behalf of a PI. UFunds is not a multi-user environment. If you received access to UFunds in a previous RFA cycle or have through the Pilot Grant Program, your credentials are still active. New users to UFunds must first request access using a Gmail address here: <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.*

Online application forms and instructions are available on the IMPACT Collaboratory site at: <https://impactcollaboratory.org/cda/>

**Proposal Contents:** Please use Arial 11pt font and one inch margins.

- [NIH Form 1: Face Page](#)
- [NIH Biosketch](#) (include applicant's and mentors' biosketches) (PDF Upload)
- **Project abstract** (300 word limit) (PDF Upload)
- **Specific Aims** (limit to 1 page) (PDF Upload)
- **Candidate Section** (limit to 3 pages) (PDF Upload)
  - Candidate Information and Goals for Career Development, including the candidate's current and prior experience in research related to PLWD or their care partners.
  - Candidate's Background
  - Career Goals and Objectives
  - Candidate's Plan for Career Development / Training Activities During Award Period

- **Research Plan Section** (limit to 6 pages) (PDF Upload)
  - Significance
  - Innovation
  - Preliminary Studies
  - Research Strategy
  - Training in the Responsible Conduct of Research
- **Bibliography and References Cited** (limit to 1 page)
- **Letters of Support** (PDF Upload):
  - Letter of support from mentor (limit to 2 pages)
  - Letter of support from applicant's Departmental leadership attesting to support for 75% protected time for this award and other resources available to the applicant (limit to 1 page)
  - Additional letters of support from Co-Mentor, Collaborators, Contributors and Consultants (limit to one per additional letter and no more than three letters and no more than one page length each for any additional letter)
- **Acknowledgment Letter from IRB/HRPP Official.** Applicants must submit a letter of acknowledgment from their institution's IRB/HRPP official stating that should the study be funded, they agree to cede IRB oversight to an independent IRB chosen by the IMPACT Collaboratory (currently Advarra). An acknowledgment letter is also required from all collaborating institution(s) that will be engaged in human subjects research activities. A template is available upon request.
- **PHS 398 Budget Form 4 and Form 5 with Budget Justification** ([PHS 398 Instructions](#)) (combine Budget Forms and Justification into a single PDF Upload)
  - **Form 4:** Detailed Budget for Initial Budget Period (Direct Costs Only)
  - **Form 5:** Budget for Entire Proposed Project Period (Direct Costs Only)
  - Budget Justification: Use [Continuation Format Page](#)
- **Appendices are NOT permitted**

Human Subjects and Data Safety Plans are NOT required at the time of grant submission. Successful candidates will be required to submit additional materials and receive approval by the IMPACT Collaboratory's overseeing IRB and possibly its Data and Safety Monitoring Board (DSMB) depending on the nature of the research.

A budget detailing research-related expenses and salary support with an accompanying budget justification is required. The project period is for two years, and the annual budget in each year may not exceed \$100,000 in direct costs. Indirect costs are capped at 8% of total direct costs.

Applicants may apply for additional funds, up to \$10,000 per year, to support their research project. Justification for requesting these funds is required as part of the

## Budget Considerations

budget justification. These funds may not be used for tuition or for salary or stipend support for the Candidate, Mentor(s), Consultant(s) or Collaborator(s).

Applicants do not need to include costs for travel and accommodation to the 2-day IMPACT Collaboratory Training Workshop and Retreat in Bethesda, Maryland during Years 1 and 2 of the CDA. These costs will be supported by the IMPACT Collaboratory.

Full proposals will be reviewed by three interdisciplinary, non-conflicted reviewers from the IMPACT Collaboratory using review criteria adapted from the NIA K Award series.

#### Overall Impact

##### Candidate

- Does the candidate have a clear commitment to improving care for PLWD and care partners?
- Does the candidate have the potential to develop as an independent and productive researcher in the field of ePCTs among PLWD?
- Are the candidate's prior training and research experiences appropriate for this award?
- Is the candidate's academic record of high quality?
- Do the letters of reference provide evidence that the candidate has a high potential for becoming an independent investigator in the field of ePCTs among PLWD?

##### Career Development Plan/Career Goals and Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are there adequate plans for monitoring and evaluating the candidate's progress?
- Is there sufficient evidence of commitment to a career in conducting research in ePCTs among PLWD?

##### Research Plan

- Are the proposed research questions, design, and methodology of significant scientific merit?
- Is the research plan feasible within the two-year grant period?
- Is the research plan relevant to the candidate's research career objectives?

##### Research Plan continued

- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills in ePCTs among PLWD?
- Is the research plan likely to move the candidate to a more competitive position for next stage funding (e.g., a K-series award)?
- Is the scope and timeline of the research project appropriate for a two-year CDA?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Does the mentor have qualifications relevant to ePCTs among PLWD?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is there evidence of the primary mentor's and/or mentorship team's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?

Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?

1. Engage in the IMPACT Collaboratory's scientific community, including:
  - a. Participating in the training and academic activities of IMPACT Collaboratory.
  - b. Attending and presenting at the annual 2-day IMPACT Collaboratory Training Workshop and Retreat in Bethesda, Maryland in Bethesda, MD.
  - c. Attending webinar-based IMPACT Collaboratory grand rounds.
2. 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.
3. Adhere to single IRB, Data and Safety Monitoring, and Data and Resource Sharing policies.
4. If appropriate, register with [ClinicalTrials.gov](https://clinicaltrials.gov) in accordance with NIA guidelines. Maintain the protocol registration system (PRS) record and complete all reporting requirements, including uploading results.
5. Submit required annual progress reports and final report at the end of CDA period.
6. Provide budget reports upon request and at the end of the CDA period.
7. Follow IMPACT Collaboratory invoicing guidelines.
8. Respond to IMPACT Collaboratory queries for information after project ends.

For eligibility and research-related questions, please contact:  
Christopher M. Callahan, MD, MACP, Training Core Leader at  
[IMPACTcollaboratory@hsl.harvard.edu](mailto:IMPACTcollaboratory@hsl.harvard.edu)