NIH NRSA Application Checklist.

Research Workforce Development, A. Hall November 2022

This document supplements but does not replace NIH guidance. Please be sure to read the program solicitation and guidelines thoroughly--and check for updates--before preparing your proposal. As of this writing, the F31 parent guideline is <u>PA-21-051</u> the F31 diversity announcement is <u>PA-20-251</u> and the F32 announcement is <u>PA-20-242</u>. You will also need to reference the NIH SF424 <u>Application Guide</u>, and the <u>Fellowship Instructions Forms Version F</u> [pdf].

APPLICANT COMPONENTS (Refer to details below).

Done	Section	Description
	Cover Letter	Include application title, Funding Announcement
	Assignment Request Form	Your desired study section
	Biosketches	Key personnel. Include PMCID for all references.
	Senior/Key Person	Key personnel and role
	Budget	Stipend, Tuition, Institutional Allowance
	Project Narrative	3 sentences.
	Project Summary	30 lines of text
	Introduction to Application	Resubmissions only. 1 page limit
	Applicant's Background	6-page limit
	and Goals for Fellowship Training	
	Specific Aims	1-page limit
	Research Strategy	6-page limit
	Respective Contributions	1-page limit
	Selection of Sponsor and Institution	1-page limit
	Training in Responsible Conduct of Research	1-page limit. Template available to modify
	Sponsor and Co-Sponsor Statements	6-page limit
	Letters of support from collaborators, contributors and consultants	6-page limit. Combined as a single PDF
	Institutional Environment and commitment to training	Template available to modify
	Training Rigor & Reproducibility	Template available to modify
	Diversity Eligibility	Template available to modify

Fellowship Budget Components

Done	Section	Description
	Tuition	GW graduate tuition '22-'23 CCAS <u>here</u> ; \$1885 per credit
	Health insurance	Graduate SHIP <u>here</u> ; \$2700 per year Postdoctoral Scholar medical benefits
	NRSA stipend FY2022 here	Indicate source of funds to bring up to GW stipend.

Before you begin:

Please submit an **Intent to Submit Form** to GW Grants and Contracts to alert them to your intended submission date. They will work with you on the SF 424 cover page information and upload documents for routing. Be nice to them, they are helping you.

NIH proposals are submitted electronically by MyResearch via the NIH ASSIST System.

The individual Fellowship applicant for whom support is being requested is designated as the PD/PI on the application and must be registered in eRA Commons as PI. Contact Debbie Pomerantz to get eRA Commons user account.

Proposals MUST be submitted on or before 5:00pm Local Time on Deadline Date. If an NIH "standard deadline" date falls on a weekend or *Federal* holiday, the deadline is extended to the following business day.

Note: You must provide a complete (draft) application to GW Grants and Contracts 5-7 business days before the NIH deadline to allow approvals. You can revise your documents during the review period and submit final versions before the application is submitted to NIH by GW.

Application Format

- Each section is submitted as its own PDF file. Limit file names to 50 characters or less and use only standard characters. Do not use any other special characters (e.g., "&", "*", "%", "/", or "#") in the file name.
- Margins are ½" all around (in Microsoft Word, choose "narrow")
- Font = black; Arial, Garamond, Georgia, Helvetica, Times New Roman, or Verdana typeface are recommended; size 11 or larger; must be no more than 15 characters per linear inch (including characters and spaces)
- Do not include headers or footers
- Project Title limited to 200 characters including spaces and punctuation
- Use section headings
- **1. Cover Letter:** Format guidelines found in SF424 Application Guide. Include Application title, Funding Opportunity title
- 2. Project Summary /Abstract 30 lines max; summary of the research, fellowship training plan, and environment. Briefly describe the research project to be conducted under the fellowship award, describe the fellowship training plan and the environment in which the research training will take place. The entire "Project Summary/Abstract" attachment is limited to 30 lines of text.

