NIA IMPACT COLLABORATORY
TRANSFORMING DEMENTIA CARE

Full Proposal Application Guide for Pilot Studies

IMPACT Funding Opportunity Number: RFA-IMPACT-21-P03A

Contents

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1. How to Use This Guide

This guide provides detailed instructions, above and beyond what is listed in the RFA, for how to complete components required in your full proposal.

Refer to the original *Request for Applications for the Pilot Grants* (*RFA-IMPACT-21-P03A*) on the IMPACT Collaboratory's website at https://impactcollaboratory.org/pilot-grants-program/ for the:

- Program Overview
- Funding Opportunity Description
- Informational Webinars
- Frequently Asked Questions
- Award Information
- Eligibility
- Full Proposal Requirements
- Scientific Merit Review Criteria
- Stakeholder Review Criteria and Process
- Just-in-Time
- Pilot Grant Recipient Award Requirements

2. Key Dates

Full Proposals Due in UFunds - *Invitation only*	Friday, June 18, 2021 @ 5:00 PM ET
Scientific Merit Review	July 2021
Notifications	Anticipated September 2021
Just-in-Time Materials Due	2 weeks from date requested
Earliest Notification of Award / Project Start Date	October 2021 (IRB approval required)
Award Cycle	October 2021 - September 2022

3. How to Apply – Full Proposals by Invitation Only

You may only submit a full proposal if you were formally invited to do so in your LOI notification letter for the current funding cycle. Only one full proposal may be submitted per invited PI per funding cycle.

Full proposals must be submitted online through Brown University's UFunds system at https://ufunds.brown.edu **no later than** Friday, June 18, 2021 @ 5:00 PM ET.

To access the application, log in to UFunds using the same account that you used to submit your Letter of Intent. UFunds is not a multi-user environment. Multiple users cannot work on the same application.

You will need to enter your IMPACT LOI Project ID (as listed in your notification letter) within the full proposal application.

4. Full Proposal Guidance – IMPACT Consultation Team

Each Principal Investigator will be assigned to meet with an IMPACT Collaboratory Consultation Team for advice on generating a high-quality full proposal that is as pragmatic as possible. The Principal Investigator and the biostatistician collaborator will meet with the assigned Consultation Team shortly after their Letter of Intent is invited for a full proposal. Other members of the investigative team are welcome to attend the consultation meeting, but the PI and biostatistician collaborator must be present. In addition, we will hold an implementation workshop to provide applicants (when needed) with guidance and strategies around potential implementation challenges or concerns.

5. Full Proposal Guidance – Investigator Navigation

The IMPACT Collaboratory Investigator Navigation Team is available (after Team Consults) to help connect applicants to the appropriate Core Groups and Teams for additional guidance when needed. These Cores and Teams are a multidisciplinary group of over 60 investigators that will provide technical support and guidance to investigators during the development phase of the full proposal based on needs identified by the applicant. The Investigator Navigation Team can be reached at IMPACTnavigator@hsl.harvard.edu.

6. Full Proposal Requirements – UFunds Components

All components are required unless stated otherwise and must be uploaded in PDF format.

Unless specified otherwise below, refer to the *PHS 398 Instructions* and *PHS 398 Fillable Forms* on the NIH's website to complete the applicable PHS398 forms: https://grants.nih.gov/grants/funding/phs398/phs398.html.

We provide IMPACT-specific templates for some attachments, noted below in green text.

Free text must be single-spaced using 11-pt Arial font and 0.5" margins.

1. ☐ **PHS 398: Form Page 1: Face Page**

2. ☐ **PHS 398: Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells**

3. ☐ **PHS 398: Project/Performance Site Format Page**
   - REQUIRED only if there are more than two Project/Performance Sites.
   - Definition of Project/Performance Site: https://grants.nih.gov/grants/glossary.htm#ProjectPerformanceSite

4. ☐ **PHS 398: Form Page 4: Detailed Budget for Initial Budget Period**
   - A **separate** form must be uploaded **for each subaward:**
     - One form for the PI (mandatory)
     - If applicable, one form for each subaward (cannot exceed two)
   - The maximum budget (total across all sites) is $175,000 in direct costs. Indirect costs may be budgeted at your institution's negotiated facilities and administrative rate.
   - The cost for the use of Advarra, the independent sIRB, is NOT the responsibility of the individual pilot study and should not be included in the pilot study budget.
   - The budget should include travel for the PI (but not for co-investigators) to attend the in-person 2.5 day Annual Collaboratory meeting in Bethesda, MD.
   - Subawards (cannot exceed two) are allowed, and each subaward must have at least one Key Personnel.
   - **Whenever feasible, purchase of services and consulting agreements are strongly preferred to subawards. Purchase of services and consulting agreements should be listed within the PI's main budget.**

5. ☐ **PHS 398: Form Page 5: Budget for the Entire Proposed Project Period**
   - A **separate** form must be uploaded **for each subaward:**
     - One form for the PI (mandatory)
     - If applicable, one form for each subaward (cannot exceed two)
   - Each element listed on the *Form Page 4: Detailed Budget for Initial Budget Period* must be **clearly justified**.
   - Use *PHS 398 Continuation Format Page* as needed.

