

NIH T32 Guide – Forms D

This checklist is meant to be used as a tool and does not replace the detailed requirements for submission information, which are found in the SF424 (R&R) Application Packages – Research Instructions for NIH and Other Agencies

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/training-forms-d.pdf

| PI Name: |
|---|
| Title: |
| A "new" application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A "revision" application must have the same title as the currently funded grant. NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation. |
| Project Dates: |
| Standard Due Dates for Competing Applications: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm |
| The usual start date for an institutional training grant is July 1, but there are other possible start dates. Refer to the <u>Table of IC-Specific Information</u> , Requirements and Staff Contacts in your FOA or contact the awarding component staff for further information. |
| Solicitation: |
| Parent Announcements (For Unsolicited or Investigator-Initiated Applications): http://grants.nih.gov/grants/guide/parent_announcements.htm |

Format Attachments Requirements

- must be in PDF format
- font size must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible)
- text color must be black with the following recommended fonts: arial, garamond, georgia, helvetica, palatino linotype, times new roman, verdana
- do not include headers or footers in attachments
- use paper size no larger than standard letter paper size (8.5" x 11")
- provide at least one-half inch margins (top, bottom, left, right) for all pages

Additional formatting information can be found here: http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

SF424 (R&R) Forms

\square Cover Letter Attachment (no page limit but generally 1 – 2 pages)

Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions. Applicants are encouraged to include a cover letter with the competing application. The cover letter should no longer be used for assignment requests. The new PHS assignment form is used for that purpose. Instead the cover letter should be used to relay information such as:

- Reason for late application
- Explanation of why a Subaward isn't active in all periods of the proposed project
- Statements regarding agency approval documents (e.g., requests over \$500,000)
- Intent to submit a video as part of the application (NOT-OD-12-141)
- Indication that the proposed study will generate large-scale human or nonhuman genomic data (NOT-OD-14-111 and NOT-OD-15-027)

Full instructions pages T-28 & T-29

☐ **Project Summary/Abstract** (30 lines of text maximum)

State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Provide an abstract of the entire application. Include the objectives, rationale and design of the research training program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees including their levels (i.e., predoctoral, postdoctoral, short-term) and intended trainee outcomes.

Full instructions pages T-41 & T-42

☐ **Project Narrative** (2 or 3 sentence maximum)

Using no more than two or three sentences, describe the relevance of this research to public health. Full instructions page T-42

☐ Bibliography & References Cited (no page limit)

Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number for each article. The Bibliography & References Cited attachment should be used only to cite references supporting the need, rationale, and approach for the training program described in the Research Training Program Plan. Do not include lists of publications of project directors, mentors or trainees in this section, as this information will be included in the biosketches and Data Tables. Full instructions pages T-42 & T-43

☐ Facilities & Other Resources (no page limit)

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. If there are multiple performance sites, describe the resources available at each site. Describe any special facilities used for working with biohazards or other potentially dangerous substances. Describe the facilities and resources that will be used in the proposed training program, including any foreign performance sites. Indicate how the applicant organization will support the program, financial or otherwise (e.g., supplementation of stipends, protected time for mentoring, support for student activities). This could also 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. Full instructions pages T-43 & T-44

□ Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Full instructions page T-44

□ Other Attachments

An Advisory Committee is not a required component of the training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory Committee to monitor progress of the training [career development] program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Name the file "Advisory_Committee.pdf".

R&R Senior/Key Person Profile

Unless otherwise specified in an agency announcement, senior/key personnel are the program director/principal investigator (PI/PD) and other individuals who contribute to the scientific development or execution of the project in a substantive, measureable way whether or not salaries are requested.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the

project. These individuals are typically presented at effort of "zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). OSCs should be listed after all senior/key persons. A biosketch is required for all senior/key persons and Other Significant Contributors.

Do not include proposed mentors and training faculty members (except in the rare cases where they are also senior/key persons). Biographical sketches for mentors and other participating faculty will be included in the "Participating Faculty Biosketches" attachment

☐ Biographical Sketch (5 page limit)

see Appendix B for biographical sketch reference sheet

PHS 398 Training Budget Form

Use this form for T32 applications regardless of the amount of the requested budget. If you are requesting a budget with \$500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting the application. Some NIH Institutes/Centers (IC) do not require prior approval.

