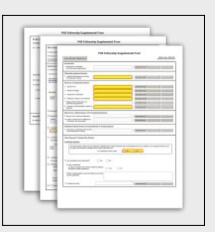
G.430 - PHS Fellowship Supplemental Form

The PHS Fellowship Supplemental Form is used only for fellowship applications.

This form includes fields to upload several attachments including the Specific Aims, Research Strategy, and Applicant Background and Goals.

The attachments in this form, together with the rest of your application, should include sufficient information needed for evaluation of the project and fellow, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies.





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Appendix

1. **29. Appendix**

Who should use the PHS Fellowship Supplemental Form:

Use the PHS Fellowship Supplemental Form only if you are submitting a fellowship application.

Fellowship applicants and sponsors are strongly encouraged to speak with a PHS Program Official for Institute- or Center (IC)-specific guidance before preparing this application. Refer to the Table of IC-specific Information, Requirements, and Staff Contacts in your NOFO. In addition, a list of contacts specifically for extramural training at the NIH ICs can be found at <u>NIH Extramural Research Training Representatives</u> page. For AHRQ, see <u>Research Training</u> <u>Staff Contacts</u>. You are encouraged to check these websites for the most current contact information.

It is important that the attachments in this form be developed in collaboration with your sponsor, but they should be written by you, the fellowship candidate.

Read all the instructions in the NOFO before completing this section to ensure that your application meets all IC-specific criteria.

Applicants must follow all policies and requirements related to formatting, page limits, and proprietary information. See the following pages for more information:

- Format Attachments
- Page Limits
- NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information
- NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act

Introduction

1. Introduction to Application (for Resubmission applications)

Who must complete the "Introduction to Application" attachment:

An "Introduction" attachment is required only if the type of application is resubmission or if the NOFO specifies that one is needed. An introduction is not allowed for new or renewal applications.

See <u>Types of Applications</u> for descriptions.

Format:

Follow the page limits for the Introduction in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO.

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Resubmission applications: See specific instructions on the content of the Introduction on the NIH's <u>Resubmission Applications</u> page.

Candidate Section

2. Goals, Preparedness, and Potential

Who must complete the "Goals, Preparedness, and Potential" attachment:

The candidate's "Goals, Preparedness, and Potential" attachment is required.

Format:

Follow the page limits for Candidate's Goals, Preparedness, and Potential in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO.

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Organize the Candidate's Goals, Preparedness, and Potential for the Research Training Proposal in the specified order and use the instructions provided below. Start each section with the appropriate heading – Overall Training Goals, Candidate's Preparedness, Candidate Self-Assessment, and Scientific Perspective. Candidates are expected to write the application, including the research training project section. However, the sponsor should review drafts and provide constructive feedback to the candidate throughout the application process.

A. Overall Training Goals

Candidates should describe the goals for the proposed research training plan and the long-term goals for a career in biomedical research workforce. Relate the

fellowship goals to the long-term career goals. Candidates should describe their motivation for pursuing a career in the biomedical research workforce.

B. Candidate's Preparedness

This section provides information regarding the educational, scientific, and professional experiences that prepare the candidate for the proposed research training plan. Note: information listed in the candidate's biosketch may be expanded upon, but not simply duplicated, in this section. The candidate should address the following:

- How relevant activities and experiences contributed to the candidate's scientific development and preparation for the current research training plan. Examples may include coursework, research experiences, conference attendance, internships, and employment.
- Any additional activities and experiences that demonstrate an interest and commitment to a career in the biomedical research workforce. Examples may include seeking out opportunities for research skill development or engaging in leadership, service, teaching, or outreach activities.

C. Candidate's Self-Assessment

The purpose of this self-assessment is to provide an opportunity for the candidate to define their current characteristics (such as relevant skills, abilities, traits or attitudes) and areas to develop that are likely to contribute most significantly to success in the proposed research training plan and career path. For example, the candidate may include but is not limited to describing technical (techniques or technical methods, quantitative/computational approaches), operational (practices that promote rigorous and reproducible science, research safety, animal, or human welfare) or professional (management, leadership, communication, teamwork) skills. The candidate should describe:

- Two to four current characteristics that are likely to contribute to achieving the research training goals.
- Two to four specific areas of development during the fellowship to attain the stated research training and career goals.

D. Scientific Perspective

This section is intended to provide information about the candidate's potential to think about and express ideas within a scientific field. In this section, candidates should explain the following:

- Why this field of science is important and the ways the chosen research training project will advance the field.
- A broader, unresolved scientific question in the chosen scientific field, the importance of the problem, and the ways biomedical research might advance the scientific field.

