G.420 - PHS 398 Research Training Program Plan Form

Who should use the PHS 398 Research Training Program Plan Form:

Use the PHS 398 Research Training Program Plan Form only if you are submitting a training application or a multi-project application that has an "NRSA Training" Component.

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

Note on required tables: The instructions for the required Data Tables (1-8) are located on the NIH's Data Tables page. Please read the “Introduction to Data Tables” before beginning to prepare your data tables. The Introduction to Data Tables includes important definitions that should be used consistently both in the "Data Tables" attachment of your application and in all other parts of the application. The Data Tables must be included in the "Data Tables" attachment to avoid being counted against the page limits of other attachments.

Note on non-required tables: Additional tables (i.e., those that are generated by the applicant or not required by the FOA) should be identified by letter, rather than number, to avoid confusion with the sequentially numbered required tables.

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 to Application (for Resubmission and Revision)

Who must complete the “Introduction to Application” attachment:

An "Introduction to Application" attachment is required only if the type of application is resubmission or revision 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 NIH Table of Page Limits unless otherwise specified in the FOA. Note that page limits for the Introduction may differ based on the type of application (i.e., resubmission or revision).

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 Resubmission Applications page.

Competing Revision Applications: See specific instructions on the content of the Introduction on the NIH's Competing Revisions page.

Additional Instructions for Multi-project:

Other Components: The "Introduction" attachment is optional for resubmissions and revisions applications. Although the "Introduction" attachment is optional, you may get a system warning if there is no attachment.

Training Program Section

2. Program Plan

Who must complete the "Program Plan" attachment:

The "Program Plan" attachment is required.

Format:

Follow the page limits for the Program Plan in the NIH Table of Page Limits unless otherwise specified in the FOA. The Program Plan (including sections "A. Background;" "B. Program Plan;" and "C. Recruitment Plan to Enhance Diversity," when applicable) must fit within the Program Plan page limit unless otherwise specified in the FOA.

Note that Data Tables may be referred to or summarized in this section; however, the actual tables are not to be included in this attachment.

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

Content:

Organize the Program Plan attachment in the specified order and use the instructions provided below unless otherwise specified in the FOA. Start each section with the appropriate heading – Background, Program Plan, and Recruitment Plan to Enhance Diversity. In addition, start each subsection of the Program Plan with the appropriate subheading.

Check the FOA and the instructions for the Data Tables to determine which tables should be included in the application and discussed in the Program Plan subsection.

A. Background

Provide the rationale for the proposed research training program, the relevant background history, and the need for the proposed research training.

Indicate how the proposed program relates to current training activities at the applicant institution.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program.

If required, complete Tables 1-3 (these tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables as applicable.

Table 1. Census of Participating Departments and Interdepartmental Programs: Describe the organization of the proposed training program, the participating departments and interdepartmental programs, and the extent to which faculty, graduate students, and/or postdoctorates from those departments/interdepartmental programs participate in the programmatic activities to be supported by the training grant.

Table 2. Participating Faculty Members: Describe the distribution of participating faculty by academic rank, department or interdepartmental program, areas of research emphasis, and the rationale for the faculty selected to participate in the training grant. Analyze the data in terms of the overall experience of the faculty in training predoctorates and/or postdoctorates. Comment on the inclusion of faculty whose mentoring records may suggest limited, recent training experience at either training level (predoctoral or postdoctoral).

Table 3. Federal Institutional Research Training Grant and Related Support Available to Participating Faculty Members: Summarize the level of research training support at the institution. Comment on instances where the tabular data indicate that there may be substantial overlap of participating faculty.

B. Program Plan

Note: Applicants for institutional career development awards (e.g., K12) must complete a Research Career Development Program Plan instead of the Training Program Plan. Refer to specific instructions in the FOA.

a. Program Administration

Program Director information: Describe the program director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, and experience in research training. Indicate the program director's percent effort in the proposed program.

