G.430 - PHS Fellowship Supplemental Form

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 FOA. In addition, a list of contacts specifically for extramural training at the NIH ICs can be found at NIH <u>Training Advisory Committee Roster</u>. For AHRQ, see <u>Research Training Staff Contacts</u>. You are encouraged to check these websites at any time 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 applicant.

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

Applicants must follow all policies and requirements related to proprietary information, page limits, and formatting. 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 (RESUBMISSION)

Who must complete the "Introduction" attachment:

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

Descriptions of different types of applications are listed here: NIH Types of Applications.

Format:

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

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

Content:

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

Fellowship Applicant Section

2. Applicant's Background and Goals for Fellowship Training

Who must complete the "Applicant's Background and Goals for Fellowship Training" attachment:

The "Applicant's Background and Goals for Fellowship Training" attachment is required.

Format:

Follow the page limits for Applicant's Background and Goals for Fellowship Training in the NIH Table of Page Limits unless otherwise specified in the FOA.

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

Content:

Organize the Applicant's Background and Goals for Fellowship Training attachment in the specified order and use the instructions provided below unless otherwise specified in the FOA. Start each section with the appropriate heading - Doctoral Dissertation and Research Experience, Training Goals and Objectives, Activities Planned Under this Award.

A. Doctoral Dissertation and Research Experience:

Briefly summarize your past research experience, results, and conclusions, and describe how that experience relates to the proposed fellowship. In some cases, a proposed fellowship may build directly on previous research experiences, results, and conclusions. In other situations, past research experiences may lead a candidate to apply for a fellowship in a new or different area of research. Do not list academic courses in this section.

Applicants with no research experience: Describe any other scientific experiences.

Advanced graduate students (i.e., those who have or will have completed their comprehensive examinations by the time of award): Include a narrative of your planned doctoral dissertation (may be preliminary).

Postdoctoral fellowship applicants: Specify which areas of research were part of your predoctoral thesis or dissertation and which, if any, were part of a previous postdoctoral project.

B. Training Goals and Objectives:

- Describe your overall training goals for the duration of the fellowship and how the proposed fellowship will enable the attainment of these goals.
- Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award.
- Discuss how the proposed research will facilitate your transition to the next career stage, if applicable.

C. Activities Planned Under this Award:

The activities planned under this award should be individually tailored and well integrated with your research project.

- Describe, by year, the activities (research, coursework, professional development, clinical activities, etc.) you will be involved in during the proposed award. Estimate the percentage of time to be devoted to each activity. The percentage should total 100 for each year.
- Describe the research skills and techniques that you intend to learn during the award period.
- Describe the planned, non-research activities (e.g. those related to professional development and clinical activities) that you plan to engage in during the award period.
- Provide a timeline detailing the proposed research training and related activities for the entire duration of the fellowship award.

Research Training Plan Section

A Research Training Plan is required for all types of fellowship awards and is a major part of the fellowship application. It is important to relate the proposed research to the applicant's scientific career goals. Explain the relationship between the applicant's research on the fellowship award and the mentor's ongoing research program.

The information in these introductory paragraphs to the Research Training Plan Section applies to all Research Training Plan Section attachments: Specific Aims, Research Strategy, Respective Contributions, Selection of Sponsor and Institution, Progress Report Publication List, and Training in the Responsible Conduct of Research.

For most types of research, the plan should include:

- a specific hypothesis,
- a list of the specific aims and objectives that will be used to examine the hypothesis,
- a description of the methods/approaches/techniques to be used in each aim,
- a discussion of possible problems and how they will be managed, and
- alternative approaches that might be tried if the initial approaches do not work.

The Research Training Plan is expected to be tailored to the experience level of the applicant and to allow him/her to develop the necessary skills for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the focus of the Research Training Plan.

Although applicants for fellowship awards are expected to write the Research Training Plan, the mentor should review a draft of the plan and discuss it in detail with the applicant. Review by other knowledgeable colleagues is also helpful. Although it is understood that fellowship applications do not require the extensive experimental detail usually incorporated into regular research grant applications, a fundamentally sound Research Training Plan should be provided.

3. Specific Aims

Who must complete the "Specific Aims" attachment:

The "Specific Aims" attachment is required unless otherwise specified in the FOA.

Format:

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

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

Content:

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 have 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).

4. Research Strategy

Who must complete the "Research Strategy" attachment:

The "Research Strategy" attachment is required.

Format:

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

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

Content:

Organize the Research Strategy in the specified order and use the instructions provided below, unless otherwise specified in the FOA. Start each section with the appropriate section heading – Significance, Innovation, 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.