Research Training Plan

3. Training Activities and Timeline

Who must complete the "Training Activities and Timeline" attachment:

The "Training Activities and Timeline" attachment is required.

Format:

Follow the page limits for Specific Aims in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO.

Attach this information as a PDF. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

The research training plan activities should be individually tailored and well-integrated. The planned activities should address the candidate's goals and identified areas for development. The application should describe the collaborative process between the candidate and the sponsor(s) in the development, writing, review, and editing of the research training plan, including the research training project aims and strategy.

- Describe, by year, the planned activities (coursework, professional development, research training project, mentoring, clinical activities, etc.) during the proposed award. Note that the Research Training Project Strategy will be detailed in a separate section described below. Estimate the percentage of time to be devoted to each activity. The percentage should total 100 for each year.
- Explain how the training activities will develop the areas defined in the selfassessment section and help to meet the fellowship goals.
- Provide specific examples of how the proposed research training will facilitate the transition to the next career stage.
- Describe why the Sponsor(s), collaborators, and research training environment are appropriate for the proposed research training plan. Candidates should expand upon, but not duplicate information found in the Facilities and Other Resources section or in the Sponsor(s) section describing the Research Training Environment.
 - The research training is expected to broaden the candidate's perspective, opportunities, and networks. Therefore, postdoctoral candidates requesting training at their doctorate organization or senior fellowship candidates requesting training at their current organization must explain why further training at that organization would be valuable.
 - If the candidate is proposing a research training experience at a foreign institution, describe how the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. The need for and level of proficiency in reading, speaking, and comprehending the foreign language should be addressed.
- Note: Detailed timelines of research training activities involving animals, human subjects, or clinical trials are requested in other sections of the fellowship application and should not be included here. The timeline provided here should be distinct from the Study Timeline in the PHS Human Subjects and Clinical Trials Information form.

Research Training Project Aims and Strategy

A Research Training Project Strategy is required for all types of fellowship awards. Candidates should relate the proposed research training project to the career goals and explain the relationship between the candidate's research training project and the sponsor's ongoing research program.

The Research Training Project section is expected to be tailored to the experience level of the candidate and to allow for the development of the necessary skills for further career advancement. The research training project should be achievable within the requested funding period.

For most types of applications, the Research Training Project should include the following:

- Specific aims and objectives
- Methods, approaches, and techniques for each aim and objective.
- Discussion of possible challenges and how they will be managed.
- Alternative approaches that might be tried if the initial approaches do not work.

Candidates should propose a rigorous research training project based on a strong scientific foundation. Fellowship applications do not require preliminary data or extensive experimental detail; however, candidates should provide sufficient scientific and technical details for reviewers to understand and assess the merits of the scientific foundation and research training project.

4. Research Training Project Specific Aims

Who must complete the "Research Training Project Specific Aims" attachment:

The "Research Training Project Specific Aims" attachment is required.

Format:

Follow the page limits for Specific Aims in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO. Specific Aims attachment that includes graphics will generate a warning by the Agency upon submission.

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

State concisely the broader goals of the proposed research training project (for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a barrier to progress in the field, or develop new technology).

List succinctly the specific objectives or aims of the research training project to be completed by the candidate during the funding period. Summarize the expected outcome(s). Include the potential impact that the results of the proposed research training project will have on the research field(s) involved.

5. Research Training Project Strategy

Who must complete the "Research Training Project Strategy" attachment:

The "Research Training Project Strategy" attachment is required.

Format:

Follow the page limits for the Research Strategy in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO. Although multiple sections of information are required in the Research Training Project Strategy as detailed below, the page limit applies to the entirety of the single attachment.

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Although the fellowship research training project may fall within the larger funded research program of the sponsor(s), the research training project strategy must be written in the candidate's own words. Using language written by others is not allowed in this section because the application is intended to provide information regarding the candidate's understanding of the research training project and ability to communicate the scientific rationale and approaches. Additionally, this section will provide information to evaluate the training potential of the research training project. Candidates may solicit feedback and incorporate suggestions from the sponsor(s) and other scientists into the research training project strategy, but the text must be written by the candidate.

Organize the Research Training Project Strategy in the specified order and use the instructions provided below, unless otherwise specified in the NOFO. Start each section with the appropriate section heading – for example, Scientific Foundation and Rationale, and Approach. Cite published experimental details in the Research Strategy and provide the full reference in G.220 - R&R Other Project Information Form, Bibliography and References Cited.

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

- Use the Research Training Project 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; and protection and monitoring plans.

