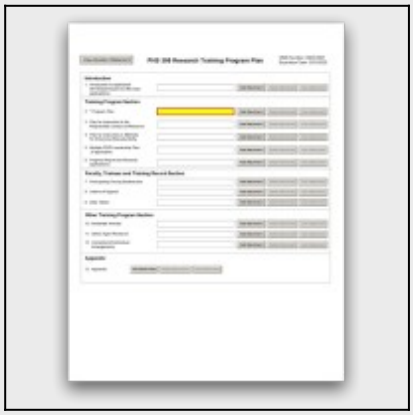
G.420 - PHS 398 Research Training Program Plan Form

The PHS 398 Research Training Program Plan Form is used only for Training applications and Multi-project applications with an "NRSA Training" Component.

This form includes fields to upload several attachments including the Program Plan, Faculty Biosketches, and Data Tables.

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



View larger image

Quick Links

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 NOFO 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 NOFO) 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 formatting, page limits, and proprietary information. See the following pages for more information:

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

Introduction

1. Introduction to Application (for Resubmission and Revision applications)

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 NOFO 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 NOFO. 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.

> Note: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple

PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the introduction.

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 NOFO. The Program Plan (including sections "A. Background" and "B. Program Plan") must fit within the Program Plan page limit unless otherwise specified in the NOFO.

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 NOFO. Start each section with the appropriate heading – Background or Program Plan. In addition, start each subsection of the Program Plan with the appropriate subheading.

Check the NOFO 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. Describe the training program goals and objectives related to the program rationale.

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

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 and areas of research emphasis. Describe 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 organization. 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 NOFO.

a. Program Administration *(Training Program Director(s)/Principal Investigator(s))*

Program Director information: Describe the program director's qualifications for providing leadership of the program, including relevant scientific background, current research areas, experience in research training, and commitment to training future researchers. Indicate the program director's percent effort in the proposed program. Describe how the PD(s)/PI(s) will receive training on effective mentoring practices to promote trainee success and foster an inclusive, safe, and supportive research training environment.

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.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the program plan and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the program plan.

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. In programs where trainees will have multiple mentors, describe how the training faculty will effectively coordinate communication, training, and mentorship responsibilities.

Use this section to document the ability of the faculty to support the research activities of the proposed trainees, the training experience of the participating faculty members, the success of their trainees in generating publishable research results, and how previous mentoring experience will support their role in the proposed training program (for early career faculty participating in the program, mentoring experience from their time as a postdoctoral scientist or in a non-faculty position can be included).

Describe planned mentor training activities for the participating faculty to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds. 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. Active 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 5. Publications of Trainees Supported by this Program:** 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:** List publications for students and/or postdoctorates 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 programs that propose short-term training, any didactic training must be well structured and appropriately justified for the duration of the training experience. Short-

term trainees must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or enhancing their research skills and knowledge in preparation for a health-related research career.

For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational and mentoring practices, and to evaluation of the training program.

Describe how the program and faculty will provide training in scientific reasoning, rigorous research design, relevant experimental methods, relevant quantitative and data science approaches, and data analysis and interpretation, appropriate to the level and prior preparation of the trainees.

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.

Describe career development activities for trainees involved in the program. Include discussion of how trainees will be provided with information about the careers in the biomedical research workforce for which their training may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers. Describe involvement of relevant program faculty and staff in activities to promote trainee career progression.

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.

Training programs that anticipate offering trainees opportunities to be involved in human subjects research funded by other research grants may include a brief description of those opportunities in this section, although such a description is not required.

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, as well as plans to respond to appropriate feedback. 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 and Retention Plans

Describe, in general terms, the size of the pool of the training program candidate pool, including information about the types of prior clinical and research training and the career level. Describe specific plans to recruit candidates and explain how these plans will be implemented (plans may expand upon but should not duplicate those found in the "Recruitment Plan to Enhance Diversity" attachment). 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. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program. Note: While program admissions processes can consider a variety of factors – such as how a trainee candidate's experiences and perspectives further their commitment to program goals and a career in the biomedical research workforce - programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or candidate as an eligibility or selection criteria.