□ Budget Justification

see Appendix C for Budget Justification description and examples

PHS 398 Research Training Program Plan Form

☐ Introduction to Application (for resubmission or revision only, 3 page limit)

NIH allows a thirty-seven month window for resubmission (only one resubmission is allowed for each new, unfunded application). Include an introduction for all resubmissions that summarizes substantial additions, deletions, and changes to the application and responds to the issues and criticism raised in the summary statement. Full instructions page T-87 and http://grants.nih.gov/grants/policy/amendedapps.htm

□ Program Plan (25 page limit)

Organize the Program Plan attachment in the specified order and use the instructions provided 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.

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.

B. Program Plan

The Program Plan should include the following sections: A. Program Administration; B. Program Faculty; C. Proposed Training; D. Training Program Evaluation; E. Trainee Candidates; F. Institutional Environment and Commitment to Training; G. Qualifications of Trainee Candidates and Admissions and Completion Records

C. Recruitment Plan to Enhance Diversity

Describe efforts to recruit trainees from Diversity Groups A and B, as well as group C (when applicable) – see <u>Supplemental Instructions</u>, <u>Part III</u>, <u>Section 1.19</u>: <u>Recruitment Plan to Enhance Diversity</u> for the descriptions of Diversity Groups. 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 university at large.

Full instructions pages T-88 – T-92

☐ Plan For Instruction in the Responsible Conduct of Research (3 page limit)

The plan must address the five required instructional components outlined in the NIH Policy:

- Format the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only online instruction is not acceptable)
- 2. Subject Matter the breadth of subject matter, i.e., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics
- 3. Faculty Participation the role of the mentor(s) and other faculty involvement in the instruction
- 4. Duration of Instruction 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

Full instructions pages T-92 & T-93

| ☐ 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. |
|---|
| Multiple PD/PI Leadership Plan (if applicable) Any applicant who designates multiple PD/PIs must include a Multiple PD/PI Leadership Plan. 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 for the purpose of communicating with the NIH, although other individuals may contact the NIH on behalf of the Contact PD/PI when necessary. 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. Full instructions page T-94 |
| ☐ Progress Report (renewal applications only) 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's/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, 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. Full instructions page T-95 |
| □ Participating Faculty biosketches Combine all participating faculty biosketches into a single PDF. Faculty biosketches for participating faculty must follow the instructions for a biographical sketch with the following exception: a personal statement, while encouraged, is not required. Full instructions pages T-95 |
| □ <u>Letters of Support</u> Combine all Letters of Support into a single PDF file. Include a letter from a Senior Administration Official. This letter should be a signed letter on institutional letterhead, and it should describe the applicant institution's commitment to the planned program. Full instructions page T-96 |

☐ **Data Tables**The information

The information provided in the required data tables 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. Instructions for Data Tables 1 – 8 are located on NIH's <u>Data Tables</u> 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. Full instructions page T-96

☐ Human Subjects

Human subjects should be answered as "no" and the following language included as the Human Subjects Narrative attachment:

Brown University will ensure that trainees only participate in exempt human subjects research or non-exempt human subjects research that has IRB approval. This training program will involve the use of human subjects solely as part of other research project grants, and no portion of the Training Grant Award will be used to support the involvement of human subjects in this research.

☐ Data Safety Monitoring Plan

Complete this section if you answered "yes" to Item 1, Clinical Trial. Refer to Supplemental Instructions, Part II Section 4.1.5, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ <u>Vertebrate Animals</u>

Vertebrate animals should be answered as "no" and the following language included as the Vertebrate Animals Narrative attachment:

This training grant will involve the use of live vertebrate animals solely as part of other research project grants, and no portion of the Training Grant Award will be used to support the purchase, use, or husbandry of live vertebrate animals in this research.

☐ Select Agent Research

If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period (list of agents: http://www.selectagents.gov/), either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place:

- 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.
- 3. Provide a description of all facilities where the select agent(s) will be used.