• Candidates are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion (e.g., see <u>Question</u> 2.4 Inclusion of Women and Minorities).

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

1. Scientific Foundation and Rationale

- Provide the context for the proposed research training project. Include information on published and unpublished findings serving as the scientific foundation for the proposed research training project. Describe the strengths and weaknesses in the rigor of the prior research that serves as the key support for the proposed project.
- Describe the rationale for the research training project, including unaddressed areas for research and why this area of research is interesting and important.
- Describe how achieving the proposed research training project goals will advance biomedical research in the candidate's chosen field.

2. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the <u>Resource Sharing Plan</u> attachment, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans, as appropriate. Resources and tools for rigorous experimental design can be found at the <u>Enhancing Reproducibility through Rigor and Transparency</u> website.
- 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 <u>Research Methods Resources</u> 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 NIH Guide Notice on <u>Sex as a Biological Variable in NIH-funded Research</u> for additional information.
- Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. If applicable, a full discussion on the use of select agents should appear in the <u>Select Agent Research</u> attachment below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed, but an approved cell line from the NIH <u>hESC Registry</u> cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

• If proposing to gain <u>clinical trial research experience</u>, briefly describe your role on the clinical trial.

As applicable, also include the following information as part of the Research Strategy, keeping within the sections listed above.

Progress Report for Renewal Applications:

Renewal applications for individual Fellowships are rare. You should consult with your program official before preparing such an application.

Note that the Progress Report falls within the Research Strategy document and is therefore included in the page limits for the Research Strategy. If you are submitting a renewal application, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. In the Progress Report, you should:

- Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement.
- Explain any significant changes to the specific aims and any new directions, including changes resulting from significant budget reductions.
- Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH Glossary definition for <u>clinical research</u>. Use the Progress Report section to discuss, but do not duplicate information collected elsewhere in the application.

Do not include a list of publications, manuscripts accepted for publication, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.

6. Progress Report Publication List (for Renewal applications)

Who must complete the "Progress Report Publication List" attachment:

A "Progress Report Publication List" is required only if the type of application is renewal.

See <u>Types of Applications</u> for descriptions.

Format:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

In the rare instance that you are submitting a renewal application, list the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

You are allowed to cite interim research products. **Note:** Interim research products have specific rules and citation requirements. See related <u>Interim Research Products</u> <u>FAQs</u> on citing interim research products and claiming them as products of your NIH award.

Provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for the following types of articles:

- Articles that fall under the <u>Public Access Policy</u>;
- Articles that were authored or co-authored by the fellowship candidate and arose from NIH support;
- Articles that were authored or co-authored by the fellowship candidate and arose from AHRQ funding provided after February 19, 2016 (see Guide Notice on Policy for Public Access to AHRQ-Funded Scientific Publications).

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 <u>list of such</u> journals.

Citations that are not covered by the NIH Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference. Note that copies of these publications are not accepted as appendix material.

7. Training in the Responsible Conduct of Research

Who must complete the "Training in the Responsible Conduct of Research" attachment:

The "Training in the Responsible Conduct of Research" attachment is required. The written content of this attachment may be derived from organizational sources; however, the candidate should understand the content and importance of completing the training outlined in the attachment.

Format:

Follow the page limits for Training in the Responsible Conduct of Research in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO.

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the <u>NIH Grants Policy Statement, Section 11.2.3.4</u>: <u>Responsible Conduct of Research</u>:

- 1. **Format:** Describe the required format of instruction (i.e., face-to-face lectures, coursework, and/or real-time discussion groups). A plan with only on-line instruction is not acceptable.
- 2. **Subject Matter:** Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics).
- 3. **Faculty Participation:** Describe the role of the sponsor/mentor(s) and other faculty involvement in the instruction.
- 4. **Duration of Instruction:** Describe the total number of contact hours of instruction, taking into consideration the duration of the program.
- 5. **Frequency of Instruction:** Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the candidate's current career stage, including the inclusive dates instruction was last completed.

Senior fellows may fulfill the requirement for instruction in RCR by participating as lecturers and discussion leaders.

For more information:

See the <u>NIH Grants Policy Statement, Section 11.2.3.4</u>: <u>Responsible Conduct of</u> <u>Research.</u>

Commitment to Candidate, Mentoring, and Training Environment

8. Sponsor(s) Commitment

Who must complete the "Sponsor(s) Commitment" attachment:

The "Sponsor(s) Commitment" attachment is required. The sponsor and each cosponsor must provide statements as described below.

Format:

Follow the page limits for Sponsor(s) Commitment attachment in the NIH Table of <u>Page</u> <u>Limits</u>, unless otherwise specified otherwise in the NOFO.