Administrative information: Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

Special Instructions for Multiple PD/PI: If multiple PD/PIs are proposed, explain in this section your rationale for how this will facilitate program administration. In addition, you must complete the Multiple PD/PI Leadership Plan attachment in this form.

b. Program Faculty

Referring to the data presented in Table 2. Participating Faculty Members, describe each faculty member's research that is relevant to the program and indicate how trainees will participate in the research. Provide information on the extent to which participating faculty members have cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

Use this section to document the ability of the faculty to support the research activities of the proposed trainees, the training record of the participating faculty members, and the success of their trainees in generating publishable research results. For any

proposed participating faculty (i.e., program faculty) members lacking research training experience, describe a plan to ensure that they will successfully guide trainees. Describe the criteria used to appoint and remove faculty as program faculty and to evaluate their participation.

If required, complete Tables 4-5 (these Tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables, as applicable.

> **Table 4. Research Support of Participating Faculty Members:** Analyze the data in terms of total and average grant support. Additionally, comment on the inclusion of faculty without research grant support and explain how the research of trainees who may work with these faculty members would be supported.
>
> **Table 5A-C. Publications of Those in Training:** Summarize these data, including, for example, the average number of publications, and how many students have published their work. For pre- and postdoctoral training programs, indicate how many trainees are published as first author, and how many completed their doctoral or postdoctoral training without any first-author publication.
>
> **Note for New Applications and/or if required by the FOA:** If you do not have current trainees but still must include Table 5, list publications for trainees who are representative of those who would be appointed if the grant is awarded.

c. Proposed Training

Describe the proposed training program. Indicate the training level(s) and number of trainees, the academic and research background needed to pursue the proposed training, and, as appropriate, plans to accommodate differences in preparation among trainees. For postdoctoral trainees, indicate the proposed distribution by degree (e.g., M.D., Ph.D.). Describe course work, research opportunities and the extent to which trainees will participate directly in research, activities designed to develop technical and/or professional skills, and the duration of training, i.e., usual period of time required to complete the training offered.

For multi-disciplinary and/or multi-departmental programs, indicate how the individual disciplinary and/or departmental components of the program are integrated and coordinated and how they will relate to an individual trainee's experience.

For training programs that emphasize research training for clinicians, describe the interactions with basic science departments and scientists. Include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is expected for all postdoctoral trainees with health professional degrees. Describe fully any trainee’s access to and responsibility for patients, including time commitment.

Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the mentor and research areas are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated. Include detailed mentoring plans as appropriate.

d. Training Program Evaluation

Describe an evaluation plan to review and determine the quality and effectiveness of the training program. This should include plans to obtain feedback from current and

former trainees to help identify weaknesses in the training program and to provide suggestions for program improvements. Specified evaluation metrics should be tied to the goals of the program. In addition, describe plans for assessing the career development and progression of trainees, including publications, degree completion, and post-training positions.

Renewal Applications: Discuss evaluation results, and indicate whether the program has been modified as a result.

e. Trainee Candidates

Describe, in general terms, the size and qualifications of the pool of trainee candidates, including information about the types of prior clinical and research training and the career level required for the program. Describe specific plans to recruit candidates and explain how these plans will be implemented (see also "Section C. Recruitment Plan to Enhance Diversity" within the Program Plan). Describe the nomination and selection process to be used to select candidates who will be offered admission to the program and criteria for trainees' reappointment to the program.

If required, complete Tables 6A and/or 6B (these Tables will be included in the Data Tables attachment), and summarize the data here using the guidance below. In your narrative, refer to specific tables as applicable.

> **Tables 6A and/or 6B. Applicants, Entrants, and their Characteristics for the Past Five Years (Predoctoral and Postdoctoral)**. Summarize the data in terms of the overall numbers of potential trainees, their credentials, their characteristics, their eligibility for support, and enrollment trends.

f. Institutional Environment and Commitment to Training

Include information in the application that documents the support and commitment of the applicant organization and participating units and departments to the goals of the proposed program. This could include, for example, space, shared laboratory facilities and equipment, funds for curriculum development, release time for the PD/PI and participating faculty, support for additional trainees in the program, or any other creative ways to improve the environment for the establishment and growth of the research training program.

Include a signed letter, on institutional letterhead, that describes the applicant organization's commitment to the planned program (see instructions in the Letters of Support section). Institutions with ongoing research training, student development, or career development programs that receive external funding should explain what distinguishes the proposed program from existing ones at the same trainee level; how the programs will synergize, if applicable; whether trainees are expected to transition from one support program to another; and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones.

g. Qualifications of Trainee Candidates and Admissions and Completion Records

Describe the ability of the participating departments/programs to recruit and retain trainees through the completion of their training, the selectivity of the admissions process, and the success of the departments/programs in recruiting individuals from diverse backgrounds (see also Section C. Recruitment Plan to Enhance Diversity within the Program Plan).