6. ☐ **NIH format Biosketches**
   - A **separate** biosketch (maximum 5 pages each) must be uploaded for:
     - The PI (mandatory)
     - The Biostatistician (mandatory)
     - If applicable, the rest of the Key Personnel (combine into a single PDF)
   - Each subaward must have at least one Key Personnel. However, not all Key Personnel must be associated with a subaward.
   - Fillable *Biographical Sketch Format Page*, instructions, and samples: https://grants.nih.gov/grants/forms/biosketch.htm

7. ☐ **PHS 398: Resources Format Page**
   - A **separate** form must be uploaded **for each subaward** and include a description of the resources available at each Project/Performance Site:
     - One form for the PI (mandatory)
     - If applicable, one form for each subaward (cannot exceed two)
   - Definition of Project/Performance Site: https://grants.nih.gov/grants/glossary.htm#ProjectPerformanceSite

8. ☐ **PHS 398: Checklist Form Page**
   - A **separate** form must be completed **for each subaward:**
     - One form for the PI (mandatory)
     - If applicable, one form for each subaward (cannot exceed two)
   - If you have more than one form, upload them as a single PDF.

9. ☐ **General Audience Summary**
   - Max 500 words
   - Provide a consumer-friendly overview of the proposed research for people who are not trained in the sciences.
   - This summary will be reviewed by key stakeholders (people living with dementia, care partners, and health system leaders) and will be considered when selecting applications for funding. The summary should be written in language understandable to the general public.
   - Concisely describe the background, significance, target population, intervention to be studied, information to be obtained, and the potential impact of your proposed pilot study.
   - Use *PHS 398 Continuation Format Page*

10. ☐ **Specific Aims**
   - 1 page
   - Use *PHS 398 Continuation Format Page*

11. ☐ **Research Plan**
   - 6 pages. Appendices are NOT permitted.
   - Refer to *Request for Applications for the Pilot Grants* (RFA-IMPACT-21-P03A) for the Research Plan requirements: https://impactcollaboratory.org/pilot-grants-program
   - Use *PHS 398 Continuation Format Page*

12. ☐ **Bibliography and References Cited**
   - Use *PHS 398 Continuation Format Page*

13. ☐ **Health Equity**
   - 1 page
   - Describe how health equity is addressed in the proposed study and will be considered in the future ePCT. As described in the RFA, rationale should be provided about how aspects of the design address the needs of people from diverse backgrounds. If a project does not meet this expectation, provide a compelling rationale for why the design does not address issues of health equity and how the results of the proposed pilot study might support a subsequent ePCT that does address health equity issues. For example:
     - Selection of health care system(s)
     - Target study population demographics
     - Tailoring of the intervention to different backgrounds, languages, cultures
     - Monitoring differential implementation, adherence, attrition/retention
     - Assessing outcomes
   - While it may not be possible to address all issues within the limited scope of a pilot study, at minimum, the proposal should address how the pilot project experience will inform the design of the future larger, Stage IV effectiveness ePCT in terms of its relevance to people with AD/ADRD from diverse backgrounds and/or their care partners.
   - Use *PHS 398 Continuation Format Page*

14. ☐ **Vertebrate Animals Section**
    - REQUIRED only if live vertebrate animals are involved in the project.
    - Use *PHS 398 Continuation Format Page*

15. ☐ **Consortium/Contractual Arrangements**
    - REQUIRED only if there are subcontracts.
    - Use *PHS 398 Continuation Format Page*

16. ☐ **Pilot Study Pragmatic Design Worksheet**
    - **Use the *Pilot Study Pragmatic Design Worksheet* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/

17. ☐ **Letter of Support from Each Participating Healthcare System / Site**
    - Pilot studies must implement the intervention in two or more healthcare systems or sites (e.g., nursing homes, hospitals, healthcare provider practices).
    - A letter of support is required **from each participating healthcare system/site**. Applicants may have one letter of support or many depending on the nature of their pilot study.
    - Each letter of support must clearly stipulate that:
        - (1) The proposal includes people living with dementia and/or their care partners, and/or the proposal addresses the care of people living with dementia and their care partners in the milieu of COVID-2019 outbreak **AND**
        - (2) There is a strong likelihood that the intervention can be feasibly integrated and adopted into the clinical flow by frontline providers.
    - Space is allotted in UFunds to provide contact details for up to two letters of support. If a letter of support is signed by more than one person, please provide contact details for only one of the signatories.
    - If you have more than two letters of support, upload the additional letters as a single PDF.

