Margaret Q. Landenberger Foundation
Foundation Application Instructions
August 2024

Submission: Applications are due by 5pm on November 15, 2024. A single PDF containing all the required documentation should be emailed to susan.whartnaby@bbh.com.

PI Eligibility: The Margaret Q. Landenberger award is intended for early stage investigators who have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who have not previously competed successfully as PD/PI for a substantial NIH independent research award (R01). PIs who have been awarded R03, R21, or K awards are eligible.

Application Instruction Summary: The foundation utilizes an NIH-based format for applications. The instructions below are based on the NIH instructions (PHS 398). NIH restrictions on font size and document margins should also be followed. If you have any questions about the format please consult https://grants.nih.gov/grants/funding/phs398/phs398.pdf

Overview of Proposal Sections (page limits)

1. PI / Institutional Information
2. Project Summary (30 lines of text)
3. Budget with Budget Justification
4. Biosketch (5 page limit)
5. Resources
6. Specific Aims (1 Page limit)
7. Research Strategy (6 Page limit)
8. References Cited (no page limit)
9. Letters of Support

1. PI and Institution Information (NIH Facepage)

The first part of the Face Page (Form Page 1) must be printed on a single page. The Face Page must not have any shading or colors.

Title of Project

Do not exceed 81 characters, including the spaces between words and punctuation**.** Choose a descriptive title that is specifically appropriate.

Response to Specific Request for Applications (RFA) or Program Announcement (PA)

Not applicable

Name of Program Director/Principal Investigator (PD/PI)

Name the one person responsible to the applicant organization for the scientific and technical direction of the project.

Degree(s)

Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.).

Position Title

Provide the academic or professional title of the PD/PI. If more than one title, indicate the one most relevant to the proposed project (e.g., Professor of Biochemistry, Chief of Surgical Service, or Group Leader).

Mailing Address

Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the PD/PI will use this address. For electronic mail, enter the appropriate e-mail address (not a website URL).

Department, Service, Laboratory, or Equivalent

Indicate organizational affiliation, such as Department of Medicine, Materials Research Laboratory, or Social Sciences Institute.

Major Subdivision

Indicate school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "None."

Telephone and Fax Numbers

Provide a daytime telephone number and, if available, a fax number.

eRA Commons User Name

Not applicable

Human Subjects Research

Check "No" if activities involving human subject are not planned at any time during the proposed project period, and leave 4a-d blank.

Check "Yes" if activities involving vertebrate animals are planned at any time during the proposed project period.

Vertebrate Animals

Check "No" if activities involving vertebrate animals are not planned at any time during the proposed project period, and leave 5a blank. Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

Check "Yes" if activities involving vertebrate animals are planned at any time during the proposed project period.

Animal Welfare Assurance

Enter the OLAW approved Animal Welfare Assurance number of the applicant organization in 5a. To determine whether the organization holds an Animal Welfare Assurance, see the lists of Domestic and Foreign Assured institutions.

Enter “None” in 5a if the applicant organization does not have an OLAW-approved Animal Welfare Assurance. **Do not enter the Animal Welfare Assurance number of any Project/Performance Site or collaborating institution.** When an applicant organization does not have an Animal Welfare Assurance, the Authorized Organization Representative’s signature constitutes declaration that the applicant organization will submit an Animal Welfare Assurance when requested by OLAW.

Dates of Proposed Period of Support

Request no more than 2 years of support, unless specifically authorized in the FOA. Note that some programs specify fewer years.

Budget Request

Costs Requested for Initial Budget Period

Direct Costs

From Form Page 4, enter the "Subtotal Direct Costs for Initial Budget Period."

Total Costs

No indirect costs are provided by the foundation, so the total costs will be the same as the direct costs.

Costs Requested for Proposed Period of Support

Direct Costs

From Form Page 5, enter the sum of "Subtotal Direct Costs" for all years.