3. Research Training Plan

- a. Introduction (1 page required only for a resubmission). Summarize changes made to application based on reviewer comments
- b. Specific Aims Page **(1 page)**: Concisely state what is known, and what gap your study. will address, indicate goals/objectives of the proposed research. Summarize expected outcomes, including the impact the results will exert on the research field.
- c. Research Strategy (6 pages): Include the following within these sections
 - i. Significance
 - 1. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
 - 2. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

ii. Approach

- 1. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- 2. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 3. Describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- **4. Narrative -** short 2-3 sentences for lay audience explaining "relevance to public health"
- 5. Bibliography and References cited Each reference must include all authors' names, article/journal title, book title, vol#, pg.#, year of publication and if applicable, NIH Manuscript Submission or PMCID numbers if available.
- 6. Facilities/Resources (no page limit). Identify facilities (Laboratory, Animal, Computer, Office, Clinical and Other) and resources directly applicable to the proposed work. Describe how GWs scientific environment will contribute to the project's success. If there are multiple performance sites, describe resources available at each site. Provide a detailed description of the institutional facilities and resources available to the Fellowship applicant. The information provided is important to establish the feasibility of the goals of the fellowship training plan.
- 7. Equipment (no page limit). List equipment available to the program to demonstrate capability of research site. List major equipment already available. Identify locations and pertinent capabilities.
- **8. Other Attachments**: Maybe required by FOA.
 - a. If this is an (F31) Pre-doctoral Fellowships (F31) to Promote Diversity, a Certification Letter is required. The Certification Letter (titled Diversity_Eligibility_Ltr) from the institution is certifying eligibility of the Fellowship applicant for the program. The letter should avoid revealing sensitive personal information, such as the candidate's specific racial/ethnic background or type of disability. The Certification Letter must be on institutional letterhead and scanned so that an institutional official signature is visible.
 - b. **Need attachment if asking for child care costs**: If requesting funding for child care, an attachment must be named "**Childcare_Cost_Request.pdf**" (without quotation marks). The attachment must specify the requested childcare costs amount, and number of years requested. The Recipients are not required to submit supporting documentation with each request. Recipients must maintain all supporting documentation (e.g., proof provider is licensed). NIH reserves the right to request proof at any time. See guidance online.
- **9. Biosketches (5 page maximum/person)**: Required for the PD/PI-applicant fellow, sponsor, co-sponsor(s), and other significant contributors. For each, include:
 - a. <u>Education</u> Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing.
 - b. <u>Personal statement</u> -briefly describe why you are well-suited for the award. Relevant factors may include training, previous work, technical expertise, collaborators or scientific environment, past performance in research field. If you wish to explain impediments to your past productivity, you may include a description of the factors.

Identify up to **4** peer-reviewed publications that specifically highlight your experience and qualifications for this project.

- c. <u>Positions and Honors</u>-chronological order, include all applicable non-degree training, employment, and military service.
- d. <u>Contributions to Science-Describe up to 5 of your most significant contributions to science to date.</u> For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the relevance of the finding(s) to science, technology, or public health; and your specific role in the described work. For each contribution, you may reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations.
- e. Provide a URL to a full list of your 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. Manuscripts listed as "pending publication" or "in preparation" should be included and identified. Indicate if you previously used another name that is reflected in any of the citations. Add your **ORCID ID** as well.
- f. Scholastic Performance. Predoctoral applicants (F31) should include <u>all</u> courses in the Scholastic Performance section. Postdoctoral applicants (F32) should include <u>all</u> scientific and/or professional courses in the Scholastic Performance section. List by institution and year all graduate scientific and/or professional courses with grades. In addition, explain any grading system used if it differs from a 1-100 scale; an A, B, C, D, F system; or a 0-4.0 scale. Also indicate the levels required for a passing grade.