18. ☐ **Acknowledgment Letters from IRB/HRPP Officials**
    - **A letter of IRB acknowledgment is required from each Project/Performance Site including the PI's institution and all collaborating institutions conducting human subjects research.**
    - **Use the *Acknowledgment Letter from IRB/HRPP Official* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/
    - Definition of Project/Performance Site: https://grants.nih.gov/grants/glossary.htm#ProjectPerformanceSite
    - Each letter must include an acknowledgement of support **from the IRB office** of the participating site, indicating their agreement to rely upon the IMPACT Collaboratory's chosen IRB, currently Advarra, for all relevant human subjects oversight should the study be selected for funding.
    - **For a site that does not have its own IRB**, the letter should be signed by a compliance officer or other person with authority to act on behalf of the site.
    - Advarra is an independent IRB and research quality and compliance consulting service that is fully accredited by AAHRPP (https://www.advarra.com/).
    - Upload the letters from collaborating institutions as a single PDF.

19. ☐ **Clinical Trial Milestone Plan**
    - **Use the *Clinical Trial Milestone Plan* form:** https://impactcollaboratory.org/pilot-required-materials-and-resources/
    - Since your pilot has not yet started, mark all dates as Anticipated (not Actual).

20. ☐ **Study Record: PHS Human Subjects and Clinical Trials Information Form**
    - **Use the *Study Record: PHS Human Subjects and Clinical Trials Information Form* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/
    - Carefully follow the accompanying NIH instructions at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/research-forms-f.pdf for all items in the form **unless IMPACT-specific guidance is listed below**.
    - Within the form, there are "Add Attachment" buttons for uploading documents.

    IMPACT-specific guidance:

    ☐ **Section 1 – Basic Information**
    - All studies must meet the NIH Definition of a Clinical Trial. NIH's definition can be found here: https://grants.nih.gov/policy/clinical-trials/definition.htm
    - Your study is not expected to fall under an Exempt category.

    ☐ **Section 2 - Study Population Characteristics**
    - 2.9 – Inclusion Enrollment Reports
        - All studies should include at least one inclusion/enrollment report and table. If you are using an existing dataset, you should fill out the "Cumulative/Actual" table. If you have more than one study cohort (e.g., both caregivers and persons living with dementia are each considered study subjects in your study), please fill out a separate table for each.

    ☐ **Section 3 – Protection and Monitoring Plans**
    - 3.1 – Protection of Human Subjects
        - Be sure to describe your informed consent process and/or waiver/alteration of informed consent justifications clearly. Please take 15 minutes to watch the NIA IMPACT Collaboratory Training Model entitled "When is it Appropriate to Alter or Waive Research Informed Consent in Embedded Pragmatic Clinical Trials?" by Emily Largent, PhD, JD, RN found at https://impactcollaboratory.org/pragmatic-trials-training-modules/ An accompanying **IMPACT Waiver Guide** can be found at https://impactcollaboratory.org/pilot-required-materials-and-resources/

- 3.2 – Multi-site study?
  - Because of the pass-thru nature of the funding through Brown University, these studies are considered multisite and must adhere to the NIH sIRB policy, regardless of the specific nature of the study itself. As such, **reply 'Yes'** to this question.
  - Providing the single IRB plan **IS** required for this funding mechanism, despite the general NIH instructions.
  - **Use the *Single IRB Plan* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/

- 3.3 – Data and Safety Monitoring Plan (DSMP)
  - NIH requires a DSMP for all pilot studies funded by the IMPACT Collaboratory regardless of design or level of risk.
  - **Use the *Data and Safety Monitoring Plan* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/. In the template, replace green italicized text with your study-specific information. No changes to other elements of the template are permitted. Save the completed template as a PDF, and attach it within the *Study Record: PHS Human Subjects and Clinical Trials Information Form*.
  - The IMPACT Collaboratory Data and Safety Monitoring Board (DSMB) (or a designated Safety Officer for less risky studies if deemed applicable) is established and will oversee all pilot studies.

☐ **Section 4 – Protocol Synopsis**

- 4.7 - Dissemination Plan
  - The IMPACT Collaboratory requires that all funded studies be registered with ClinicalTrials.gov. The purpose of the Dissemination Plan is to describe how you will ensure compliance with the requirements of ClinicalTrials.gov.
  - **Use the *Dissemination Plan* template:** https://impactcollaboratory.org/pilot-required-materials-and-resources/. In the template, replace green italicized text with your study-specific information. No changes to other elements of the template are permitted. Save the completed template as a PDF, and attach it within the *Study Record: PHS Human Subjects and Clinical Trials Information Form*.
  - NOTE: The Dissemination Plan should not be confused with NIH's Resource and Data Sharing Plan. These plans serve entirely different purposes. If your project is selected for funding, a Resource and Data Sharing Plan will be provided for your review and acknowledgement during onboarding.

☐ **Section 5 – Other Clinical Trial-related Attachments**

- This is not applicable for IMPACT pilots. Do **not** upload additional attachments.

7. Questions?

For questions about:	Contact:
• Eligibility or research-related	IMPACTcollaboratory@hsl.harvard.edu
• Access or use of the UFunds system	Faye Dvorchak Project Director faye_dvorchak@brown.edu
• PHS Human Subjects and Clinical Trials Information form and attachments	Julie Lima IMPACT IRB Team julie_lima@brown.edu
• All other required PHS forms • Administrative questions about developing your budget and proposal	Laura Bridge Subcontract and Finance Specialist laura_bridge@brown.edu