Describe trainee retention plans (that is, activities designed to sustain the scientific interests and participation of trainees from all backgrounds in 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 6. Training Program Candidates, 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 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. Training Outcomes

Describe the ability of the participating departments/programs to recruit potential trainees and retain trainees through the completion of their training, the results of the admissions process (e.g., how many offers and matriculants), and the experience of the departments/programs in recruiting potential trainees from diverse backgrounds (see "Recruitment Plan to Enhance Diversity" attachment).

Discuss the applicant pools, including both training-grant eligible and non-training-grant eligible individuals, and the characteristics of current program participants, referring to the data in Table 6, 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.

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

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 8. Program Outcomes: Referring to relevant components of Table 8, 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 goals and 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 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.

3. 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:

Scope

For purposes of this requirement, "recruitment" means outreach efforts intended to encourage individuals to apply for the training grant program. These are efforts that occur prior to the candidate review and selection process. "Recruitment" does not mean the appointment or hiring of an individual into the training grant program.

History and Achievements

Describe efforts to diversify the program applicant pool by recruiting potential trainees from underrepresented groups, for example, underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds, for the existing training program. Refer to the Notice of NIH's Interest

in Diversity for examples of groups underrepresented in the biomedical research enterprise.

Proposed Plans

Describe steps to be taken during the proposed award period to identify and recruit potential training program candidates from underrepresented groups, for example individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds (see Notice of NIH's Interest in Diversity). Additionally, literature shows that women from these backgrounds face particular challenges at the graduate level and beyond in scientific fields. 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 potential trainees 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 potential trainees from underrepresented groups.

Renewal Applications: Include an account of experiences in recruiting potential trainees 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 the Notice of NIH's Interest in Diversity.

4. 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 NOFO. 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 NOFO.

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 NIH Grants Policy Statement, Section 11.3.3.5: Training 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 NIH Grants Policy Statement, Section 11.3.3.5: Training in the Responsible Conduct of Research.

5. Plan for Instruction in Methods for Enhancing Reproducibility

Who must complete the "Plan for Instruction in Methods for Enhancing Reproducibility" attachment:

A "Plan for Instruction in Methods for Enhancing Reproducibility" attachment is required for all training grant activity codes except D71, unless otherwise noted in the NOFO. Applications lacking a Plan for Instruction in Methods for Enhancing Reproducibility will not be reviewed.

Format:

Follow the page limits for the Plan for Instruction in Methods for Enhancing Reproducibility in the NIH Table of Page Limits, unless otherwise specified in the NOFO.

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

Content:

The plan must describe how trainees will be instructed in principles important for enhancing research reproducibility. These principles include, at a minimum, the following:

- evaluation of the foundational research underlying a project (i.e., the rigor of the prior research);
- rigorous experimental design and data interpretation;
- consideration of relevant biological variables such as sex;
- authentication of key biological and/or chemical resources; and
- transparency in reporting.

Include a description of how instructional strategies will be integrated into the overall training program at multiple stages of trainee development and in a variety of formats and contexts. Describe how program faculty will reiterate and augment key elements of methods for enhancing reproducibility in the context of trainees' research projects.

Renewal Applications: Describe any changes in instruction over the past project period and plans that address any weaknesses in the current instruction for methods for enhancing reproducibility.

6. 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.

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

Resubmission Applications: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan.

Renewal Applications: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the

applicant must provide a rationale for the change in the program plan and include the required Multiple PD/PI Leadership Plan.

For more information:

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

7. Progress Report (for Renewal applications)

Who must complete the "Progress Report" attachment:

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

Format:

Follow the page limits given below, unless otherwise specified in the NOFO.

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

Content:

Organize the Progress Report according to the specified sections. Start each section with the appropriate heading – Program Overview or Progress of Those Appointed to the Grant.

Program Overview (Page limit: 5 pages)

Provide an overview of accomplishments and progress achieved in the period since the last competitive review. Focus on elements specific to the training program (rather than on opportunities generally available in the institution's other departments or other programs).

If training goals from the previous period were not met, provide explanations and explain alternative approaches taken to address them.

Describe how the funds provided under Training Related Expenses were used to benefit the program.

List any workshops or seminars sponsored by the program. Include the workshop/seminar titles, speakers, and relevance to the theme and training objectives of the program.

