1. This Guide

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

Refer to the Request for Applications – IMPACT Funding Opportunity Number: RFA-IMPACT-21-D01 on the IMPACT Collaboratory’s website at https://impactcollaboratory.org/demonstration-grants-program for the:

- Key Dates
- Program Overview
- Funding Opportunity Description
- Informational Webinar
- Frequently Asked Questions
- Award Information
- Eligibility
- How to Apply
- Demonstration Project Requirements
- Proposal Contents
- Budget Considerations
- Scientific Merit Review Criteria and Process
- Just-In-Time
- Demonstration Project Grant Award Recipients

2. UFunds

Applications will be accepted through the Brown University UFunds system at: https://ufunds.brown.edu/

The UFunds application will open on February 15, 2021 at 8:30 am ET. Applications may be submitted on a rolling basis but no later than April 30, 2021 at 5:00 pm ET.

Applicants can access UFunds with a Brown University email address or can request Gmail access to UFunds by completing this form: https://tinyurl.com/UFundsAccess. A confirmation will be sent to the Gmail address once UFunds access has been granted. The registration process can take up to 2 business days, so please request access as early as possible.

If Gmail access to UFunds was granted for a previous RFA, the credentials are still active.

UFunds is not a multi-user environment. A PI may work in UFunds directly, or someone else may work in UFunds on behalf of a PI – but multiple users cannot work on the same application.

Only one application may be submitted per PI per funding cycle.
3. Attachments Required in Application

All components below 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.

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

We provide some IMPACT-specific templates, which are detailed in green text.

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
   ▪ Your abstract goes in the PROJECT SUMMARY field.

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 (cannot exceed two).
   ▪ The maximum budget (total across all sites) is $500,000 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.
   ▪ Consider the costs necessary to fulfill the requirements of the IMPACT Collaboratory Resource and Data Sharing Plan posted at: https://impactcollaboratory.org/demo-required-materials-and-resources/
   ▪ The budget should include travel for the PI(s) (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 (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**
   - Biosketches (maximum 5 pages each) must be uploaded for:
     - The PI (mandatory)
     - The MPI 2 (if applicable)
     - 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](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](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)

9. □ **Specific Aims**
   - 1 page
   - Use *PHS 398 Continuation Format Page*

10. □ **Research Plan**
    - 6 pages. Appendices are NOT permitted.
    - Refer to the *Request for Applications – IMPACT Pragmatic Clinical Trials Demonstration Project Program* (RFA-IMPACT-21-D01) for the Research Plan requirements:
      - [https://impactcollaboratory.org/demonstration-grants-program/](https://impactcollaboratory.org/demonstration-grants-program/)
    - Use *PHS 398 Continuation Format Page*

11. □ **Multiple Principal Investigator Leadership Plan**
    - REQUIRED only if multiple Project PIs

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

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

14. □ **Consortium/Contractual Arrangements**
    - REQUIRED only if there are subcontracts.
    - Use *PHS 398 Continuation Format Page*
15. Demonstration Project Pragmatic Design Worksheet
   - Use the Demonstration Project Pragmatic Design Worksheet template: https://impactcollaboratory.org/demo-required-materials-and-resources/

16. Letter of Support from Each Health Care System Partner
   - Include letter(s) of support from the health care system partner(s) that relates their commitment to the proposed research and clearly stipulates:
     1) how the project fits with organizational priorities and directly impact delivery of health care within the organization,
     2) how the intervention could be feasibly integrated and adopted into the clinical workflow by frontline providers,
     3) the quality of the proposed data systems (e.g., EHR) for subject identification and outcome ascertainment,
     4) a description of how essential data can be extracted and applied for the planned investigation and in subsequent clinical care, and
     5) the commitment of information technology (IT) staff to the project.
   - Space is allotted in UFunds to provide contact details for one uploaded letter of support (i.e., Letter of Support from Health Care System Partner #1). If that 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 one letter of support, upload the additional letters as a single PDF.

17. Acknowledgment Letters from IRB/HRPP Officials
   - 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 Advarra, the central single Institutional Review Board (sIRB) chosen by the IMPACT Collaboratory.
   - An acknowledgment letter is also required from any collaborating institution that will also be engaged in human subjects research activities.
   - 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.

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

a. □ Section 1 – Basic Information
   - 1.4 – Clinical Trial Questionnaire.
     - All responses should be marked “Yes”. 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

b. □ 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.

c. □ Section 3 – Protection and Monitoring Plans
   - 3.2 – Multi-site study?
     - If for no other reason than the pass-thru nature of the funding through Brown University (for non-Brown awardees), 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.
     - Save the completed template as a PDF, and attach it within the Study Record: PHS Human Subjects and Clinical Trials Information Form.
3.3 – Data and Safety Monitoring Plan (DSMP)
  - NIH requires a DSMP for all projects funded by the IMPACT Collaboratory regardless of design or level of risk. Use the Data and Safety Monitoring Plan template: https://impactcollaboratory.org/demo-required-materials-and-resources/
  - In the template, remove/replace all green italicized information 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) has been established and will oversee all pilot studies.

d. Section 4 – Protocol Synopsis
  - 4.1.d – Study Phase
    - The ClinicalTrials.gov definition of study phase should be used (https://prsinfo.clinicaltrials.gov/definitions.html#StudyPhase), and your response should likely be N/A.
  - 4.7 - Dissemination Plan
    - The IMPACT Collaboratory requires that all demonstration projects 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/demo-required-materials-and-resources/
    - In the template, remove/replace all green italicized information 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.

e. Section 5 – Other Clinical Trial-related Attachments
  - Do not upload any additional attachments.
f. Double check attachments.
Ensure that your PHS Human Subjects and Clinical Trials Information Form includes all of the following attachments:

- Item 2.3a – Inclusion of Individuals Across the Lifespan
- Item 2.4 – Inclusion of Women and Minorities
- Item 2.5 – Recruitment and Retention Plan
- Item 2.7 – Study Timeline
- Item 2.8 – Inclusion Enrollment Report(s)
- Item 3.1 – Protection of Human Subjects
- Item 3.2 – Single IRB Plan
- Item 3.3 – Data and Safety Monitoring Plan
- Item 3.5 – Overall Structure of the Study Team
- Item 4.3 – Statistical Design and Power
- Item 4.7 – Dissemination Plan

4. Questions?

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<th>For questions about:</th>
<th>Contact:</th>
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<td>* Eligibility or research-related</td>
<td><a href="mailto:IMPACTcollaboratory@hsl.harvard.edu">IMPACTcollaboratory@hsl.harvard.edu</a></td>
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<tr>
<td>* Access or use of the UFunds system</td>
<td>Faye Dvorchak</td>
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<tr>
<td>* PHS Human Subjects and Clinical Trials Information form</td>
<td>Julie Lima</td>
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<tr>
<td>* All other required PHS forms</td>
<td>Laura Bridge</td>
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<td>* Administrative questions about developing your budget and</td>
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