NIH F31/F32 FELLOWSHIP APPLICATION DEVELOPMENT

1. **Identify** federal institute or private foundation with stated missions confluent with proposed research;
2. **Review** funding announcement and notify Research Office of intent to submit;
3. **Meet** with advisor/sponsor, Director of Statistics Core, Grant Analyst

NRSA APPLICATION COMPONENTS

I. **Research Training Plan Components**

**Cover Letter: No more than one page.**
Must include 1) Application title; 2) Funding Opportunity title and number; 3) Statement that you have attached any required agency approval documentation for the type of application submitted; 4) list of Referees including the names, degrees, and affiliations of the individuals from whom you have asked to submit reference letters. Optionally, include: 1) disciplines involved, if multidisciplinary; 2) Request of an assignment (referral) to a particular Institute/Center or Scientific Review Group; 3) list of individuals (e.g., competitors) who should not review your application and why.

**Project Summary/Abstract: No more than 30 lines of text.**
The Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research training program design and methods for achieving the stated goals. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. Do not include proprietary, confidential information or trade secrets in the description section, since this will become public information if the project is funded.

**Project Narrative: No more than three sentences.**
Describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

**Specific Aims: Specific Aims are limited to one page.**
State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
Research Strategy: **Research Strategy is limited to six pages.**
The Research Training Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies. This section should be well-formulated and presented in sufficient detail that it can be evaluated for both its research training potential and scientific merit. It is important that it be developed in collaboration with your sponsor, but it should be written by you, the fellowship applicant. All figures and photographs should be included inline in the strategy, not in the Appendix or elsewhere in the application. Be succinct and remember that there is no requirement to use all six pages allotted. Internet Web site addresses (URLs) may not be used to provide information necessary to the review, except for reference citations, because reviewers are under no obligation to view the Internet sites. Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading — Significance, Approach and Preliminary Studies (if applicable). Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited.

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

**Approach**
- 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.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in a separate section.
- Include any courses that you plan to take to support the research training experience.

If an applicant has multiple Specific Aims, then the applicant may address Significance and Approach for each Specific Aim individually or collectively.

**Preliminary Studies:** include information on preliminary studies, if any. Discuss the applicant's preliminary studies, data and/or experience pertinent to this application. When applicable, provide a succinct account of published and unpublished results, indicating progress toward their achievement.

**Appendix:** no page limit, but do not use the Appendix to circumvent the page limitations of any section for which a page limit applies.
Do not include photographs or color images of gels, micrographs, etc. The Appendix can include up to three publications if accepted/published and not publicly available. A summary sheet is encouraged. Patents, surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.

**References:** no page limit.
Must include PMCID numbers where available. If you use Endnote, import citations from PubMed, download the NIH output style from the Endnote website, and this will be done automatically.

**Special disclosures/sections required if you are conducting:** Clinical Trials; Phase-III Clinical Trials; vertebrate animals research; select agent research; research on model organisms; genome-wide assay studies; stem cell research. See full instruction set if your research includes these elements.
II. Applicant, Institution and Sponsor Information

Sponsor and Co-Sponsor Information: *This item is limited to six pages.* The sponsor should be an active investigator in the area of the proposed research training and be committed both to the research training of the Fellowship Applicant and to the direct supervision the applicant’s research. The sponsor must document the availability of sufficient research support and facilities for high-quality research training. The sponsor, or a member of the mentoring team, should have a successful track record of mentoring predoctoral students. Applicants are encouraged to identify more than one mentor, i.e., a mentoring team, if this is deemed advantageous for providing expert advice in all aspects of the research and training program. In such cases, one individual must be identified as the principal sponsor who will coordinate the applicant’s research training program. The applicant must work with his/her sponsor(s) in preparing the application. The sponsor should describe the research training plan for the applicant (coordinated with the applicant’s research strategy). The sponsor and any co-sponsors are also expected to provide an assessment of the applicant’s qualifications and potential for a research career. The research environment and the availability and quality of needed research facilities and research resources (e.g., equipment, laboratory space, computer time, available research support, etc.) must also be described. The description should include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Training in career skills, e.g. grant-writing and presentation skills are strongly encouraged.

1. Research Support Available: In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. Include this information for any co-sponsor as well.

2. Sponsor's/Co-Sponsor's Previous Fellows/Trainees: Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.

3. Training Plan, Environment, Research Facilities: Describe the research training plan that you have developed specifically for the Fellowship applicant. Include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals. The description should include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Training in career skills, e.g. grant-writing and presentation skills are strongly encouraged.

4. Number of Fellows/Trainees to be Supervised During the Fellowship: Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.

5. 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.

Selection of Sponsor and Institution: *This item is limited to one page.*

1. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here.

2. 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.

Respective Contributions: *This item is limited to one page.*

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.