Discuss the quality and depth of the applicant pools, including both training-grant eligible and non-training-grant eligible individuals, the competitiveness of the program, and the charactersitics of current program participants, referring to the data in Tables 6A and/or 6B, as applicable.

Use all of this information to justify the number of positions requested.

If required, complete Tables 7-8 (these Tables will be included in the Data Tables attachment) and summarize the data using the guidance below. In your narrative, refer to specific tables as applicable.

Table 7. Appointments to the Training Grant for Each Year of the Current Project Period: Describe the utilization of awarded training positions. If any trainee positions were not filled, if any trainees terminated early, or if the distribution of appointed positions differs from the distribution of awarded positions, provide an explanation.

Table 8A-D. Program Outcomes: Referring to relevant components of Table 8 (e.g. 8A, 8B, 8C and/or 8D, as appropriate), describe how training positions are used (i.e., distribution by mentor, year in program, years of support per trainee), and the success of the program in achieving its training objectives. For those who have completed their training, describe the extent of their current involvement in research, including research grant support received subsequent to completion of the training program.

Renewal applications: Discuss the selectivity of appointments to the training grant, and if any postdoctoral trainee with a health professional degree was appointed to a Kirschstein-NRSA training grant for less than 2 years of research training, explain why.

C. Recruitment Plan to Enhance Diversity

Who must complete the "Recruitment Plan to Enhance Diversity:"

A Recruitment Plan to Enhance Diversity is required for all training grant activity codes **except** T34, T36, U2R, and all D-series activity codes. All other applications without a Recruitment Plan to Enhance Diversity will be considered incomplete and will not be reviewed.

Content:

History and Achievements

Describe efforts to recruit trainees from Diversity Groups A and B, as well as group C (when applicable), into the existing training program. Refer to Supplemental Instructions, Part III, Section 1.19: Recruitment Plan to Enhance Diversity for the descriptions of Diversity Groups. As applicable, refer to the data presented in Tables 6 and 7. Use these data to document the program's past record of recruiting trainees who are underrepresented and to provide information on their support.

Proposed plans

Describe steps to be taken during the proposed award period to identify and recruit graduate students and postdoctorates from Diversity Groups A and B, as well as group C (when applicable). Refer to Supplemental Instructions, Part III, Section 1.19: Recruitment Plan to Enhance Diversity for the descriptions of Diversity Groups. Consider the success and/or failures of recruitment strategies used in the

past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school, and/or the university at large. In most cases, centralized institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups, and training grant faculty are expected to be actively involved in recruitment efforts.

New Applications: Include a description of plans to enhance recruitment, including the strategies that will be used to enhance the recruitment of trainees from underrepresented backgrounds.

Renewal Applications: Include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period, including successful and unsuccessful recruitment strategies. Information should be included on how the proposed plan reflects the program's past experiences in recruiting individuals from underrepresented groups.

For more information:

Refer to Supplemental Instructions, Part III, Section 1.19: Recruitment Plan to Enhance Diversity.

3. Plan for Instruction in the Responsible Conduct of Research

Who must complete the "Plan for Instruction in the Responsible Conduct of Research" attachment:

A "Plan for Instruction in the Responsible Conduct of Research (RCR)" attachment is required for all training grant activity codes except T36, unless otherwise noted in the FOA. Applications lacking a Plan for Instruction in RCR will not be reviewed.

Format:

Follow the page limits for the Plan for Instruction in the Responsible Conduct of Research 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:

The plan must address the five required instructional components outlined in the NIH Policy on Instruction in RCR, as more fully described in the Supplemental Instructions, Part III, Section 1.16: Policy on Instruction in the Responsible Conduct of Research:

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 roles of mentor(s) and other faculty involvement in the instruction.
4. **Duration of Instruction:** Describe the total number of contact hours of instruction.
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.

The plan must also describe how participation in RCR instruction will be monitored.