PHS 398 Fellowship Supplement

- 10. Introduction: Use ONLY for Resubmission. Limited to ONE PAGE unless specified otherwise in FOA.
- 11. Applicant's Background and Goals Section I(6 page limit) [Upload as one PDF document. Use section headings.]
 - a. <u>Doctoral Dissertation and Research Experience</u>: Summarize your research experience in chronological order. Advanced graduate students, who have (or will have) completed their comprehensive examinations by the time of award, must also include a narrative of their doctoral dissertation (may be preliminary). If you have no research experience, list other scientific experience. Do not list academic courses. In summarizing their research experience, include the areas studied and conclusions drawn. Postdoctoral fellowship applicants should also specify which areas of research were part of their thesis or dissertation and which, if any, were part of a previous postdoctoral project.
 - b. <u>Training Goals and Objectives</u>: Describe your overall training goals for the duration of the fellowship, and explain how the proposed fellowship will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. As

applicable, discuss how the proposed research will facilitate your transition to the next career stage.

- i. The activities planned under this award should be individually tailored and well-integrated with your research project. Describe the skills and techniques that you intend to learn as well as any planned, non-research activities (e.g. those relating to professional development and clinical activities) during the award period.
- c. <u>Activities Planned Under this Award</u>: Describe, by year, the activities (research, coursework, etc.) youwill be involved in during the proposed award and estimate the percentage of time to be devoted to each activity, based on a normal working day for a full-time fellow as defined by the sponsoring institution; the percentage should total 100 for each year. Provide a timeline detailing the proposed research training and related activities for the entire duration of the program

12. Research Training Plan

- a. Specific Aims (1 page): Concisely state goals/objectives of the proposed research.

 Summarize expected outcomes, including the impact the results will exert on the research field.
- b. Research Strategy (6 pages): Include the following within these sections

i. Significance

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

ii. Approach

- 1. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- 2. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 13. Respective Contributions (1 page limit): Describe the collaborative process between you and your sponsor/co- sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research.
- **14. Selection of Sponsor and Institution (1 page limit)**: Describe the rationale/justification for the selection of the sponsor and institution.
 - a. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here.
 - b. Doctorate or Current Institution. (<u>For postdoctoral and senior fellows only</u>) Since training is expected to broaden a fellow's perspective, postdoctoral fellowship applicants requesting training at either their doctorate institution or at the institution where they have been training for more than a year must explain why further training at that institution would be valuable.
 - c. Foreign Institution. If you are proposing a research training experience at a foreign institution, show that the foreign institution and sponsor offer special opportunities for training that are not currently available in the United States. Key factors in the selection of a foreign institution should be described. If applicable, the need for and level of proficiency in reading, speaking, and

comprehending the foreign language should be addressed.

- 15. Responsible Conduct of Research (1 page limit) RWD has template language that may be modified] The plan must address the five, required instructional components outlined in the NIH policy:
 - a. Format 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);
 - b. Subject Matter the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics;
 - c. Faculty Participation the role of the mentor(s) and other faculty involvement in the instruction;
 - d. Duration of Instruction the total number of contact hours of instruction; and
 - e. Frequency of Instruction instruction must occur during each career stage and at least once every four years.
- **16. Sponsors & Co-Sponsors** (if any) **(6 page limit)** Create a heading at the top of the first page titled "Section II-- Sponsor and Co-Sponsor Information."
 - a. Research Support Available
 - i. In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should provide a contingency plan for how the fellow's research will be supported. Include this information for any co-sponsor as well.
 - ii. The role of the sponsor in the integrated research and training plan should be described. If a sponsor team is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively.
 - b. Sponsor's/Co-Sponsor's Previous Fellows/Trainees.
 - i. Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide information on time spent in the lab their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.
 - c. Training Plan, Environment, Research Facilities
 - i. Describe the research training plan that you have developed specifically for the Fellowship applicant. The training plan should be individualized for the applicant, keeping in mind the candidate's strengths and any gaps in needed skills, and should be designed to enhance both research and clinical training (if applicable). Include items such as classes, seminars, opportunities for interaction with other groups and scientists and any professional skills development opportunities. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals. This information should be coordinated with information provided under Description of Institutional Environment and Commitment to Training. For F31, F32, F33 applicants, the training plan should facilitate the applicant's transition to the next stage of his/her career.
 - d. Number of Fellows/Trainees to be Supervised. During the Fellowship. Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.
 - e. Applicant's Qualifications and Potential for a Research Career. Describe how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and your own expertise as the sponsor

will assist in producing an independent researcher.