1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. Innovation

• Fellowship applicants should not include an Innovation section except in the unusual circumstance where it is specified in the FOA.

3. Approach

 Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan attachment, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

- 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.
- 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 <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 hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

If you have multiple Specific Aims, you may address Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

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 (including data collected by others in the lab), if any. Discuss the applicant's preliminary studies, data, and/or experience pertinent to this application.

Progress Report for Renewal Applications:

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

Renewal applications for individual fellowships are rare. You should consult with your program official before preparing such an application. 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>, particularly if relevant to studies proposed in the renewal application. You should not submit a PHS Inclusion Enrollment Report unless the enrollment is part of new or ongoing studies in the renewal 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.

5. Respective Contributions

Who must complete the "Respective Contributions" attachment:

The "Respective Contributions" attachment is required.

Format:

Follow the page limits for Respective Contributions in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

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

Content:

Describe the collaborative process between you and your sponsor/co-sponsor(s) in the development, review, and editing of this Research Training Plan. Also discuss your respective roles in accomplishing the proposed research.

6. Selection of Sponsor and Institution

Who must complete the "Selection of Sponsor and Institution" attachment:

The "Selection of Sponsor and Institution" attachment is required.

Format:

Follow the page limits for Selection of Sponsor and Institution in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

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

Content:

Describe the rationale/justification for the selection of both the sponsor and the institution.

- 1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the applicant organization, provide an explanation here.
- 2. Foreign Institution. If you are proposing a research training experience at a foreign institution, describe how that 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.
- 3. Postdoctoral and Senior Fellowship Applicants requesting training at their Doctorate or Current Institution: Training is expected to broaden a fellow's perspective. Therefore, if you are requesting training at either your doctorate institution or any institution where you have been training for more than a year, you must explain why further training at that institution would be valuable. Individuals applying for senior fellowships who are requesting training at the institution at which they are employed should provide a similar explanation.

7. Progress Report Publication List (RENEWAL)

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

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

Descriptions of different types of applications are listed here: NIH <u>Types of Applications</u>.

Format:

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

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.

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

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.

8. 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.

Format:

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

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

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>Supplemental Instructions</u>, <u>Part III</u>, <u>Section 1.16</u>: <u>Policy on Instruction in the 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 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 applicant'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 NIH Guide Notices on the <u>Availability of Resources for Instruction in the Responsible Conduct of Research</u> and on the <u>Requirement for Instruction in the Responsible Conduct of Research</u>.

See the <u>Supplemental Instructions</u>, <u>Part III</u>, <u>Section 1.16</u>: <u>Policy on Instruction in the Responsible Conduct of Research</u> for information on the NIH Policy on Training in RCR.

Sponsor(s), Collaborator(s), And Consultant(s) Section

9. Sponsor and Co-Sponsor Statements

Who must complete the "Sponsor and Co-Sponsor Statement" attachment:

The "Sponsor and Co-Sponsor Statement" attachment is required. Both the Sponsor and all Co-Sponsors must provide statements as described below.

Format:

Follow the page limits for Sponsor and Co-Sponsor Statements in the <u>NIH Table of Page</u> Limits unless otherwise specified otherwise in the FOA.

The Sponsor and Co-Sponsor Statements must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

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

Create a heading at the top of the first page titled "Sponsor and Co-Sponsor Statements." Organize each statement in the specified order and use the instructions below, unless otherwise specified in the FOA. Start each section with the appropriate section heading – Research Support Available; Sponsor's/Co-Sponsor's Previous Fellows/Trainees; Training Plan, Environment, Research Facilities; Number of Fellows/Trainees to be Supervised During the Fellowship; and Applicant's Qualifications and Potential for a Research Career.

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

A. Research Support Available

In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, name of the PD/PI, start and end dates, and the amount of the award. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should describe a contingency plan for how the fellow's research will be supported.

The role of the sponsor/co-sponsor in the Research Training Plan should be described. If one or more co-sponsors is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.

B. Sponsor's/Co-Sponsor's Previous Fellows/Trainees

State the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative, and for those five, provide information on their time spent in the lab, their present employing organizations, and their present position titles or occupations.

C. Training Plan, Environment, Research Facilities

The applicant's Research Training Plan should be individualized for the applicant, keeping in mind the candidate's strengths and any gaps in needed skills. The Research Training Plan should be designed to enhance both research and clinical training (if applicable).

Describe the Research Training Plan that you have developed specifically for the fellowship applicant. Be sure to include the following points:

- Include items such as classes, seminars, opportunities for interaction with other groups and scientists, and any professional skills development opportunities.
- Describe the research environment and available research facilities and equipment.
- Indicate the relationship of the proposed research training to the applicant's career goals.
- Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals.

