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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-D02 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
- Proposal Contents
- Demonstration Project Requirements
- Consultation from IMPACT
- IRB Oversight
- Budget Considerations
- Scientific Merit Review
- Just-In-Time
- Demonstration Project Grant Award Recipients

2. UFunds

Applications are due in the UFunds system no later than Friday, January 14, 2022 at 5:00 pm ET.

Access to the Demonstration Project application in UFunds (https://ufunds.brown.edu) is by invitation only. UFunds access can be granted to a Brown University email address or to a Gmail email address. Faye Dvorchak (faye_dvorchak@brown.edu) will reach out to the PI to establish appropriate access to the application in UFunds.

A PI can submit an application in UFunds, or someone else can be granted permission to submit on behalf of a PI. However, UFunds is not a multi-user environment. If the PI would like more than one person to work on the application in UFunds, Faye can explain a possible workaround before the application is started.

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.

Do not use hyperlinks or URLs except when citing relevant publications in Biosketches and publication lists. Do not use hyperlinks or URLs in your Specific Aims, Research Plan, or NIH fillable forms. Applications that do not follow these instructions may be withdrawn from review and funding consideration. Refer to the NIH Policy on Use of Hypertext in NIH Grant Applications: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html.

We provide some IMPACT-specific templates, which are detailed in green text. Hyperlinks found in the templated text may remain.

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
   - 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:
     - One form for the PI (mandatory)
     - If applicable, one form 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 demonstration project and should not be included in the 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:
     - 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. □ 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

7. □ 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)

8. □ 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

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

10. □ Research Plan
   - 6 pages. Appendices are NOT permitted.
   - Refer to Appendix 1 in the Request for Applications – IMPACT Pragmatic Clinical Trials Demonstration Project Program (RFA-IMPACT-21-D02) for the Research Plan requirements:
     https://impactcollaboratory.org/demonstration-grants-program/
   - Use PHS 398 Continuation Format Page

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

12. □ Multiple Principal Investigator Leadership Plan
    - REQUIRED only if multiple Project PIs
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 subawards.
   - 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 impacts 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, 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 each collaborating institution that will also be engaged in human subjects’ research activities.
   - Use the *Acknowledgment Letter from IRB/HRPP Official template:*  
     https://impactcollaboratory.org/demo-required-materials-and-resources/
   - 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
     for all items in the form unless IMPACT-specific guidance is listed below.
     Within the form, there are “Add Attachment” buttons for uploading
     documents. Please use meaningful filenames for these attachments (i.e.,
     the names or numbers of the sections).
     Do not use the following special characters or formats in the form’s text fields
     because the content will be rejected by NIH’s system:
     o “Smart quotes” or “curly quotes” that curve into your text: Use
       straight quotes (typed from your keyboard) instead
     o “Em-dash” (long dash): Use a short dash instead.
     o Special fonts, bolding, bullets, subscript, superscript
     o If you copy/paste from a word processing application, strip out
       the characters and formats.

IMPACT-specific guidance:

a. □ Section 1 – Basic Information
   o 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
       Your study is not expected to fall under an Exempt category.

b. □ Section 2 - Study Population Characteristics
   o 2.9 – Inclusion Enrollment Reports
     ▪ All studies must include at least one Inclusion Enrollment Report.
     ▪ ‘Using an Existing Dataset or Resource’: Per NIH instructions, if
       your study will only use an existing dataset or resource, with no
       prospective recruitment and no new contact with participants, mark
       “Yes”. However, if your study involves any kind of prospective
       recruitment or new contact with participants – even in combination
       with use of an existing dataset or resource – mark “No”.
     ▪ Enrollment tables:
       o If you answered “Yes” to the question above, complete at
         least one ‘Cumulative (Actual)’ enrollment table.
       o If you answered “No” to the question above, complete at
         least one ‘Planned’ enrollment table.
       o If you have more than one study cohort (e.g., if caregivers
         and persons living with dementia are both considered study
subjects), fill out a separate enrollment table for each cohort. If you answered “Yes” to the question above, all tables will be ‘Cumulative (Actual)’ tables; if you answered “No,” tables can be all ‘Planned’ or a mix of ‘Cumulative (Actual)” and “Planned.”

c. □ Section 3 – Protection and Monitoring Plans
   o 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/
   o 3.2 – Multi-site study?
      ▪ Reply ‘Yes’ to this question. 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.
      ▪ Save the completed template as a PDF, and attach it within the Study Record: PHS Human Subjects and Clinical Trials Information Form.
   o 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 hyperlinks and URLs in the DSMP template have been determined allowable by NIA.
      ▪ 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
   o 4.1.d – Study Phase
     ▪ The ClinicalTrials.gov definition of study phase should be used (https://prsinfor.clinicaltrials.gov/definitions.html#StudyPhase), and your response should likely be N/A.
   o 4.7 – Dissemination Plan
     ▪ Demonstration projects must be registered with ClinicalTrials.gov but only after being officially funded. 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.
     ▪ 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.

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. Please use meaningful filenames for these attachments (i.e., the names or numbers of the sections).
   ▪ 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 2.9 – 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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<tr>
<th>For questions about:</th>
<th>Contact:</th>
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<tbody>
<tr>
<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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<td></td>
<td>Project Director</td>
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<td><a href="mailto:faye_dvorchak@brown.edu">faye_dvorchak@brown.edu</a></td>
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<tr>
<td>• PHS Human Subjects and Clinical Trials</td>
<td>Julie Lima</td>
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<td>Information form and attachments</td>
<td>IMPACT IRB Team</td>
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<td></td>
<td><a href="mailto:julie_lima@brown.edu">julie_lima@brown.edu</a></td>
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<td>• All other required PHS forms</td>
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<td>• Administrative questions about developing</td>
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<td>your budget and proposal</td>
<td><a href="mailto:impact-subawards@brown.edu">impact-subawards@brown.edu</a></td>
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