The Sponsor and Co-Sponsor Statements must be appended together and uploaded as a single PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Complete these items as comprehensively as possible so that a meaningful evaluation of the commitment to the research training can be made by the reviewers.

Create a heading at the top of the first page titled "Sponsor(s) Commitment" and organize each statement in the specified order and use the instructions below, unless otherwise specified in the NOFO. Start each section with the appropriate section heading – A. Mentoring Approach and Candidate Mentoring Plan; B. Prior Commitment to Training and Mentoring; C. Commitment to the Candidate's Research Training Plan; D. Research Training Environment; and E. Candidate's Potential.

Each sponsor and co-sponsor statement must address the following sections (A-E).

A. Mentoring Approach and Candidate Mentoring Plan

Effective mentorship is critical to the development and retention of scientists and the advancement of research. Sponsors and co-sponsors must describe their mentoring approach and the specific mentoring plan for the candidate to ensure career advancement in the biomedical research workforce. The mentoring plan should be tailored to the overall training goals outlined by the candidate and go beyond simply providing access to research environments. Effective mentoring plans may include areas such as enhancing the candidate's understanding of scientific research, promoting the candidate's professional development, maintaining effective communication, aligning expectations, fostering independence, and promoting equitable, inclusive, and accessible training environments.

B. Prior Commitment to Training and Mentoring

This section may be used to demonstrate the sponsor(s) past commitment to effective training, mentoring, and career development. Previous experience is not a pre-requisite to serve as a sponsor. Sponsor(s) may provide examples from no more than 2-5 recent trainees at the level of the candidate and describe the individualized training and mentoring offered. Simply listing former trainees and their career outcomes does not provide evidence of effective mentoring. The sponsor(s) should describe the impacts of the individualized training and mentoring on each former trainee's scientific, educational, or career development. For early-stage sponsor(s), examples may include informal training and mentoring activities conducted as a student or postdoctoral fellow.

C. Commitment to the Candidate's Research Training Plan

This section should contain confirmation of the sponsor(s) commitment to the candidate's research training plan and that sponsor(s) have sufficient time to devote to the training and mentoring given their other professional and supervisory obligations. The sponsor(s) should provide:

- An endorsement of the candidate's research training plan and the sponsor's responsibilities for each component of the research training plan timeline.
- A description of the frequency, duration, and nature of meetings with the candidate throughout the training plan timeline.
- A listing of how many other scientists in the research team will be supervised during the proposed fellowship award period and how the candidate will receive consistent, individualized attention.

D. Research Training Environment

The information contained in the "Training Plan Environment" section of the Sponsor's and Co-sponsors' Statements should be coordinated with information provided in the Research Training Plan section or the Other Project Information Form: Facilities and Other Resources so that material is not duplicated.

The sponsor should describe the research training environment and how it will meet the needs of the candidate to achieve the outlined goals. The co-sponsor may include information if different from the sponsor's description. Include any additional relevant items to promote the development of the candidate not listed elsewhere in the application. For example, describe:

- The sponsor(s) research training environment and how the environment will support the candidate's development and attainment of the defined career goals. Sponsor(s) are encouraged to describe efforts to create safe, inclusive, supportive, and accessible research environments. Describe the day-to-day research environment with special attention to training and how the candidate will benefit from the environment.
- Organizational research training environments such as available centralized research facilities or equipment needed to complete the research training project not listed elsewhere in the application.
- Relevant and accessible organizational research training program(s) related to the candidate's area of interest.
- Opportunities for professional development and intellectual interactions, for example, scientific meetings, journal clubs, seminars, and opportunities for presentations. Include items such as classes, opportunities for interaction with other scientists and any professional skills development opportunities.

Describe how the sponsor will work with the candidate to develop and publish rigorous scientific products such as publications and presentations.

E. Candidate's Potential

The section is intended to provide information about the candidate's main areas for development during the training as well as their potential to benefit from the research training plan and to have a productive career in the biomedical research workforce. Sponsor(s) should provide the following for the candidate:

- Examples of personal characteristics (for example, skills, abilities, traits, attitudes) that are likely to significantly contribute to further advancement in the candidate's defined career path. Take into consideration relevant indicators for success, such as scientific curiosity, resourcefulness, and persistence.
- Areas for development to improve the candidate's prospects of transitioning into a productive career in the biomedical research workforce. Areas may include, but not limited to the following skills: technical (e.g., new techniques or technical methods, quantitative or computational approaches), operational (e.g., practices that promote rigorous, reproducible, and responsible research) or professional (e.g., management, leadership, communication, teamwork). Indicate whether the proposed training plan will address these areas and contribute to the candidate's development and attainment of the stated career goals.
- An overall assessment of the candidate's preparedness and likelihood for success in the proposed research training plan. Provide examples, such as scientific or intellectual contributions, that highlight the likelihood of achieving the training goals and advancing to a career in the biomedical research workforce.