Indicate whether the training program uses Individual Development Plans (IDPs). If so, describe how IDPs were used in this reporting period to help manage the trainees'/scholars' training and career development.

Note: Do not include actual IDPs or blank IDP forms.

Note for AHRQ trainees: Neither IDPs nor information about IDPs is required.

You may refer to information that is included elsewhere in the application, such as the Program Plan or outcomes described in the Training Data Tables, but do not repeat that information in the Progress Report.

Progress of Those Appointed to the Grant (Page limit: 1 page per appointee)

For each trainee or scholar appointed to the grant in the period covered since the last competitive review, provide a summary of his or her training and progress, including the following information, as applicable:

- Degrees working toward or received;
- Mentor(s);
- Description of the trainee/scholar's research project and progress;
- Career development activities (e.g., individualized coursework or workshops attended);
- Conference presentations;
- A description of the trainee's contribution to any planned or published papers resulting from research conducted while supported by this award (e.g., designed or conducted experiment, analyzed data, drafted paper); and
- Honors, awards, fellowships, and any other support received during the period of training. **Note:** Support before and after the appointment is reported in the Data Tables and should not be reported here.

Do not include the following, either in the Progress Report or elsewhere in the application (including the Appendix), unless otherwise specified in the NOFO:

- Biosketches of current or former trainees/scholars;
- Any sensitive personally identifiable information, such as photographs or any other individual demographic information;
- Actual IDPs or blank IDP forms;
- Promotional material for workshops, seminars, or other events (flyers, agendas, etc.);
- Course syllabi; and
- Program brochures.

Applications that include any of these materials will be withdrawn and not reviewed.

Note: A My Bibliography report of publications arising from work conducted by trainees while supported by the training grant is not required in the application. However, it will be collected in the Interim Final Research Performance Progress Report.

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, andTraining Record Section

8. 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.

9. 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. Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the funding opportunity.

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.
- A President, Provost, Dean, Department Chair, or other key institutional leader with institution-wide responsibilities. This letter should be a signed letter on institutional letterhead, and it should describe and acknowledge institutional commitment to the following areas:
    - Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices;
    - Responding appropriately to allegations of discriminatory practices, including any required notifications to the HHS Office of Civil Rights; and
    - Adopting and following institutional procedure for requesting NIH prior approval of a change in the status of the Program Director/Principal Investigator (PD/PI) or other senior/key personnel if administrative or disciplinary action is taken that impacts the ability of the PD/PI or other key personnel to continue his/her role on the NIH award as described in the training grant application.

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

For more information:

Notice of Clarification Regarding Harassment and Discrimination Protections in NIH Training Applications

NIH Grants Policy Statement, Section 4.1.2: Civil Rights Protections

NIH Grants Policy Statement, Section 8.1.2.6: Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NOA.

10. 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

11. 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 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 live vertebrate animals in the work outlined

in the “Program Plan” attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

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

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

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

See the following pages for more information:

- NIH’s Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirement (an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

12. Select Agent Research

Who must complete the “Select Agent Research” attachment:

Include a “Select Agent Research” attachment if the proposed training activities will 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 NIH Grants Policy Statement, Section 4.1.24.1: Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents).

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 organization, 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.

13. 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. Use of hyperlinks and URLs is not allowed in this section unless specified by the funding opportunity.

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 recipient.

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.

14. Other Plan(s)

For NIH Training Grant Applicants, the Data Management and Sharing (DMS) Plan is not required.

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

Additional Instructions for Multi-project:

Overall Component: Include a single consolidated "Data Management and Sharing Plan" in the Overall Component.

Other Components: Do not include a "Data Management and Sharing Plan" within other components. Any component-specific information should be described within the overall "Data Management and Sharing Plan" attachment in the Overall Component.

Appendix

15. Appendix

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

Additional Instructions for Multi-project:

Overall and Other Components: The "Appendix" attachment is optional.

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. Use of hyperlinks and URLs is not allowed unless specified by the funding opportunity.

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 NOFO.

Use filenames for attachments that are descriptive of the content.

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

Content:

The only allowable appendix materials are:

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

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

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

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

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

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

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

For more information:

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