

Application Instructions

Program Goal

The goal of this program is to test approaches and tools that organizations can readily use to improve the value of the healthcare they provide to patients and communities. The Greater Value Portfolio grant program funds research projects for two years with a maximum amount of \$400,000 per award (plus a 10% indirect) for the purpose of advancing promising approaches to achieve a higher value healthcare system.

Standards for Selection

Applications will be evaluated on the alignment of the research aim with the program's goal; the scientific merit of the research question and methods; the degree to which the past experience of the key personnel is related to the project activities, including efforts to integrate research findings into healthcare improvement; the appropriateness of the overall cost to the project goals and duration; and the project's potential for creating greater value in healthcare.

Application Format

Complete the following steps only after receiving an invitation to submit an application. Submissions that do not comply with all requirements will not be considered by the review committee.

The application includes forms as well as narrative sections that must all be completed according to instructions. **Please refer to the Application Summary Checklist (page 7 of this document) before submitting your application.** The checklist does not need to be included in your application submission.

Applicants must submit their application electronically to the Foundation (chappell@donaghue.org) by June 16, 2022. Your electronic submission should contain four files only. Please do not include a cover letter.

1. The application should be saved as a PDF file and labeled "**PILastName_df_app_GVP_submission year**" e.g., Smith_DF app_GVP_2022. Your document footer should also contain this file name.
2. All letters of support should be housed in one PDF file labeled "**PILast Name_df_letters of support.**" Letters should contain signatures.
3. All CVs and or biosketches should be housed in one PDF file labeled "**PILastName_df_CVandbiosketches**"
4. Finally, all publications should be housed together in one PDF file labeled "**PILastName_df_publications.**"

If you have any questions about any of the submission requirements, you may contact Shamira Chappell at chappell@donaghue.org.

Application Content (applications must include all of the following sections in the order specified below)**Section 1****Application Face Sheet (form)**

The form provided must be signed by the principal investigator and responsible institutional officer.

Section 2**a. Project Summary (narrative)**

Applicants should be aware that this section may be used by the Donaghue Foundation in newsletters, annual reports, and social media for those projects that are awarded a grant. This summary must not exceed 250 words and must include the following:

1. Research goal(s), aims and how the proposed project addresses value in healthcare
2. Description of the partnering healthcare organization
3. What approaches do you anticipate using to implement research findings into practice and policy if the implementation is deemed warranted?

b. Glossary of Acronyms and Abbreviations (list)

Provide an alphabetical list of acronyms and abbreviations used in the application along with the full word or phrase.

Section 3: Project Description (narrative)

The project description (sections 3-8) must be 13 pages or fewer, excluding references. Include all figures and tables within these 13 pages. Supplemental material (including appendices) will not be accepted, except for copies of unpublished or less well-known instruments proposed for use. Use standard typeface, 11-12 point font, single-spaced, with one-inch margins.

Provide the following information in this order with each underlined subheading:**Introduction, background, and significance of the project topic (1 page).**

Address the importance of the problem to be researched. Include a description of the current state of knowledge, noting if there have been meta-analyses or systematic reviews in the area and what their conclusions have been. Discuss the questions to be addressed and the long-term implications of the proposed work, specifically how this promotes greater value in healthcare as described in the program announcement.

Research study (Letter each section)

- a. How will the proposed research study contribute to improving value and how value will be assessed? **(1 page)**
- b. Preliminary data **(1 page)**. Present data from research previously done that is related to the research question(s) to be addressed in this project.
- c. Methods, research plan, and analyses **(II c-e, 4-5 pages)** Describe validation of study instruments, the study population, plans to recruit that population, and your analysis that determined the required sample size. If prepackaged software is to be used for statistical analysis, cite the name(s). Also, describe anticipated analyses, including data screening, replacement of missing data, hypothesis testing, secondary or post hoc analyses and qualitative methods to be used.

- d. Describe the data you will be using in your research. Include the purpose of the data, how and when the data were or will be collected, any checks used to assure the validity of the data, and any non-random biases that might impact the data.
 - d.2 Describe the review done to ensure that research questions, protocols, sampling, and data analyses do not inadvertently mask or exacerbate racial, ethnic, or gender health inequities.
 - d.3 Describe who owns the data and, if you are not the owner, what assurances you have that you will be able to use and publish from the data.
- e. Describe any planned opportunities for co-design or planned approaches to re-assess the intervention if warranted throughout the study period.