Biographical Sketches for Applicant, Sponsor, and co-Sponsors: *limited to four pages each.*

Each sketch is comprised of 1) Personal Statement, 2) Positions and Honors, 3) 15 peer-reviewed publications most relevant to the proposal, and 4) Research Support. See PHS 398 sample and template.
Fellowship References (3-5): The sponsor cannot be counted as a reference. Electronic submission of a Fellowship Reference Form is a separate process from submitting an application electronically. Fellowship Reference Forms are due by the application receipt deadline date. Fellowship Reference Forms are submitted directly through the eRA Commons, while the application is submitted through Grants.gov. Applicants must arrange to have at least three (and no more than five) references submitted using the Fellowship Reference Form on their behalf to the eRA Commons Web site. All fellowship applicants must include a list of Referees in the Cover Letter. The list must include the names, degrees, and affiliations of the individuals from whom you have asked to submit reference letters. At least three references are required. Your references should be carefully selected. Only those individuals who can make the most meaningful comments about your qualifications for a research career should be used. Whenever possible, select at least one referee who is not in your current department. If not submitting a reference from the dissertation advisor or chief of service, provide an explanation. Request reference reports only from individuals who will be able to submit them in time. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay. Give these reference forms to the referees well in advance of the application due date. Technical submission instructions for referees can be found in the Individual Fellowship Application Guide SF424 (R&R), Section 5.4, Part B. The referees must provide information including (a) the PD/PI (Fellowship applicant) Commons user name, (b) the PD/PI first and last name as they appear on the PD/PI’s Commons account, and (c) the Funding Opportunity Announcement number in order for the references to be matched to the application.

Responsible Conduct of Research: This item is limited to one page.
Every fellow must receive instruction in the responsible conduct of research appropriate to the career stage of the applicant. The section must document prior participation or instruction in responsible conduct of research during the applicant's current career stage (including the date instruction was last completed) and propose a plan to either receive instruction in responsible conduct of research or participate as a course lecturer, etc., depending on the applicant's career stage. Applications must include a description, limited to no more than one page, of the sponsoring institution’s plans to provide, and the fellowship applicant’s plans for obtaining, instruction in the responsible conduct of research, including the format, subject matter, faculty participation, duration and frequency of instruction. The plan should be tailored to the needs of the fellow, and may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. The role of the sponsor in the instruction in responsible conduct of research must be described.

Goals for Fellowship Training and Career: This item is limited to one page.
The fellowship applicant must describe his/her overall career goals, and explain how the proposed research training will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award.

Activities Planned Under This Award: This item is limited to one page.
The fellowship applicant must describe by year the activities (research, coursework, etc.) s/he will be involved in under 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. Also, briefly explain activities other than research and relate them to the proposed research training. Predoctoral fellowships (F31) may reflect up to five years.

Doctoral Dissertation and Research Experience: This item is limited to two pages.
Summarize your research experience (limited to 2 pages) 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, Postdoctoral and Senior Fellowship applicants should 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.
III. Human Subjects Research

For all research involving human subjects, a part of the peer review process will include careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children. The Scientific Review Group (SRG) will assess the adequacy of safeguards of the rights and welfare of research participants, and the appropriate inclusion of women, minorities, and children, based on the information in the application. The evaluation of the inclusion plans will be factored into the overall score that the SRGs award for scientific and technical merit of the application. Much of the information on the protection of human subjects that you are required to provide in the Fellowship application is identical to information that you will be required to provide for IRB review at your own institution.

Protection of Human Subjects: no page limitation. This component consists of the four following sections.

1. **Risks to Human Subjects**
   a. Human Subjects Involvement and Characteristics, and Design
      • Describe the proposed involvement of human subjects in the work outlined in the Research Strategy section.
      • Describe and justify the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.
      • Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation.
      • Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners (including those in detention or otherwise institutionalized, and those who are incarcerated during the course of the study), or others who may be considered vulnerable.
      • If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention’s dose, frequency, and administration.
      • List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.
   b. Sources of Materials
      • Describe the research material obtained from living individuals in the form of specimens, records, or data.
      • Describe any data that will be collected from human subjects.
      • Indicate who will have access to individually identifiable private information about human subjects.
      • Provide information about how the specimens, records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.
   c. Potential Risks
      • Describe the potential risks to subjects (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
      • Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

2. **Adequacy of Protection Against Risks**
   a. Recruitment and Informed Consent
      • Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
      • Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted to the PHS agencies unless requested.
   b. Protections Against Risk
      • Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
      • Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to additional instructions for Pregnant Women, Human Fetuses and Neonates; Prisoners; and Children.
Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB, the NIH and others, as appropriate, to ensure the safety of subjects.

3. Potential Benefits of the Proposed Research to Human Subjects and Others
   - Discuss the potential benefits of the research to research participants and others.
   - Discuss why the risks to subjects are reasonable in relation to the benefits to research participants and others.