The information contained in the "Training Plan, Environment, Research Facilities" section of the Sponsor's and Co-sponsors' Statements should be coordinated with information provided under the <u>Description of Institutional Environment and Commitment to Training</u> attachment below.

F30 Applications: The Research Training Plan should provide opportunities to integrate clinical experiences during the research training component; a plan for a smooth transition to the clinical training component; and should have the potential to facilitate the applicant's transition to a residency or other program appropriate for his/her career goals. Sponsors and co-sponsors should discuss these clinical aspects of the applicant's training as well.

F31, F32, F33 Applications: The Research Training Plan should facilitate the applicant's transition to the next stage of his/her career. Sponsors and co-sponsors should discuss this aspect of the Research Training Plan as well.

D. Number of Fellows/Trainees to be Supervised During the Fellowship

Indicate how many pre- and/or post- doctoral fellows/trainees the Sponsor/Cosponsor is expected to supervise during the award period. Co-sponsor statements must also include this information.

E. Applicant's Qualifications and Potential for a Research Career

Describe how the fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level. Include information about how the Research Training Plan, and your own expertise as the sponsor or co-sponsor, will assist in producing an independent researcher.

10. 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 Reference Letters page.

Format:

Follow the page limits for Letters of Support from Collaborators, Contributors, and Consultants in the NIH Table of Page Limits unless otherwise specified in the FOA.

Letters of support must be appended together and uploaded as a single PDF file. See NIH's Format Attachments page.

Content:

If any collaborators, consultants, or advisors are expected to make substantive contributions to the fellow's planned project and research training, attach letters of support from those individuals here, describing their anticipated role and contributions.

Institutional Environment And Commitment To Training Section

11. Description of Institutional Environment and Commitment to Training

Who must complete the "Description of Institutional Environment and Commitment to Training" attachment:

The "Description of Institutional Environment and Commitment to Training" attachment is required, and includes "Educational Information" for F30 and F31 applications.

Format:

Follow the page limits for the Description of Institutional Environment and Commitment to Training in the <u>NIH Table of Page Limits</u> unless otherwise specified in the FOA.

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

Content:

Document a strong, well-established research program related to the candidate's area of interest. Describe opportunities for intellectual interactions with other investigators,

including courses offered, journal clubs, seminars, and presentations. Indicate the facilities and other resources that will be made available for both career enhancement and the research proposed in this application. Refer to the resources description in G.220 - R&R Other Project Information Form, Facilities and Other Resources, and information provided in the Sponsor and Co-sponsor Statements attachment.

F30 and F31 applications: Educational Information

Describe the institution's dual-degree (F30) or graduate (F31) program in which the applicant is enrolled. This description should include the structure of the program, the required milestones and their usual timing, the number of courses, any teaching commitments or qualifying exams, and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program's timeline, and the frequency and method by which the program formally monitors and evaluates a student's progress.

For F30 applications specifically, describe any clinical tutorials during the graduate research years and any activities to ease transition from the graduate to the clinical years of the dual-degree program. Describe any research-associated activities during the clinical years of the dual-degree program.

Include the name of the individual providing this information at the end of the description. This information is typically provided by the director of the graduate program or the department chair.

Other Research Training Plan Section

Vertebrate Animals

Are Vertebrate Animals Used?

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

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 19 and 20 below.

If you have answered "Yes" for activities involving vertebrate animals: Answer Ouestions 19 and 20 below in consultation with both your Sponsor and AO.

12. 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.

13. 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.220 - R&R Other Project Information Form.

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.

Content:

If 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 vertebrate animals in the work outlined in the "Research Strategy" attachment. 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.

Provide a concise, complete description of the animals and proposed procedures. In addition to the three points above, you should also:

- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in 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
- Supplemental Instructions, Part III, Section 2.2: Vertebrate Animals (an applicable Animal Welfare Assurance will be required if the grantee institution does not have one)

14. 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 Format Attachments page.

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 Supplemental Instructions, Part III, Section 2.13: Select Agent Research.

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 42 CFR 73.3, 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 applicants 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 institution, 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 institution, 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.

15. Resource Sharing Plan

Format:

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

Content:

Data Sharing Plan: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. **For more information**, see the NIH <u>Data Sharing Policy</u> or the NIH Guide Notice on <u>Sharing Research Data</u>.

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 Supplemental Instructions, Part III, Section 1.5.2: Sharing Model Organism Policy and the NIH Guide Notice on Sharing Model Organisms for Biomedical Research.

