NIH F31 NRSA Predoctoral Fellowship Proposal Checklist **November 2024**

This document supplements NIH guidance. Please be sure to read the program solicitation and guidelines thoroughly before preparing your proposal. The F31 guidelines are here: https://grants.nih.gov/grants/guide/pa-files/PA-23-272.html. Additionally, please reference the NIH Fellowship Instructions Forms I and the SF424 Application Guide.

APPLICATION PROCESS

- NIH proposals are submitted electronically by ORSP via the internal Kuali System.
- All PD/PIs and all individuals with a student role must be registered in the eRA Commons. If new, the PI must register on the eRA Commons at https://commons.era.nih.gov/commons/ and link their ORCID ID with their commons account.

FORMAT SPECIFICATIONS FOR ATTACHMENTS

- PDF files only – file names are 50 characters or less and use only standard characters - A through Z, a through z, 0 through 9, underscore (_), hyphen (-), space ( ), and period (.). Do not use any other special characters (e.g., "&", "*", "%", "/", or "#") in the file name.
- Margins are ½" all around
- Font = black; Arial, Garamond, Georgia, Helvetica, Palatino Linotype, 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 only standard characters
- Use section headings

ATTACHMENTS/INFORMATION NEEDED

1. Cover Letter: Format guidelines found in SF424 Application Guide.
    a. Application title
    b. Funding Opportunity title
    c. For late applications include specific information about the timing and nature of the cause of the delay.
    d. When submitting a Changed/Corrected Application after the due date, a cover letter is required explaining the reason for late submission of the Changed/Corrected Application.
    e. Explanation of any subaward budget components that are not active for all periods of the proposed grant.
    f. Statement that you have attached any required agency approval documentation for the type of application submitted.
    g. When intending to submit a video as part of the application, the cover letter must include information about the intent to submit it; if this is not done, a video will not be accepted.
    h. Include a statement in the cover letter if the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy.
    i. List of Referees: Include names, degrees & affiliations of people submitting reference letters. At least one Referee should be outside the applicant's department. Referees must submit to the eRA Commons website by the application deadline. **At least three, and not more than 5 reference letters are required.**
2. Project/Performance Site Locations:
    a. Include addresses and DUNS Number for all appropriate locations in addition to Marquette
    b. Provide a letter of intent, along with a scope of work and budget from the other institution(s).
3. Project Summary/Abstract **(no more than 30 lines)**: Provide a concise description of project objectives and methodologies suitable for dissemination to the public.
    a. In addition to summarizing 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.
4. Project Narrative **(2-3 sentences)**: Describe relevance of research to public health in lay terms.
5. Bibliography & References Cited in Project Narrative and Fellowship Research Training Plan component **(no page limit)**: Each reference must include all authors' names, article/journal title, book title, vol#, pg.#, year of

publication and if applicable, NIH Manuscript Submission or PubMed Central reference numbers. Do not use "et al" anywhere in this section.

6. Facilities and Other Resources **(no page limit)**: (http://www.marquette.edu/orsp/InstitutionalBoilerplates.shtml)
    a. Identify facilities (Laboratory, Animal, Computer, Office, Clinical and Other) and resources directly applicable to the proposed work.
    b. Describe how Marquette's scientific environment will contribute to the project's success.
    c. If there are multiple performance sites, describe resources available at each site.
    d. Provide in the Attachment a detailed description of the institutional facilities and resources available to the Fellowship applicant. The information provided is of major importance in establishing the feasibility of the goals of the fellowship training plan.
7. Equipment **(no page limit)**: List major equipment already available. Identify locations and pertinent capabilities.
8. Other Attachments (if applicable)
    a. Certification Letter for Predoctoral Fellowships (F31) to Promote Diversity - Applications submitted for individual predoctoral fellowships (F31) to promote diversity in health-related research are required to attach a certification letter (titled Diversity_Eligibility_Ltr) from the institution 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.
9. Biosketches **(5 page maximum/person)**: Required for the PD/PI-applicant fellow, sponsor, co-sponsor(s), and other significant contributors. Downloadable forms for both PD/PI-applicant fellows and sponsors located on the NIH website here: https://grants.nih.gov/grants/forms/biosketch.htm.
    a. Education - Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing.
    b. Include personal statement briefly describing 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. Identify up to **4** peer-reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of the factors.
    c. Positions and Honors in chronological order, include all applicable non-degree training, employment, and military service.
    d. Contributions to Science. Describe up to 5 of your most significant contributions to science to date. 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. You may 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.
    f. Scholastic Performance. Predoctoral applicants/candidates (including undergraduates and post-baccalaureates): List by institution and year all undergraduate and graduate 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.
10. Applicant's Background and Goals for Fellowship Training: **(6 page limit) [Upload as one PDF document. Use section headings.]**
    a. Doctoral Dissertation and Research Experience: 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, 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.

b. Training Goals and Objectives: 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.

c. Activities Planned Under this Award: Describe, by year, the activities (research, coursework, etc.) you will 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. 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. Provide a timeline detailing the proposed research training and related activities for the entire duration of the program

11. Research Training Plan: **[Note: Create separate attachments for each section. Use section headings.]**
    a. Introduction **(1 page - only if a resubmission)** summarize changes made to application based on reviewer comments
    b. 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.
    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.
            3. 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. Unless addressed separately in a Resource Sharing Plan, 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. 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.
            4. 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 the Select Agent Research Plan.
            5. If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.
12. 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.
13. Selection of Sponsor and Institution **(1 page limit)**: Describe the rationale/justification for the selection of the sponsor and institution.
        i. 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.
        ii. Doctorate or Current Institution. (For postdoctoral and senior fellows only) 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. Individuals applying for Senior Fellowships who are requesting training at the institution at which they are employed should provide a similar explanation.

iii. 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.