Renewal Applications: Describe any changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

For more information:

See the Supplemental Instructions, Part III, Section 1.16: Policy on Instruction in the Responsible Conduct of Research.

See the NIH Guide Notices

- Submission of Plans for Instruction in the Responsible Conduct of Research for T and D Applications,
- Submission of Plans for Instruction in the Responsible Conduct of Research for T32 Applications, and
- Requirement for Instruction in the Responsible Conduct of Research .

4. Plan for Instruction in Methods for Enhancing Reproducibility

Do not submit a “Plan for Instruction in Methods for Enhancing Reproducibility” attachment unless it is specifically required in the FOA.

5. Multiple PD/PI Leadership Plan (if applicable)

Who must complete the “Multiple PD/PI Leadership Plan” attachment:

Any applicant who designates multiple PD/PIs (on the G.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the G.240 - R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.

Do not submit a leadership plan if you are not submitting a multiple PD/PI application.

Additional Instructions for Multi-project:

Overall Component: The “Multiple PD/PI Leadership Plan” attachment is required only in the Overall Component.

Format:

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

Content:

The emphasis in a training grant's Multiple PD/PI Leadership Plan should be on how multiple PD/PIs will benefit the program and the trainees. A single PD/PI must be designated as Contact PD/PI (in G.200 - SF 424 (R&R) Form, PD/PI Contact Information) for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD/PI when necessary. Because training programs are intended to be coherent, NIH will not allocate the budget or training positions between multiple PD/PIs. A single award will be made. Multiple PD/PI plans should include reasonable numbers of PD/PIs and each should be included for a specific and clearly

stated purpose. Usually, program mentors and participating faculty are not listed in the G.240 - R&R Senior/Key Person Profile (Expanded) Form; rather, they only provide biosketches in the Participating Faculty Biosketches attachment below.

A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

For more information:

For background information on the multiple-PD/PI initiative, see NIH's Multiple Principal Investigators page.

6. Progress Report (for RENEWAL Applications Only)

Who must complete the "Progress Report" attachment:

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

Format:

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

Content:

Indicate the period covered since the last competitive review and briefly describe the accomplishments of the training program. Describe any specific effects of this training program on curriculum and/or research directions. Describe how the funds provided under Training Related Expenses were used to benefit the program.

For each trainee supported during the period covered, include the following information about his/her training, as applicable:

- Degrees working toward or held
- Mentor(s)
- Description of the trainee/scholar's research project and progress
- Coursework
- Conference presentations
- A description of the trainee's role in any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper)
- Fellowships or other support
- Workshops attended
- Career development activities

Indicate whether the institution utilizes Individual Development Plans (IDPs), and if so, describe how they were used in this reporting period to help manage the training and career development of the trainees. Do not include actual IDPs. **Neither IDPs nor information about IDPs is required for AHRQ trainees**.

Note that a My Bibliography report of publications arising from work conducted by trainees while supported by the training grant is not required at the time of submission, but will be requested as Just-in-time (JIT) information prior to award.

Additional Instructions for Multi-project:

Overall and Other Components: If you include a "Progress Report Publication List" attachment, you can include it in either the Overall Component or within the Other Component, but do not attach the same information in multiple locations.

Faculty, Trainees, and Training Record Section

7. Participating Faculty Biosketches

Format:

Combine all participating faculty biosketches into a single PDF and attach this information here. Follow the attachment guidelines on NIH's Format Attachments page.

Content:

Faculty biosketches for participating faculty must follow the instructions for a biographical sketch (refer to G.240 - Senior/Key Person Profile (Expanded) Form) with the following exception: a personal statement, while encouraged, is not required.

Please note that the biosketches of the PD/PI and any other senior/key personnel (e.g., co-directors, if applicable, and program staff) should not be included here, but they should instead be included in the G.240 - R&R Senior/Key Person Profile (Expanded) Form.

8. Letters of Support

Format:

Combine all Letters of Support into a single PDF file and attach this information here. Do not place these letters in the Appendix. Follow the attachment guidelines on NIH's Format Attachments page.

Content:

Attach letters here from:

- Consultants, if applicable. Letters should include rate/charge for consulting services and confirm their role(s) in the project.
- Senior Administration Officials. This letter should be a signed letter on institutional letterhead, and it should describe the applicant institution's commitment to the planned program.