Full instructions pages T-99 & T-100

□ Consortium/Contractual Arrangements

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s) The Letter of Intent from the Consortium site is uploaded here. Full instructions page T-100

□ Appendix

A maximum of 10 PDF attachments is allowed in the appendix. 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. The only allowable appendix materials are: blank informed consent/assent forms; blank surveys, questionnaires, data collection instruments; FOA-specific items

PHS Assignment Request Form

The optional Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs). This information was previously collected in the Cover Letter Attachment, but now this optional information must be provided on the Assignment Request Form and not in the Cover Letter Attachment. Full instructions pages T-102 & T-103

NIH T32 Checklist - Forms D

| Cover Letter (generally 1 – 2 pages, only if applicable) |
|--|
| Project Summary/Abstract (30 lines of text maximum) |
| Project Narrative (2 or 3 sentences maximum) |
| Bibliography & References Cited |
| Facilities & Other Resources |
| Equipment |
| Biographical Sketch (5 page limit) |
| Budget Justification |
| Introduction to Application (for resubmission or renewal only, 1 page limit) |
| Program Plan (25 page limit) |
| Plan for Instruction in the Responsible Conduct of Research (3 page limit) |
| Multiple PD/PI Leadership Plan (if applicable) |
| Progress Report (renewal application only) |
| Participating Faculty Biosketches (5 page limit/Biosketch) |
| Letters of Support |
| Data Tables |
| Human Subjects |
| Data Safety Monitoring Plan (if clinical trial) |
| Vertebrate Animals |
| Select Agent Research (if application involves the use of select agents) |
| Consortium/Contractual Arrangements |
| Appendix |
| Assignment Request Form |

Appendix A – Additional Items Required For Subcontractors

| Official organization name, DUNS number, address |
|--|
| Administrative contact information for Institution |
| Contact information from PI |
| NIH biographical sketch for Subaward PI |
| Letter of Intent to collaborate/consortium letter from Authorized (OSP) Official |
| Letter of Support from collaborating Senior/Key Personnel |
| COI Disclosure from PI (or evidence that their Institution is in compliance) |
| Information about Facilities/Equipment/Resources to add to Brown application |
| Budget on R&R Budget Pages and budget justification |
| Scope of Work (describes the actual work being completed by the Collaborator) |

NIH General Biographical Sketch Reference Sheet

The biographical sketch may not exceed five pages and follows the format below:

A. Personal Statement

- Briefly describe why you are well-suited for your role in the project described in this application
- Identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project
- May explain impediments to your past productivity and include a description of factors such as family care responsibilities, illness, disability, and active military service

B. Positions and Honors

 List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

- Briefly describe up to five of your most significant contributions to science
- For each contribution, reference up to four-peer reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) *note: applicants may use 'et al' in lieu of listing all authors in a citation
- The description of each contribution should be no longer than one half page including figures and citations
- May provide a URL to a full list of published work this URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required, and reviewers are not required to look at the list.

D. Research Support

- List both selected ongoing and completed research projects for the past three years (Federal or non-Federally supported)
- Begin with the projects that are most relevant to the research proposed in the application
- Do not include number of person months or direct costs

Appendix C - Budget Justification

Budget Justification

Use the budget justification to provide the additional information requested in each budget category identified and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support, and other direct cost categories.

T32 budgets include:

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience. Stipend levels, as well as funding amounts for tuition and fees are announced annually in the *NIH Guide for Grants and Contracts*, and are also posted on Research Training-Resources-Polices and Notices webpage.

Example:

We are requesting 4 predoctoral training slots per year for a period of five years. As discussed in the application, we believe this level of support is commensurate with our trainee pool as well as the resources of our program. The 2017-18 stipend for graduate students in the BioMed Division is \$30,618 per year, and per NIH guidelines, we request \$23,844 in stipend funding per trainee.

Funds are also requested to support tuition and health fees of 4 trainees for a period of 5 years, at the current NIH cap of \$16,000 per trainee. Actual tuition costs for the 2017-18 academic year are \$54,580 per trainee, and health fees are \$888 per trainee, for a total of \$55,468 per trainee. A 4.5% inflator has been used to calculate these costs in years 2 – 5.

Trainee Travel

Trainee travel to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable trainee expense for predoctoral and postdoctoral trainees. The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicants should consult the <u>Table of IC-Specific Information</u>, Requirements and Staff Contacts on the FOA for further information.

Example:

Funds are requested to support trainee travel to a regional and/or national scientific meeting each year. \$300 per trainee per year is requested.

Training Related Expenses

NIH will provide funds to help defray other training related expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff directly related to the research training program. The most recent levels of training related expenses are described on the Ruth L. Kirschstein National Research Service Award (NRSA) site.

Example:

Institutional costs of \$4,200 per year per trainee are requested to defray the costs of other training related expenses such as trainee health insurance, printing of posters for students attending conferences, purchase of reference books and lab manuals for shared used by students in the program, outreach activities such as website development, and travel costs for the external advisors.