Clinical Trial Training (if proposed)

Note: If the candidate is proposing to gain experience in a clinical trial as part of the research training plan, then the sponsor or co-sponsor should include information in the statement to document leadership of the clinical trial. Include the following:

- A statement/attestation that the sponsor or co-sponsor will be responsible for the clinical trial.
- Source of funding.
- ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable;
- A description of the expertise available to guide the candidate in the proposed clinical trials research experience.
- The sponsor(s) must have primary responsibility for leading and overseeing the trial and must describe the level of oversight.
- Include details on the specific roles/responsibilities of the fellow and sponsor(s), keeping in mind that the terms of a fellowship award do not permit the fellow to lead a clinical trial.

9. Letters of Support from Collaborators, Contributors, and Consultants

Note that Letters of Support are not the same as Reference Letters, which are required for some fellowship award applications. For more information about Reference Letters see the NIH <u>Reference Letters</u> page.

Format:

Follow the page limits for Letters of Support from Collaborators, Contributors, and Consultants in the NIH Table of <u>Page Limits</u>, unless otherwise specified in the NOFO.

Letters of support must be appended together and uploaded as a single PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

If any collaborators, consultants, or advisors are expected to contribute to the scientific development or execution of the candidate's research training plan, attach letters of support from those individuals here, describing their anticipated role and contributions.

10. Description of Candidate's Contribution to Program Goals

Who must complete the "Description of Candidate's Contribution to Program Goals" attachment:

Applicants to diversity-related NOFOs (e.g., diversity-related F31): The "Description of Candidate's Contribution to Program Goals" attachment is required.

All other Fellowship applicants: Skip the "Description of Candidate's Contribution to Program Goals" attachment, as it is not required.

Format:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

The sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the fellowship program to promote <u>diversity</u> in health-related research. The letter should avoid revealing sensitive personally identifiable information, such as the candidate's specific racial/ethnic background or type of disability.

For NIH's Interest in Diversity, see the Notice of NIH's Interest in Diversity.

Signatures:

The "Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.

Other Research Training Plan Section

Vertebrate Animals

Are Vertebrate Animals Used?

This field is pre-populated from the G.<u>220 - R&R Other Project Information Form</u>.

If you have answered "No" for activities involving vertebrate animals and activities involving vertebrate animals are not planned at any time during the proposed project at any performance site: Skip Questions 13 and 14 below.

If you have answered "Yes" for activities involving vertebrate animals: Answer Questions 13 and 14 below in consultation with both your Sponsor and AO.

11. Are vertebrate animals euthanized?

An answer is required if you answered "Yes" to "Are Vertebrate Animals Used?" above.

Check "Yes" or "No" to indicate whether animals in the project are euthanized.

If "Yes" to euthanasia, is method consistent with AVMA guidelines?

An answer is required if you answered "Yes" to "Are Vertebrate Animals Euthanized?"

Check "Yes" or "No" to indicate whether the method of euthanasia is consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals.

For more information: See AVMA Guidelines for the Euthanasia of Animals.

If "No" to AVMA guidelines, describe method and provide scientific justification:

If you answered "No" to "Is method consistent with AVMA guidelines?," you must describe (in 1000 characters or fewer) the method of euthanasia and provide a scientific justification for its use.

If you answered "Yes" to "Is method consistent with AVMA guidelines?" skip this question and scientific justification.

12. Vertebrate Animals

Who must complete the "Vertebrate Animals" attachment:

Include a "Vertebrate Animals" attachment if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the G.<u>220 - R&R Other Project Information Form</u>.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the Vertebrate Animals attachment to circumvent the page limits of the Research Strategy. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

If live vertebrate animals are involved in the project, address each of the following criteria:

1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.

- 2. **Justifications:** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- 3. **Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Each of the criteria must be addressed. Failure to adequately address the criteria may negatively affect the application's impact score. In addition to the 3 criteria above, you should also:

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

See the following pages for more information:

- NIH's Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- <u>NIH Grants Policy Statement, Section 4.1.1.1: Animal Welfare Assurance</u> <u>Requirements</u> (an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

13. Select Agent Research

Who must complete the "Select Agent Research" attachment:

Include a "Select Agent Research" attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

Format:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

For more information:

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The Centers for Disease Control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the <u>Federal Select Agent Program</u> website.