Genomic Data Sharing (GDS): Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information**, see the NIH GDS Policy, the NIH Guide Notice on Genomic Data Sharing Policy, and the GDS website.

Note on GDS: For proposed studies generating human genomic data under the scope of the GDS Policy, an Institutional Certification may be submitted at the time of application submission, but it is not required at that time. The Institutional Certification, however, will be requested as Just-in-Time (JIT) information prior to award. The Institutional Certification, or in some cases, a Provisional Institutional Certification, must be submitted and accepted before the award can be issued.

For more information:

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. See Supplemental Instructions, Part III, Section 1.5: Sharing Research Resources.

16. Authentication of Key Biological and/or Chemical Resources

Do not submit an "Authentication of Key Biological and/or Chemical Resources" attachment unless it is specifically requested in the FOA.

Additional Information Section

17. Human Embryonic Stem Cells

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

For additional guidance, see the NIH Guide Notice on the <u>Change in Requirements for NIH Applications Involving Human Embryonic Stem Cells</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 applicant. 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," please 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 (month/year):

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 applicant 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 FOA. 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 FOA 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 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, please describe in an attached file:

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

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 Applicants:

Individual NRSA Fellowship Requirements: To be eligible for a Kirschstein-NRSA individual fellowship (F30, F31, F32, F33), the fellowship applicant 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 FOA.

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 applicant'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 Applicants:

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."

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.

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 "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 applicant 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 applicant currently holds a temporary U.S. visa.

If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, please also check here:

If the fellowship applicant 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

1. 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 Applicants: List, by year, the estimated costs of tuition and fees.

Postdoctoral and Senior Fellowship Applicants: List, by year, the costs associated with specific courses that both support the research training experience and that are identified and described in the "Activities Planned Under this Award" section of the Applicant's Background and Goals for Fellowship Training attachment.

For more information:

In accordance with NIH Guide Notice on <u>Ruth L. Kirschstein National Research Service Award Policy</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.

2. Present Institutional Base Salary

Who must complete the "Institutional Base Salary" section:

Only senior fellowship applicants 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).

3. Stipends/Salary During First Year of Proposed Fellowship

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

Only senior fellowship applicants 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

Appendix

Refer to the FOA to determine whether an appendix is allowed in your application.



The appendix policy will be changing as of January 24, 2017. Please note that there are two sets of instructions below, based on the application due dates.

For applications submitted for due dates on or before January 24, 2017:

Format:

See NIH's Format Attachments page. A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 Appendix attachments are needed, combine the

remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications.

For materials that cannot be submitted electronically or materials that cannot be converted to PDF (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Do not use the Appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. For additional information regarding appendix material and page limits, refer to the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.

Use file names for attachments that are descriptive of the content.

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

Applications that do not follow the Appendix requirements will not be reviewed.

Content:

You **may** include the following items in the Appendix (note, however, that some FOAs do not permit publications):

- Publications are not allowed as appendix materials except in the circumstances noted below. When submitting an article, submit the entire article as a PDF attachment. Applicants may submit up to 3 of the following types of publications:
 - Manuscripts and/or abstracts accepted for publication but not yet published.
 - Published manuscripts and/or abstracts for which a free, online, publicly available journal link is not available.
- Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
- Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.

Do **not** include the following items in the Appendix:

- Unpublished theses or abstracts/manuscripts submitted (but not yet accepted) for publication.
- Digital photographs or color images of gels, micrographs, etc. (These images must be included in the Research Strategy PDF). However, images embedded in publications are allowed.
- Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers, along with the full reference, should be included as appropriate in the Bibliography and References Cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.



For applications submitted for due dates on or after January 25, 2017:

Format:

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 Appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of Appendix items, not the total number of publications.

For materials that cannot be submitted electronically or materials that cannot be converted to PDF (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.

Do not use the Appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. For additional information regarding appendix material and page limits, refer to the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.

Use file names 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:

For applications proposing clinical trials (unless the FOA provides other instructions for these materials):

- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items
 - o If Appendix materials are required in the FOA, review criteria for that FOA will address those materials, and applications submitted without those Appendix materials will be considered incomplete and will not be reviewed.

Note: Applications that do not follow the appendix requirements will not be reviewed. Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this section.

For more information:

- 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. For more
 information, see the NIH Guide Notice on <u>Compliance with NIH Application Format</u>
 and Content Instructions.
- Unless the FOA requires that certain information be included in the Appendix, failure
 of reviewers to address appendix materials in their reviews is not an acceptable
 basis for an appeal of initial peer review. For more information, see the NIH Guide
 Notice on Appeals of NIH Initial Peer Review.