Integration between the research team and partnering organization (letter each section, 1-2 pages)

- a. Describe the partnering healthcare organization and how its current initiatives or strategic goals are aligned with the research goals.
- b. Describe how this study will help with ongoing or planned improvement activities or goals and why these activities or goals need a research design.
- c. Describe the roles and the organizational relationships among the researchers and the clinical or operational personnel who will be engaged in this project. Include a brief description of previous work done together.
- d. Describe how the timeframe of the research project aligns with the planned improvement activity in the partnering organization and the challenges and opportunities this presents.
- e. Describe what resources the partnering organization has committed to supporting this project.

Knowledge transfer and integration or implementation activities (letter each section, 1-2 pages)

- f. Provide examples of activities undertaken by members of the research team and key study personnel of the partnering organizations that have promoted incorporating research evidence into clinical or operational change.
- g. What approaches do you anticipate using to implement research findings into practice and policy if the implementation is deemed warranted? Include activities that will be conducted during and after the study period.
- h. What do you see as the impact of this project in five years?
- i. What are the practices and policies of the partnering organization concerning data sharing, publishing, and other dissemination activities?

Limitations (1-page limit)

This section should not exceed 1 page (\approx 500 words). Discuss identified anticipated limitations of the research based on study design and other factors. Please describe each identified limitation in accordance with criteria 1-4 listed below. Criteria 1 and 2 should be written in narrative format, and criteria 3 and 4 can be written in narrative or list format at the discretion of the researcher.

1. Anticipated limitations
2. Factors influencing limitations
3. Alternative approaches/strategies for mitigating limitations
4. The extent to which these limitations could impact the results of the study, or provide an opportunity for additional research

References & citations

Section 4

Project Milestones and Key Activities (form)

List milestones and key activities to be completed during the grant term. These relate to both the research component and any activities conducted during the duration of the award that will facilitate knowledge transfer and implementation of findings when the study is completed.

Section 5

a. Annual Budget (form)

The Donaghue Foundation will fund only those costs specific to conducting the proposed activities described in the application. The Foundation will not pay to support facilities, equipment, or salaries that are already supported through other funding mechanisms. Donaghue grant funds may not be intentionally applied for or used by any department or principal investigator when there are funds currently allocated or available for the proposed project (or which appear to be reasonably assured) from other sources. See “Funding Commitment and Permitted Use of Funds” in the Greater Value Portfolio program description for additional information on funding policies.

The Foundation is willing to collaborate with other funding sources in support of a project, provided that the Foundation is given assurance that the aggregate of funding does not exceed the project’s costs. For budgetary purposes, the applicant may designate the partnering organization as a subcontractor. Any organization that is listed as a funding collaborator or a subcontractor must attest to its intent to participate in the project in letter form as part of this application. The letter must be signed by an authorized representative from the partnering organization and state the organization’s intent to comply with the requirements of the research plan, Foundation grant conditions, and their capacity to provide the resources and/or personnel specified. (See Section 9 “Letters of Support.”)

The request for Donaghue Foundation funding must be clearly accounted for in each budget category in the budget request forms that follow. A detailed description of the use of funds must be provided in the Budget Justification narrative and clearly specify any parts of the budget that will be used to support knowledge uptake components as described in Section 3-IV of the project description. If the proposed project will be supported in part by other funders, use the Budget Justification to list these sources and amounts of funds.

Project costs associated with the use of subcontractors must be itemized in the category labeled Other Expenses on the budget forms.

Annual Budget Form- Complete the form showing the funds requested from the Donaghue Foundation according to the breakouts described below for each 12 month period of funding.

Personnel: All team members should be listed here. Requested salaries should be for full- or part-time professionals or technical assistants who are normally paid from the research projects to which they are assigned. The Donaghue Foundation does adhere to the NIH salary cap guidelines.

Note: Team members should be listed in the personnel category along with the principal investigator. *If a team member is from a different institution or organization, only list their name, role, and percentage of effort in the personnel category, all cost information should be included in the “other expenses” category.*

Note: percent effort on a project may exceed the percent of the total amount requested, but the percent of the total requested may not exceed percent effort.

Equipment: Requests for items of equipment will be evaluated on their merit in relation to their importance to the project.

Supplies: Supplies included in the budget must be required for the conduct of the research project.

Travel: Funds to cover the cost of travel required for the research project may be included.

Participant Costs: Include expenses related to participant reimbursement and other clinical and/or project costs related to their participation in the research.