See also the <u>NIH Grants Policy Statement, Section 4.1.24.1: Public Health Security and</u> <u>Bioterrorism Preparedness and Response Act (Select Agents)</u>.

Content:

Excluded select agents: If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per <u>42 CFR 73.3</u>, the select agent requirements do not apply. Use this "Select Agent Research" attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the <u>Select Agents and Toxins Exclusions</u> website.

Applying for a select agent to be excluded: If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

All candidates proposing to use select agents: Address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

- 1. Identify the select agent(s) to be used in the proposed research.
- 2. Provide the registration status of all entities* where select agent(s) will be used.
 - If the performance site(s) is a foreign organization, provide the name(s) of the country or countries where select agent research will be performed.
 - *An "entity" is defined in <u>42 CFR 73.1</u> as "any government agency (federal, state, or local), academic organization, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
- 3. Provide a description of all facilities where the select agent(s) will be used.
 - Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s).
 - Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
 - Describe the biocontainment resources available at all performance sites.

14. Resource Sharing Plan

Note: Effective for due dates on or after January 25, 2023, NIH Fellowship awards are not subject to the NIH Data Management and Sharing (DMS) Policy. A Data Sharing Plan or plans for Genomic Data Sharing will no longer be required within the Resource Sharing Plan attachment.

Format:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see the NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms.

Research Tools: NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. **For more information**, see the <u>Research Tools Policy on the NIH Scientific Data Sharing Website</u> and the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

15. Other Plan(s)

For NIH Fellowship Candidates, the Data Management and Sharing (DMS) Plan is not required.

For more information on the DMS Policy see <u>the NIH Data Management and Sharing</u> <u>Policy</u> on the NIH Scientific Data Sharing website or the <u>NIH Grants Policy Statement</u>, <u>Section 8.2.3.1: Data Sharing Policy</u>. See also <u>Frequently Asked Questions</u> for additional information on the DMS Policy on these and other topics.

16. Authentication of Key Biological and/or Chemical Resources

Format:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

More information:

Key biological and/or chemical resources are characterized as follows:

- Key biological and/or chemical resources may or may not have been generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on <u>Rigor and Reproducibility</u> for more information.

Additional Information Section

17. Human Embryonic Stem Cells

Use the following instructions to complete the fields in this section.

For additional guidance, see the <u>NIH Grants Policy Statement, Section 4.1.13: Human</u> <u>Stem Cell Research</u>.

Does the proposed project involve human embryonic stem cells (hESC)?

An answer to this question is required.

If the proposed project involves hESC, check "Yes" and complete the rest of the fields in the Human Embryonic Stem Cells section.

If the proposed project does not involve hESC, check "No" and skip the rest of fields in the Human Embryonic Stem Cells section.

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

If you will use hESC but a specific line from the NIH <u>hESC Registry</u> cannot be chosen at the time of application submission, check this box. Additionally, provide a strong justification (in the Research Strategy) for why an appropriate cell line cannot be chosen from the registry at this time.

If you cannot specify which cell lines will be used at the time of application submission, specific cell line information will be required as Just-in-Time information prior to award.

Cell Line(s):

List the 4-digit registration number of the specific cell line(s) from the NIH hESC Registry (e.g. 0123). Up to 200 lines can be added.

18. Alternate Phone Number

Enter an alternate phone number (e.g., cell phone) for the fellowship candidate. This should be a different number than the one provided in the PD/PI contact information in the G.200 - SF424 (R&R) Form.

19. Degree Sought During Proposed Award

Complete the following fields if you will be working toward a degree while receiving fellowship support.

Degree:

Select the type of degree you will be working toward during the proposed award. If the degree is not on the drop down menu, please select "OTH: Other."

If "other," indicate degree type:

If you selected "OTH: Other" for the "Degree," indicate the type of degree you will be working toward during the proposed award.

Expected Completion Date (MM/YYYY):

Enter the expected completion date of the degree sought during the proposed award.

20. Field of Training for Current Proposal

An answer to this field required.

Select a single "Field of Training" code that best describes the proposed area of research training. This information is used for reporting purposes only and is not used for study section assignments.

21. Current or Prior Kirschstein-NRSA Support?

Current or Prior Kirschstein-NRSA Support? Yes/No

An answer to this question is required. Check the appropriate box to indicate whether you currently have or have had prior Kirschstein-NRSA support.

