

The Program for Research Leadership 2011

Application Instructions

Please read the Program for Research Leadership Program Description before completing the application. Only applications invited following a letter of intent will be considered.

Application Format

The application includes forms as well as narrative sections, all of which must be completed according to instructions in order to be considered. Please refer to the Application Summary at the back of this document and use the provided applicable forms in completing your application. A full set of forms follow these instructions.

Applicants must submit one printed original of the entire application and associated materials and one electronic copy submitted on a CD. All files submitted on the CD must be downloadable to a PC using Adobe Reader software. All text must use typefaces in 11-12 point size, with no more than six lines of text within a vertical inch, and no less than one-inch margins all around. Please make sure your original and your electronic copy include all documents.

Your electronic submission should contain three folders only.

- 1) The first folder should contain the application and be labeled "PILastName_df_app PRL_submission year" e.g., Smith_DF app_PRL 2010. Your document footer should also contain this file name. **Scanning of the application is not permitted.**
- 2) The second folder should contain all publications and labeled PILast Name_df_publications. **Scanning of the publications is permitted.**
- 3) The third folder should contain all letters of support and labeled PILast Name_df_letters of support. Letters should be in PDF format on letterhead and contain signatures. **Scanning of the letters of support is permitted.**

Do not attach a cover letter or enclose your printed application in a folder, notebook or binder.

The Donaghue Foundation sends submissions electronically directly to the reviewers and does not check for completeness or correct deficiencies. If you have any questions about any of the submissions requirements, contact the Donaghue Foundation at leadership@donaghue.org.

Complete the following steps only after receiving an invitation to submit an application.

Submissions that do not comply with all requirements will be returned to the applicant and no corrected submission will be accepted.

Application Content

Applications must include all of the following sections in the order specified below:

Section 1: Application Face Sheet (form)

The hardcopy form provided must be signed by the senior investigator and responsible institutional officer. The electronic copy does not need to have signatures.

Section 2: Project Summary (narrative)

This summary must not exceed 250 words and must include the following:

1. Topic background and significance
2. Overall goals for the four-year project
3. The goals, aims, and methods of the research component
4. The goals and activities that are planned for the knowledge uptake component
5. The goals and activities that are planned as a part of the team building component

Section 3: Description of Team Members (form and narrative)

Provide a brief description of the responsibility of each individual team member including the senior investigator (50 -75 words for each member). Also provide a brief description of the reason why each person was selected to be a part of the project, the particular expertise that they bring to it, and what they may seek to learn from or teach to other team members. Include any letters of cooperation and curricula vitae (abbreviated) or resumes as appropriate in Section 6 (Senior Investigator's curriculum vitae).

Section 4: Project Description (narrative)

The project outline must be 12 pages or fewer, excluding references. Include all figures and tables within these 12 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 size type, no more than six lines per vertical inch, with one-inch margins. Provide the following information in this order with each subheading

- I. 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 current approaches to disseminating the knowledge that has been gained from research previously done on the topic. Discuss the questions to be addressed and the long-term implications of the proposed work.
- II. Research component
 - a. Preliminary data **(1-2 pages)**. Present data from research previously done that is related to the research question(s) to be addressed in this project.
 - b. Methods, research plan and analyses **(5-6 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 use.

III. Knowledge uptake component (1-2 pages)

Briefly describe the current state of dissemination of findings into practice from research on your selected topic. Describe the activities and planned during the four years to consider how your research finding may be translated into the next phase of incorporating it into practice, whether it is into a more refined research question, clinical practice, public health campaign, policy initiative, or other avenue.

IV. Team building component (1-2 pages)

Describe the current level of interaction among team members and the activities that are planned to foster a team-approach to the project, such as defining shared goals, enhancing communication, dividing responsibilities and ensuring appropriate rewards among team members.

V. References & citations

Section 5: Project Milestones and Key Activities (form)

List milestones and key activities to be completed during the grant term for each of the three components.

Section 6: Statement of Practical Benefit (narrative)

The Foundation uses a set of Practical Benefit Parameters to facilitate a systematic assessment of the application within the context of Ethel Donaghue's will. Miss Donaghue established the foundation to provide financial assistance for research *"to promote medical knowledge which will be of practical benefit to the preservation, maintenance and improvement of human life."* With this purpose in mind, the Trustees use these parameters to assess all applications across the spectrum of research topics supported by the Foundation. Underlying these parameters is the foundation's goal that the health research it funds has the potential to make a near term impact on improving clinical care and/or systems of care, and/or reducing the pain and suffering of individuals and communities.

Recognizing that research topics may vary widely, please respond to the questions in each parameter posed below as they relate to your grant proposal. Identify in specific, non-technical terms what is expected to be the practical benefit attained through the completion of the proposed project. Use no more than 1 or 2 pages in total to address all of the parameters.

1. Specific Benefit: What is the expected practical benefit(s) of the proposed project? Please discuss the benefit(s) as it relates to finding cures for diseases, preventing disease or its consequences and/or enhancing quality of life. For example, will the proposal lead to a best practice? Expand the evidence base? Improve understanding of specific patient populations?