Other Expenses: Use this category to list all other project expenses including those assigned to subcontractors. Itemize all subcontractor costs by category.

Indirect: Indirect costs may be requested by the applicant institution, not to exceed 10% of direct costs exclusive of equipment purchases. Collaborators and subcontractors may also include overhead costs, not to exceed 10% of the subcontractor's direct costs exclusive of equipment purchases. However, indirect costs may not be claimed by the applicant institution for direct costs which are used in the subcontractor's budget.

b. Total Cost for Proposed Project - Roll up annual costs for each project year.

c. Budget Justification (narrative)- Provide a brief and clear explanation of all significant expenses in the budget.

Section 6: Research Ethics (narrative)

a. In a brief statement, please provide evidence of specific education or training in research ethics, with specific attention to (a) protection of human research subjects, (b) avoidance of scientific misconduct, and (c) avoidance of conflicts of interest. If you are a clinician, please provide evidence of conversancy with health care ethics.

b. Briefly describe your data security and monitoring plan.

Section 7: Current and Pending Support (narrative)

List current sources of research support for the principal investigator and key personnel. Include the title of the project, status (active or pending), source of funds, and period of support.

Section 8: Informed Consent of Human Subjects (insert form)

Safeguarding the rights and welfare of human subjects in projects supported under awards from the Donaghue Foundation is of foremost importance and is the sole responsibility of the grantee institution or organization accountable for the funds awarded and administratively responsible for the conduct of the project. For the application, a draft or approved copy of the form(s) which will be used to obtain the informed consent of human subjects must accompany the proposal. A copy of any clinical treatment protocols that will be used in the study must be available upon request for review by the Foundation's review committee.

Section 9: Supplemental Materials

1. Letters of Support (attach in a separate PDF file)

The application must include the following:

- a. A letter from the principal investigator's department or section head who can attest to and monitor the PI's work, time commitments, and activities. The letter must indicate the principal investigator's qualifications to conduct the proposed research at the sponsoring institution and the level of commitment by the institution to support the researcher. The nature of the appointment or other relationship, salary commitment if any, research time and space available, and amount of the researcher's time to be spent on the project must be explicitly stated. This letter must make clear the nature of the close and continuous collaborative relationship that exists between the principal investigator and the institution such that the continuity and depth of involvement are clear.
- b. Letter from the partnering organization that attests to and confirms the information provided in Section 3 (Integration between the research team and partnering organization, and knowledge transfer and integration or implementation activities)
- c. Letter from the key team members that describe their support and relationship with the project.
- d. Letter of support from any cooperating organization other than the partnering organization(s).

All letters of support should be housed in one PDF file labeled "**PILast Name_df_letters of support.**" Letters should contain signatures.

2. Curriculum Vitae (attach in a separate PDF file)

Curriculum vitae (abbreviated) for the principal investigator and for the team members must accompany the application using the NIH biosketch format. If a member of the team does not have a curriculum vitae, please provide a resume.

All CVs and or biosketches should be housed in one PDF file labeled "**PILastName_df_CVandbiosketches**"

3. Publications (attach in a separate PDF file)

You may include up to three publications that will assist the Foundation's review committee in evaluating the principal investigator's ability to perform the work described.

All publications should be housed together in one PDF file labeled "**PILastName_df_publications.**"

All applications not in compliance with the requirements listed above are ineligible for review. To be considered, applications must be emailed to chappell@donaghue.org by **June 16, 2022**

For further information on the application procedures and forms, please visit our website at www.donaghue.org or email Shamira Chappell at chappell@donaghue.org

Application Summary

| Component | Section # | Format | Check (✓) |
|--|-----------|------------|-----------|
| Application Face Sheet | 1 | Form | |
| Project Summary | 2 | Narrative | |
| Glossary of Acronyms and Abbreviations | 2a | List | |
| Project Description | 3 | Narrative | |
| Project Milestones and Key Activities | 4 | Form | |
| Annual Budget(s) | 5 | Form | |
| Total Cost for Proposed Budget | 5a | Form | |
| Budget Justification | 5b | Narrative | |
| Research Ethics Preparation | 6 | Narrative | |
| Current and Pending Support | 7 | Narrative | |
| Informed Consent of Human Subjects | 8 | Insert | |
| <u>Supplemental Materials</u> | | | |
| Letters of Institutional Support | 9 | Attachment | |
| Curriculum Vitae | | Attachment | |
| Publications | | Attachment | |