Total Costs

No indirect costs are provided by the foundation, so the total costs will be the same as the direct costs.

Applicant Organization

Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award.

Type of Organization

Check the appropriate box. See definitions of Applicant Organization Types definitions in Supplemental Instructions Part III, 3.

Entity Identification Number, DUNS Number, Congressional District

Not applicable

Administrative Official to be Notified if Award is Made

Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

Official Signing for Applicant Organization

Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the signing official.

Applicant Organization Certification and Acceptance

An original signature, in ink, is required. Only an institutional official with formal designated or delegated authority to sign on behalf of the organization may sign the form. The signature must be dated. *In signing the application Face Page, the Authorized Organization Representative of the applicant organization certifies that the applicant organization will comply with all applicable policies, assurances and/or certifications referenced in the application.*

The applicant organization is responsible for verifying its eligibility and the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administrative rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

2. Description: Project Summary and Relevance (Form Page 2)

The first and major section of the Description is a **Project Summary**. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.

The second section of the Description is **Relevance**. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

DO NOT EXCEED THE SPACE PROVIDED.

Use text only (no figures or other information not in standard text.) Do not include proprietary, confidential information or trade secrets in the description section. If the application is funded, the project description will be entered into an NIH database and will become public information.

Project/Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there are more than two Project/Performance Sites, use the Project/Performance Site Format Page to list all the sites, including Department of Veterans Affairs (VA) facilities and foreign sites.

Senior/key Personnel

In addition to the PD/PI, Senior/key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested.

Other Significant Contributors

This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project.

Human Embryonic Stem Cells

This section does not need to be completed.

3. Budget for Entire Proposed Period of Support (Form Page 5)

FORM PAGE 5

Enter the totals under each budget category for the years of support requested, a maximum of two years. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

Budget Justification
Using form page 5 or separately, compose a short description that justifies the proposed funds.

4. Biosketch (4 pages)

Additional NIH and Other PHS Agencies Instructions for a Biographical Sketch

- Include biographical sketches of all senior/key personnel and Other Significant Contributors.
- Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications.
- Figures, tables (other than those included in the provided format pages), or graphics are not allowed in the biosketch. Do not embed or attach files (e.g. video, graphics, sound, data).

- The biosketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.

The following instructions pertain to the completion of the biosketch.

Name: Fill in the name of the senior/key person or other significant contributor in the “Name” field of the Biosketch Format Page.

eRA Commons User Name: If the individual is registered in the eRA Commons, fill in the eRA Commons User Name in the “eRA Commons User Name” field of the Biosketch Format Page. The “eRA Commons User Name” field is required for the PD/PI (including career development and fellowship applicants), primary sponsors of fellowship applicants, all mentors of candidates for mentored career development awards, and candidates for diversity and reentry research supplements. The “eRA Commons User Name” field is optional for other project personnel. The eRA Commons User Name should match the information provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) Form in your grant application.

Position Title: Fill in the position title of the senior/key person or other significant contributor in the “Position Title” field of the Biosketch Format Page.

Education/Training: Complete the education block. Begin with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral, residency, and clinical fellowship training, as applicable, listing each separately.
For each entry provide:

- the name and location of the institution
- the degree received (if applicable)
- the month and year of end date (or expected end date).
- the field of study (for residency entries, the field of study should reflect the area of residency training)

Following the education block, complete Sections A-D of the biographical sketch.

A. Personal Statement: Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include, but are not limited to, audio or video products; conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements.

See related Frequently Asked Questions for more information.

Note the following additional instructions for ALL applicants/candidates:

- If you wish to explain factors that affected your past productivity, such as family care responsibilities, illness, disability, or military service, you may address them in this "A. Personal Statement" section.
- Indicate whether you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this Biosketch or application. • Figures, tables, or graphics are not allowed.

B. Positions and Honors: List in chronological order the positions you've held that are relevant to this application, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

C. Contributions to Science: Who should complete the "Contributions to Science" section:

- All senior/key persons should complete the "Contributions to Science".