Check the FOA (particularly for non-NRSA programs) to determine whether any additional program-specific letters of support are required.

9. Data Tables

Format:

The information provided in the required data tables (Data Tables 1-8 described below) will not be counted toward the page limitation. These tables should be numbered consecutively and titled as instructed. Start each numbered table on a new page.

Bookmark each table separately in the PDF attachment. Many PDF generators will automatically create bookmarks from text formatted using predefined Heading styles in Word.

Combine all Data Tables into a single PDF file and attach it here. See NIH's Format Attachments page.

Content:

Instructions for Data Tables 1-8 are located on NIH's Data Tables page. These instructions include an Introduction to the Data Tables that provides instructions applicable to all tables, specific instructions for each table, and Sample Data Tables. The sample data tables illustrate the kind of data to include in each table for training grant applications.

If not using the Extramural Trainee Reporting and Career Tracking (xTRACT) system to prepare data tables, be sure to choose the Instruction and Blank Data Table set that correspond to both the type of application you are submitting (e.g., new application, renewal or revision application) and the kind of training to be provided (e.g., predoctoral only, postdoctoral only, pre and postdoctoral mixed, etc.).

Other Training Program Section

10. 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 section to circumvent the page limits of the Program Plan.

Content:

Trainee Participation Only in Research Involving Vertebrate Animals that is Part of Other Research Project Grants: Describe how the institution will ensure that trainees participate only in IACUC-approved vertebrate animal research if the following two conditions apply:

- the training program uses live vertebrate animals only as part of other research project grants, and
- the training grant does not support the purchase, use, or husbandry of live vertebrate animals.

Independent Trainee Research Involving Vertebrate Animals: In training programs where trainees will design and conduct their own independent vertebrate animal research, follow the instructions below:

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 "Program Plan" 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)

11. 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 of Disease Control and Prevention (CDC) and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See the Federal Select Agent Program website.

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

Content:

If participating faculty proposed in the training program are conducting or plan to conduct research involving select agents in which trainees may participate, follow the instructions below.

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, 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 Select Agents and Toxins Exclusions 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 42 CFR 73.1 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.

12. Consortium/Contractual Arrangements

Who must complete the "Consortium/Contractual Arrangements" attachment:

Include the "Consortium/Contractual Arrangement" attachment if you have consortiums/contracts in your budget.

Format:

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

Content:

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

Note: The signature of the authorized organization representative on the G.200 - SF 424 (R&R) form, Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

> *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

For more information:

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

Appendix

13. 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 section. 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 limitations of the Training Plan 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.

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):

Research publications of trainees and mentors are not normally included as part of the Training Grant Applications, but are allowed. Note that only publications reflecting the activities of the program as a whole may be included. When submitting an article, submit the entire article as a PDF attachment and limit publications to those which are not publicly available, such as:

- 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.

Some materials that are unique to training grant applications (but not typically included in research grant applications) may be included in the Appendix. In general, the Appendix may be used to provide samples of materials that are referred to in the body of the application, but are too cumbersome to include in the Research Training Program Plan without disrupting the narrative flow. Examples include:

- Syllabi for key courses, core courses and electives, including courses in the RCR;
- Retreat, seminar series, and other program activity agendas, and schedules;
- Examples of forms used to document trainee progress and monitoring by the program;
- Examples of materials used in recruitment, particularly recruitment to enhance the diversity of the applicant pool;
- Lists of meetings attended by trainees and their presentations; and
- Trainee biosketches.

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 Program Plan 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 Progress Report section of the Research Training Program Plan, and/or in the Biographical Sketch.
- As a reminder, tables other than the required Data Tables 1-8, must be incorporated into the page limit of the Program Plan. Follow the page limits for institutional training grants specified in the NIH Table of Page Limits, unless otherwise specified in the FOA. These additional tables must not be included in the Appendix.

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.

As a reminder, tables *other* than the required Data Tables 1-8 must be incorporated into the Program Plan (and will count toward the Program Plan's page limits), and must not be included in the Appendix. Follow the page limits for Institutional Training Grants specified in the NIH Table of Page Limits, unless otherwise specified in the FOA.

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 Program Plan 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 all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items
    - 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 Compliance with NIH Application Format 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.