If yes, identify current and prior Kirschstein-NRSA support below:

Select the appropriate "Level" and "Type" of Kirschstein-NRSA support. "Level" indicates either predoctoral or postdoctoral level (not the level of experience). "Type" indicates either individual fellowship or institutional research training grant.

If known, enter the start and end dates (month, day, and year) of the support and the grant number (e.g., T32 GM123456 or F31 HL345678) of the current and/or prior support.

You may enter up to four separate listings for current and/or prior support.

Note on Kirschstein-NRSA time limits: An individual cannot receive more than five years of cumulative predoctoral Kirschstein-NRSA support and three years cumulative postdoctoral Kirschstein-NRSA support (the total of institutional grants and individual fellowships) without a waiver from the awarding component. The awarding components have different policies on waiving the statutory limits on support. Therefore, the fellowship candidate must request a waiver from the probable awarding IC before requesting a period of support that would exceed these limits. Refer to the Table of IC-specific Information, Requirements, and Staff Contacts in your NOFO. The fellow's sponsor and AOR must endorse the request. The request must include justification and specify the amount of additional support for which approval is sought. Individuals seeking additional support beyond the third year of postdoctoral support are strongly advised to consult with their awarding IC Program Officer before submitting a waiver request. It is important to read carefully the applicable NOFO that may have an overall approval to exceed these limits (e.g., the F30 programs allow for up to six years of predoctoral support).

If you receive additional Kirschstein-NRSA support while this application is pending, you must promptly report such information to the awarding component to which this application has been assigned.

22. Applications for Concurrent Support?

Applications for Concurrent Support? Yes/No

An answer to this question is required. Check the appropriate box to indicate whether the fellowship applicant has applied or will be applying for other support that would run concurrently with the period covered by this application.

If yes, describe in an attached file:

Attach this information as a PDF file. See NIH's <u>Format Attachments</u> page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

If you answered "Yes" to the "Applications for Concurrent Support?" question, you must provide a description of the concurrent support. Include the type, dates, source(s), and amount in the attachment.

If you receive any support from these other applications while this application is pending, you must promptly report such information to the awarding component to which this application has been assigned.

23. Citizenship

Information on Citizenship Requirements for Fellowship Candidates:

Individual Kirschstein-NRSA Fellowship Requirements: To be eligible for a Kirschstein-NRSA individual fellowship (F30, F31, F32, F33), the fellowship candidate must be a citizen or non-citizen national of the United States or of its possessions or territories, or must have been lawfully admitted to the United States for permanent residence by the time the award is issued. Individuals on temporary student visas are not eligible for NRSA support unless otherwise specified in the NOFO.

Non-NRSA Requirements: If you are applying for a non-NRSA fellowship program supported by the NIH for which citizenship or permanent residency is not required (e.g., Fogarty International Center programs, F99/K00), you must have a valid visa in your possession that allows you to remain in the United States (or in a foreign research training setting, if applicable) long enough to be productive on the proposed fellowship project. It is the responsibility of the sponsoring institution to determine and document in the application that the individual fellowship candidate's visa will allow him or her to remain in the proposed research training setting for the period of time necessary to complete the proposed fellowship. Information may be requested by the NIH or another PHS Agency prior to issuance of an award.

All Fellowship Candidates:

Check the applicable boxes for the following questions:

U.S. Citizen: U.S. Citizen or Non-Citizen National? Yes/No

Check "Yes" if the candidate is a U.S. Citizen or Non-Citizen national; otherwise check "No."

Non-Citizen nationals are people who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).

If you answered "Yes," skip the rest of "Question 31. Citizenship" and you can continue with "Question 32. Change of Sponsoring Institution."

If you answered "No," please continue to fill out the rest of "Question 31. Citizenship" following the instructions below.

If "No" to U.S. Citizen or Non-Citizen National, please select the most appropriate response from the options provided:

Non-U.S. Citizen With a Permanent U.S. Resident Visa:

Check this box if the fellowship candidate has been lawfully admitted for permanent residence (i.e., is in the possession of a current and valid Permanent Resident Card or other legal verification of such status).

A notarized statement will be required before an award is issued. The statement must show that a licensed notary has seen the fellowship applicant's valid Permanent Resident Card (USCIS Form I-551) or other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S.

Non-U.S. Citizen With a Temporary U.S. Visa:

Check this box if the fellowship candidate currently holds a temporary U.S. visa.

If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:

If the fellowship candidate has applied for permanent residence and expects to hold a permanent resident visa by the earliest possible start date of the award, please check this box to indicate that permanent residence status is pending. A notarized statement will be required as a part of the pre-award process.