f. Fellowship applicants who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): the sponsor or co-sponsor is required to include a statement to document leadership of the clinical trial. The statement must include the following: Source of funding, ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable; and a description of how the sponsor or co-sponsor's expertise is appropriate to guide the applicant in any proposed clinical trials research experience.

17. Letters of Support from Collaborators, Contributors, and Consultants (6 page limit; combine into one pdf)

• Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc. Relevant information applicable to the fellow's planned research training and future goals may be provided by any contributor or advisor via an attachment.

18. Description of Institutional Environment and Commitment to Training (2 page limit)

- RWD has template language that may be modified.
- The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the facilities and resources description, indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. This information should be coordinated with information provided under Sponsor and Co-Sponsor Statements, Training Plan, Environment, Research Facilities.
- Additional Educational Information (required for F30 and F31 applications): Describe the institution's dual-degree (F30) or graduate (F31) program in which the applicant is enrolled, e.g. the structure of the program, required milestones and their usual timing (number of courses, any teaching commitments, qualifying exams, etc.) and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program's timeline, and the frequency and method by which the program formally monitors and evaluates a student's progress.
- This information is <u>typically provided by the director of the graduate program</u> or the department chair. Include the name of the individual providing this information at the end of the description.
- Note that a listing of the applicant's courses and grades must be included in the Fellowship Applicant Biographical Sketch, and NOT in this attachment.

19. Description of Candidate's Contribution to Program Goals - 2 page limit

- Applicants to diversity-related FOAs (e.g., diversity-related F31): The "Description of Candidate's Contribution to Program Goals" attachment is required.
- All other Fellowship applicants: Skip the "Description of Candidate's Contribution to Program Goals" attachment, as it is not required.
- The sponsoring institution must provide a document on institutional letterhead that explains how the candidate's participation will further the goals of the fellowship program to promote diversity in health- related research. Letter must be dates and signed by Institutional Official (i.e., dean or chairperson of department).

20. Other Research Training Plan (complete as needed):

- a. Vertebrate Animals required if answered "YES" to the question 'are vertebrate animals involved?
 - i. Description of procedures
 - ii. Justifications

- iii. Minimization of Pain and Distress
- iv. must additional identify all project performance sites and explain when and how animals are anticipated to be used if plans have not been finalized.
- b. Select Agent Research if Yes, include attachment addressing the following 3 points:
 - i. identify select agents to be used
 - ii. Provide the registration status of all entities* where select agent(s) will be used.
 - iii. Provide a description of all facilities where the select agent(s) will be used.
- c. Resource Sharing Plan complete as applicable
- d. Authentication of Key Biological and/or Chemical Resources If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.
- **21. Referee Letters** At least three, but no more than five, reference letters are required.
 - The letters should be from individuals not directly involved in the application, but who are familiar with the applicant's qualifications, training, and interests.
 - The sponsor/co-sponsor(s) of the application cannot be counted toward the three required references.
 - Make sure you include a list of referees (including name, departmental affiliation, and institution) in the cover letter of the application so that the NIH staff will be aware of planned reference letter submissions.
 - Referees must submit reference letters through the eRA Commons by the application due date.
 - Referees will need to provide the following information with their reference letter:
 - o PI's (fellow/candidate's) eRA Commons user name
 - o PI's first and last name as they appear on the PI's eRA Commons account
 - Number of the funding opportunity announcement to which you are applying

Application Guidance:

- SF424 Instructions
- Fellowship Information
- Page limits
- Deadline dates
- Avoid common errors