2. Scope of Effect: Who will be affected by the outcome of the proposed project and why? Please try to quantify the potential scope of effect.
3. Immediacy of Effect: How soon can benefits from the work be realized? What steps or other work following yours might be necessary in order to have your work put into practice?
4. The “But For” Test: But for the availability of Donaghue Foundation support, what are the other potential sources of funding to conduct the proposed research and related activities on this topic?
5. Incidental Effect: What incidental benefits may be obtained through the funding of the proposal? For example, will services be provided in the course of research that might otherwise be unavailable to the subjects? Or will education be accomplished that might otherwise not be undertaken?

Section 7: Curriculum Vitae (attach)

A curriculum vitae (abbreviated) for the senior investigator and for the team members must accompany the application using the NIH biosketch format. Team members who are not employed by an academic institution should submit a resume.

Section 8:

a. 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 senior investigator when there are funds currently allocated or available for the proposed project (or which appear to be reasonably assured) from other sources. See “Use of Grant Funds” in the Program for Research Leadership 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. The foundation also allows for grantees to use subcontractors to conduct aspects of the work. Any organization that is listed as a funding collaborator or a subcontractor must attest to their intent to participate in the project in letter form as part of this application. The letter must be signed by a responsible institutional officer and state the organization’s willingness 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 12 “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. 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 for the first two years. If consortium agreements or subcontract arrangements are included in the budget, mark the appropriate space on the Application Face Sheet and provide a separate detailed budget for each 12-month period.

Personnel: 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.

Note: Team members should be listed in the personnel category along with the senior 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 total remuneration requested, but percent of total remuneration 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, as well as up to \$1,500 for travel to scientific meetings related to the project.

Subject Costs: Include expenses related to subject reimbursement and other clinical and/or project costs related to subject 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 subcontractor may also include overhead costs, not to exceed 10% of the consortium or 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 a consortium budget.

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

b. Allocation of Funds (form)

Estimate the proportion of funds that will be allocated to each component for each project year.

c. Budget Justification (narrative)

Provide a brief and clear explanation of all significant expenses in the budget.

Section 9: Facilities and Physical Environment (form)

List all space, equipment and other institutional facilities available for the completion of the project. If access to facilities or equipment outside the senior investigator’s control is necessary, provide a letter of cooperation following this page in the Application.

Section 10

a: Current and Pending Support (form)

List sources of support for the senior investigator and team members (team members from non-academic institution may submit in resumes). For each listing, include: title of project, status (active, pending, planned, related or unrelated), source of funds, name of proposal's senior investigator, role of this Application's senior investigator and percent effort, entire period of support, and direct costs for current year.

b: Current and Pending Support (narrative)

Provide a summary statement of the specific aims for each project listed as having current or pending support. In cases where there is scientific and/or budgetary overlap, describe what adjustments will be made.

Section 11: Research Ethics Preparation (narrative)

In a brief statement, please provide evidence of the Senior Investigator's specific education or training in research ethics, with specific attention to (1) protection of human research subjects, (2) avoidance of scientific misconduct, and (3) avoidance of conflicts of interest. If the PI is a clinician, please provide evidence of conversancy with health care ethics. If other personnel in the study have human subject responsibilities, reference their training as it relates to this function.

Section 12: Informed Consent of Human Subjects (attach 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 informed consent of human subjects must accompany the proposal. A copy of any clinical treatment protocols which will be used in the study must be available on request for review by the Scientific Review Committee.

Section 13: Letters of Support

The application must include two types of letters of support.

1. A letter from the senior investigator's department or section head who can attest to and monitor the PIs' work, time commitments and activities. The letter must indicate the senior investigator's qualifications conduct the proposed research at the sponsoring institution and the level of commitment by the institution to support the researcher. The nature of 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. The researcher's total time spent and available must not exceed 100%.

This letter must make clear the nature of the close and continuous collaborative relationship that exists between the senior investigator and the institution such that the continuity and depth of involvement are clear.

2. Letter from the team members and cooperating organizations (if included in the project) should describe their support and relationship with the project.

Section 14: Publications (attach)

You may include up to three publications which will assist the Scientific Review Committee in evaluating the senior investigator's ability to perform the work described. If these are in an electronic format, you must include those on the CD. If the publications are in print, please include one hard copy of each publication submitted.

All applications not in compliance with the requirement listed above are ineligible for review.

To be considered, applications must be received in the Donaghue Foundation office by **12:00 Noon on application due dates**. For further information on the application procedures and forms, please visit our website at www.donaghue.org or contact the Donaghue Foundation at (860)521- 9011 or email us at leadership@donaghue.org.

Application Summary

	Section #	Form Included?
Application Face Sheet	1	Yes
Project Summary	2	Yes
Description of Team Members	3	Yes
Project Description	4	No
Project Milestones and Key Activities	5	Yes
Statement of Practical Benefit	6	No
Curriculum Vitae	7	No
Budget	8a	Yes
Allocation of Funds	8b	Yes
Budget Justification	8c	No
Facilities and Physical Environment	9	Yes
Current and Pending Support	10a	Yes
Current and Pending Support	10b	No
Research Ethics Preparation	11	No
Informed Consent of Human Subjects	12	No
Letters of Institutional Support	13	No
Publications	14	No