4. Importance of the Knowledge to be Gained
   - Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
   - Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Targeted/Planned Enrollment Table: All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race. Investigators should report: (a) the number of research participants in each ethnic category; (b) the number of research participants who selected only one category for each of the five racial categories; (c) the total number of research participants who selected multiple racial categories reported as the “number selecting more than one race,” and (d) the number of research participants in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. The full instructions address ways to document use of existing data and data collected at foreign sites.

Inclusion of Women and Minorities: no page limitation, but be succinct. Scientific Review Groups will assess each application as being acceptable or unacceptable with regard to the inclusion of women and minorities in clinical research. Address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below in 4.3.) If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described (item 3 below). Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Tables in this section.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see the full application instructions for examples pertaining to various exclusion scenarios).

4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Inclusion of Children: no page limitation, but be succinct.

- Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion (see the full instructions for examples pertaining to various exclusion scenarios).

- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply: 1) the research topic to be studied is not relevant to children; 2) Laws or regulations bar the inclusion of children in the research; 3) the knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. See the full application instructions for examples pertaining to various exclusion scenarios).
**NRSA SCORING CRITERIA**

**Overall Impact/Merit.** Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood that the fellowship will enhance the applicant’s potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria (as applicable for the project proposed).

**Scored Review Criteria.** Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

*Fellowship Applicant:* Are the applicant’s academic record and research experience of high quality? Does the applicant have the potential to develop as an independent and productive researcher in biomedical, behavioral or clinical science? *Sponsor(s), Collaborator(s), and Consultant(s):* Are the sponsor(s) research qualifications (including successful competition for research support) and track record of mentoring appropriate for the proposed fellowship? Are there (1) evidence of a match between the research interests of the applicant and the sponsor (including an understanding of the applicant’s research training needs) and (2) a demonstrated ability and commitment of the sponsor to assist in meeting these needs? Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed research project?

*Research Training Plan:* Is the proposed research plan of high scientific quality, and does it relate to the applicant’s training plan? Is the training plan consistent with the candidate’s stage of research development? Will the research training plan provide the applicant with individualized and supervised experiences that will develop research skills needed for his/her independent and productive research career?

*Training Potential:* Does the proposed research training plan have the potential to provide the fellow with the requisite individualized and supervised experiences that will develop his/her research skills? Does the proposed research training have the potential to serve as a sound foundation that will lead the fellow to an independent and productive career?

*Institutional Environment and Commitment to Training:* Are the research facilities, resources (e.g. equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate? Is the institutional environment for the scientific development of the applicant of high quality, and is there appropriate institutional commitment to fostering the fellows’ training as an independent and productive researcher?

As applicable for the project proposed, reviewers will consider the following additional terms in the determination of scientific and technical merit, but will not give separate scores for these items.

**Additional Review Criteria.** As applicable, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

*Protections for Human Subjects:* The committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation.

*Inclusion of Women, Minorities, and Children:* When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Where applicable, the following sections will also be evaluated: Vertebrate Animals, Biohazards, Select Agent Research, Resource Sharing Plans.
**INSTRUCTIONS FOR REFEREES**

Reference Forms must be submitted to the eRA Commons* and may be submitted any time after the Funding Opportunity Announcement opens and **not later than the application receipt due date**. Your “letter of reference” **must** be submitted using the Fellowship Reference Form**. Failure to submit the required reference in the appropriate format may result in the application being returned to the applicant without review.

Please put the name of the applicant at the top of the form. The form has three sections: The first section is used to compare the applicant to other individuals of similar training and experience that you have known. The second section is used to enter your evaluation—Note that the form will automatically expand to an additional page as you enter your evaluation (in two pages or less, describe the applicant’s potential for a research career). The third section is the Referee information section. When you are finished with the Fellowship Reference Form, return to the eRA Commons page and complete the following required information:

- Referee First Name (Required)
- Referee Last Name (Required)
- Referee MI Name (middle initial) (Not Required)
- Referee E-mail (Required)
- Referee Institution/Affiliation (Required)
- Referee Department (Required)
- PD/PI (Fellowship applicant) Commons User ID (Required)
- PD/PI’s Last Name, as it appears on the PD/PI’s Commons account (Required) (will be validated to ensure they match)
- Funding Opportunity Announcement Number (Required and **must** match the number of the FOA under which the application is being submitted)
- Reference Letter Confirmation Number (for resubmissions only)
- Fellowship Reference Form – two pages maximum. Complete the format page using word processing software and then convert to PDF using PDF generating software***. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application.

Note that the Fellowship Reference Form can be submitted at any time prior to the receipt deadline. It is **not** necessary to wait until after the application is submitted before the Fellowship Reference Form is submitted; the two submissions are distinct. After you have submitted your Fellowship Reference Form, both you and the applicant will receive a confirmation of receipt by e-mail. Your e-mail confirmation will include a “Reference Letter” Confirmation Number. The Confirmation Number will be required when resubmitting reference forms. Please print the confirmation e-mail for your records.

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* eRA Commons: https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp
** Fellowship Reference Form: http://grants.nih.gov/grants/funding/424/416-1reference.doc