14. Responsible Conduct of Research **(1 page limit) [ORSP has template language that may be used]** The plan must address the five, required instructional components outlined in the NIH policy:
    i. 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);
    ii. 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;
    iii. Faculty Participation - the role of the mentor(s) and other faculty involvement in the instruction;
    iv. Duration of Instruction - the total number of contact hours of instruction; and
    v. Frequency of Instruction – instruction must occur during each career stage and at least once every four years.
15. 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
        i. Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.
    e. Applicant's Qualifications and Potential for a Research Career

i. 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:
   i. Source of funding;
   ii. ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable; and
   iii. A description of how the sponsor or co-sponsor's expertise is appropriate to guide the applicant in any proposed clinical trials research experience.

16. Letters of Support from Collaborators, Contributors, and Consultants **(6 page limit)**
    a. 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.
17. Description of Institutional Environment and Commitment to Training **(2 page limit)**
    a. 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.
    b. 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.
       i. This information is typically provided by the director of the graduate program or the department chair. Include the name of the individual providing this information at the end of the description.
       ii. 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.
18. Description of Candidate's Contribution to Program Goals – only required for Diversity Applications.
    a. 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.
    b. The "Description of Candidate's Contribution to Program Goals" attachment must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement.
19. Other Research Training Plan Sections (if applicable) **[Create separate attachments for each]**:
    a. Vertebrate Animals - (if applicable, no page limit). Instructions available here http://www.marquette.edu/orsp/documents/NIH-VertebrateAnimalChecklist_Oct2015.pdf
       i. If Vertebrate Animals are involved in the project, address each of the following criteria listed below.
          1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. 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 to minimize discomfort, distress, pain, and injury.

b. Select Agent Research re: use of hazardous biological agents/toxins
c. Resource Sharing Plans
    i. Sharing Model Organisms **(no page limit)**: only if creation of a new model is proposed. Outline plan to make findings available to qualified individuals within the scientific community.
d. Authentication of Key Biological and/or Chemical Resources

20. Assignment Request Form – this is a form page, available from ORSP
21. Referee Letters - Selecting a Referee
    a. **At least three, but no more than five, reference letters are required.**
    b. The letters should be from individuals not directly involved in the application, but who are familiar with the applicant's qualifications, training, and interests.
    c. The sponsor/co-sponsor(s) of the application cannot be counted toward the three required references.
    d. 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.
    e. Referees must submit reference letters through the eRA Commons by the application due date.
    f. Referees will need to provide the following information with their reference letter:
        i. PI's (fellow/candidate's) eRA Commons user name
        ii. PI's first and last name as they appear on the PI's eRA Commons account
        iii. Number of the funding opportunity announcement to which you are applying
22. Human Subjects and Clinical Trials Information **[Create separate documents for each attachment] –** all attachments get uploaded to a single PDF document that ORSP will send to you.
    a. Study Record for each proposed study involving human subjects
        i. Study Title (must be unique for each study record)
        ii. Clinical Trial Questionnaire
    b. Study Population Characteristics
        i. Conditions or focus of study
        ii. Study eligibility criteria
        iii. Age limits (minimum and maximum)
        iv. Inclusion of Women, Minorities, and Children (no page limit)
        v. Recruitment and Retention Plan (no page limit)
        vi. Recruitment Status (select not yet recruiting, recruiting, enrolling by invite, active, not recruiting, completed, suspended, terminated, withdrawn)
        vii. Study Timeline (no page limit)
        viii. Estimated date of Enrollment of First Subject
        ix. Inclusion Enrollment Report – this is a form page.
    c. Protection and Monitoring Plans
        i. Protection of Human Subjects (no page limit)
        ii. Is this a multi-site project – check N/A for fellowship applications
        iii. Data Safety Monitoring Plan (no page limit) - **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):** Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):
            1. The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of clinical trial)
            2. If applicable, the name of an independent safety monitor or a data and safety monitoring board
        iv. Will a Data and Safety Monitoring Board be appointed for this study – select yes or no

v. Overall Structure of the Study Team (no page limit)

d. Section 4 (clinical trial synopsis) and Section 5 (other clinical trial related attachments) are NOT ALLOWED for fellowship applications.

UNIVERSITY ROUTING VIA KUALI: PIs must create application in Kuali and complete the following information:

1. Basic opportunity information (Title, project dates, sponsor, deadline)
2. Key Personnel- add yourself as PI and any Marquette collaborators. Contact ORSP if you have non-Marquette collaborators that need to be added.
3. Credit Splits – complete the Allocation and Recognition percentages, as applicable
4. Certification- after adding yourself as PI, click on the black triangle next to your name and then proposal person certification tab, answer the questions.
5. Questionnaire- answer all questions.
6. COI (in its own module, outside of specific proposal; found on Common Tasks page)- update annual disclosure.