Format: Briefly describe up to five of your most significant contributions to science. The description of each contribution should be no longer than one half page, including citations.

While all applicants may describe up to five contributions, graduate students and postdoctorates may wish to consider highlighting two or three they consider most significant.

Content: For each contribution, indicate the following:

- the historical background that frames the scientific problem;
- the central finding(s);

- the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and
- your specific role in the described work.

For each contribution, you may cite up to four publications or research products that are relevant to the contribution. If you are not the author of the product, indicate what your role or contribution was. Note that while you may mention manuscripts that have not yet been accepted for publication as part of your contribution, you may cite only published papers to support each contribution. Research products can include audio or video products (see the NIH Grants Policy Statement, Section 2.3.7.7: Post-Submission Grant Application Materials); conference proceedings such as meeting abstracts, posters, or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required.

Descriptions of contributions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. These contributions do not have to be related to the project proposed in this application.

D. Additional Information: Research Support and/or Scholastic Performance

Note the following instructions for specific subsets of applicants/candidates:

- High school students are not required to complete Section D. Additional Information: Research Support and/or Scholastic Performance.
- Career development award applicants should complete the "Research Support" section but skip the “Scholastic Performance” section.
- Generally, the following types of applicants can skip the “Research Support” section and must complete only the “Scholastic Performance” section. However, when these applicants also have Research Support, they may complete both sections.
  - applicants for predoctoral and postdoctoral fellowships
  - applicants to dissertation research grants
  - candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

Research Support These instructions apply to all applicants who are completing the “Research Support” section.

List ongoing and completed research projects from the past three years that you want to draw attention to. Briefly indicate the overall goals of the projects and your responsibilities. Do not include the number of person months or direct costs.

Do not confuse “Research Support” with “Other Support.” Other Support information is not collected at the time of application submission.

- **Research Support:** As part of the Biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each your qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- Other Support: NIH staff may request complete and up-to-date “other support” information from you as part of Just-in-Time information collection.

Other Support Information: Refer to the Other Support page.

5. Resources

RESOURCES FORMAT PAGE

This information is used to assess the capability of the organizational resources available to perform the effort proposed.

- Identify the facilities to be used (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.
- For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESIs project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and

financial support such as protected time for research with salary support. PHS 398 30

- If there are multiple performance sites, describe the resources available at each site.
- Describe any special facilities used for working with biohazards or other potentially dangerous substances.

6. Specific Aims (1 Page) (Use CONTINUATION PAGE)

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Specific Aims are limited to one page.

6. Research Strategy (6 pages) (Use CONTINUATION PAGE)

Organize the Research Strategy in the specified order and using the instructions provided below or as stated in the FOA. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

Note for Applications Proposing the Involvement of Human Subjects and/or Clinical Trials:

- Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form.
- The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; protection and monitoring plans; and statistical design and power.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women, Minorities, and Children on this form).

Note for Applicants with Multiple Specific Aims: You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

1. **Significance**

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

2. **Innovation**
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).
   - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. **Approach**
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
   - For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources webpage.
   - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
   - If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
   - Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to the NIH Guide Notice on Sex as a

Biological Variable in NIH-funded Research for additional information.

- Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. A full discussion on the use of Select Agents should appear in the Select Agent Research attachment.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.

Preliminary Studies for New Applications.

For new applications, include information on preliminary studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Preliminary data can be an essential part of a research grant application and can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.

7. Bibliography and References Cited (no page limit)

Provide a bibliography of any references cited in the Research Plan and in the Human Subjects and Clinical Trials Information form (5.1.12).

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." NIH maintains a list of such journals.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. The references should be limited to relevant and current literature.

You are allowed to cite interim research products. Note: interim research products have specific citation requirements. See related Frequently Asked Questions for more information.

8. Letters of Support

Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.