24. Change of Sponsoring Institution_

Check this box if you are submitting your application with a change of sponsoring institution. If the box is checked, you must also provide the name of the former sponsoring institution.

Budget Section

25. Tuition and Fees

Who must complete the "Tuition and Fees" section:

All fellowship applicants must complete this "Tuition and Fees" section.

Content:

Indicate whether funds are being requested for tuition and fees by checking the appropriate box ("None Requested" or "Funds Requested").

Predoctoral Fellowship Candidates: List, by year, the estimated costs of tuition and fees.

Postdoctoral and Senior Fellowship Candidates: List, by year, the costs associated with specific course work (or a degree-granting program, if applicable) that supports the research training experience and that are identified and described in the "Training Activities and Timeline" attachment.

For more information:

In accordance with the <u>NIH Grants Policy Statement, Section 11.2.9.4</u>: Institutional <u>Allowance</u>, funds to offset the costs of health insurance are included in the standard Institutional Allowance, and are not to be requested as part of Tuition and Fees.

Refer to the NIH <u>Research Training and Career Development</u> website for helpful resources and FAQs about tuition and fees.

26. Childcare Costs

Who must complete the "Childcare Costs" section:

All fellowship candidates must complete this "Childcare Costs" section.

Only Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellows may receive childcare costs.

Content:

Indicate whether funds are being requested for childcare costs by checking the appropriate box ("None Requested" or "Funds Requested").

List, by year, the amount of childcare costs requested.

The NRSA childcare costs apply to full-time NIH-NRSA-supported fellowship positions. Each fellow is eligible to receive \$2,500 per budget period for costs for childcare provided by a licensed childcare provider. Childcare costs are permitted for dependent children living in the eligible fellow's home from birth under the age of 13, or children who are disabled and under age 18. Childcare costs do not apply to elder or non-child dependent care costs.

For more information:

Refer to NOT-OD-21-074 and Childcare Costs FAQs about childcare costs.

27. Present Institutional Base Salary

Who must complete the "Institutional Base Salary" section:

Only senior fellowship candidates should complete the "Institutional Base Salary" section.

Amount:

Provide your present base salary. The value must be in U.S. dollars.

Academic Period:

Indicate the period of time on which the salary is determined (e.g., academic year of 9 months, full-time 12 months, etc.).

Number of Months:

Indicate the number of months per year you receive your base salary. The number may not be more than 12, but may include a decimal to indicate partial months (e.g., 9.5).

28. Stipends/Salary During First Year of Proposed Fellowship

Who must complete the "Stipends/Salary During First Year of Proposed Fellowship" section:

Only senior fellowship candidates should complete the "Stipends/Salary During First Year of Proposed Fellowship" section.

a. Federal Stipend Requested: Amount and Number of Months

Enter the amount of the stipend being requested for the initial period of support (i.e., the first year of proposed fellowship) and the number of months requested.

b. Supplementation from Other Sources: Amount, Number of Months, Type, and Source

Enter the anticipated amount and the number of months (during the first year of the proposed fellowship) for any stipend/salary supplementation. Also enter the type of supplementation expected (e.g., sabbatical leave, salary, etc.) and the source of such funding.

Appendix

29. Appendix

Refer to the NOFO to determine whether there are any special appendix instructions for your application. See the updated NIH Guide Notice on the <u>Appendix Policy</u>.

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into

attachment #10. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Use filenames for attachments that are descriptive of the content.

A summary sheet listing all of the items included in the Appendix is encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment.

Content:

The only allowable appendix materials are:

- Blank data collection forms, blank survey forms, and blank questionnaire forms or screenshots thereof
- Simple lists of interview questions

Note: In your blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

- Blank informed consent/assent forms
- Other items *only if* they are specified in the NOFO as allowable appendix materials

No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.

Some NOFOs may have different instructions for the Appendix. Always follow the instructions in your NOFO if they conflict with these instructions.

Note: Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your NOFO.

Information that expands upon or complements information provided in any section of the application - even if it is not required for the review - is not allowed in the Appendix unless it is listed in the allowed appendix materials above or in your NOFO. For example, do not include material transfer agreements (MTA) in the Appendix unless otherwise specified in the NOFO.

For more information:

- The NIH Guide Notice on <u>Reminder: NIH Applications Must Be Complete and</u> <u>Compliant With NIH Policy and Application Instructions At Time of Submission</u>.
- Failure of reviewers to address non-required appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review. For more information, see the <u>NIH Grants Policy Statement, Section 2.4.2</u>: <u>Appeals of Initial Scientific Review</u>.
- Appendix Policy Frequently Asked Questions