

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-25-422.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 Quali System.
- All PD/PIs and all individuals with a student role must be registered in the eRA Commons. If new, the PI must request a new account from ORSP and then complete the registration 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
- List of individual pdf documents needed (as applicable) highlighted in grey below

ATTACHMENTS/INFORMATION NEEDED

1. **Cover Letter:** Format guidelines found in SF424 Application Guide. Address it to the Division of Receipt and Referral. Include the following:
 - a. Application title
 - b. Funding Opportunity title
 - c. Individual fellowship applicants must include a cover letter that contains a list of referees (including name, departmental affiliation, and institution).
 - i. **List of Referees:** Include names, degrees & affiliations (department and organization) 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.**
 - ii. **Other application material, as applicable to the proposal.** See fellowship application instructions for list of components that would need to be included
2. **Project/Performance Site Locations:**
 - a. Include addresses, UEI, and Congressional District for all appropriate additional locations 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.
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. Active hyperlinks are not allowed.
6. **Facilities and Other Resources (no page limit):** examples can be found on our website: <https://www.marquette.edu/research-sponsored-programs/national-institutes-of-health-nih.php>
 - 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. URLs and hyperlinks are not allowed
 - e. 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. **Biosketches (limited through SciENcv formatting):** Required for the PD/PI-applicant fellow, sponsor, co-sponsor(s), and other significant contributors. Applicants are required to use Science Experts Network Curriculum Vitae (SciENcv) to complete the Biographical Sketch Common Form and the NIH Biographical Sketch Supplement to produce digitally certified PDF(s) for use in application submission. Do not flatten this PDF attachment. See ORSP biosketch instruction checklist for additional information.
 - a. Instructions and sample can be found at <https://grants.nih.gov/grants/forms/biosketch.htm>
 - b. Include Personal Statement; Positions, Scientific Appointments, and Honors; and Contributions to Science.
9. **Introduction (1 page limit, as applicable)**
 - a. An "Introduction" attachment is required only if the type of application is resubmission or if the NOFO specifies that one is needed. An introduction is not allowed for new or renewal applications.
10. **Candidate Section**
 - a. **Goals, Preparedness, and Potential (3 pages)** - Organize the Candidate's Goals, Preparedness, and Potential for the Research Training Proposal in the specified order and use the instructions provided below. Start each section with the appropriate heading.
 - i. **Overall Training Goals** - Candidates should describe the goals for the proposed research training plan and the long-term goals for a career in biomedical research workforce. Relate the fellowship goals to the long-term career goals. Candidates should describe their motivation for pursuing a career in the biomedical research workforce.
 - ii. **Candidate's Preparedness** - This section provides information regarding the educational, scientific, and professional experiences that prepare the candidate for the proposed research training plan. Note: information listed in the candidate's biosketch may be expanded upon, but not simply duplicated, in this section. The candidate should address the following:
 1. How relevant activities and experiences contributed to the candidate's scientific development and preparation for the current research training plan. Examples may include coursework, research experiences, conference attendance, internships, and employment.
 2. Any additional activities and experiences that demonstrate an interest and commitment to a career in the biomedical research workforce. Examples may include seeking out opportunities for research skill development or engaging in leadership, service, teaching, or outreach activities.
 - iii. **Candidate's Self-Assessment** - The purpose of this self-assessment is to provide an opportunity for the candidate to define their current characteristics (such as relevant skills, abilities, traits or attitudes) and areas to develop that are likely to contribute most significantly to success in the proposed research training plan and career path. The candidate should describe:
 1. Two to four current characteristics that are likely to contribute to achieving the research training.
 2. Two to four specific areas of development during the fellowship to attain the stated research training and career goals.
 - iv. **Scientific Perspective** - This section is intended to provide information about the candidate's potential to think about and express ideas within a scientific field. In this section, candidates should explain the following:
 1. Why this field of science is important and the ways the chosen research training project will advance the field.
 2. A broader, unresolved scientific question in the chosen scientific field, the importance of the problem, and the ways biomedical research might advance the scientific field.
 - b. **Research Training Plan**

- i. **Training Activities and Timeline (3 pages)** - The research training plan activities should be individually tailored and well-integrated. The planned activities should address the candidate's goals and identified areas for development. The application should describe the collaborative process between the candidate and the sponsor(s) in the development, writing, review, and editing of the research training plan, including the research training project aims and strategy.
 1. Describe, by year, the planned activities (coursework, professional development, research training project, mentoring, clinical activities, etc.) during the proposed award. Note that the Research Training Project Strategy will be detailed in a separate section described below. Estimate the percentage of time to be devoted to each activity. The percentage should total 100 for each year.
 2. Explain how the training activities will develop the areas defined in the self-assessment section and help to meet the fellowship goals.
 3. Provide specific examples of how the proposed research training will facilitate the transition to the next career stage.
 4. Describe why the Sponsor(s), collaborators, and research training environment are appropriate for the proposed research training plan. Candidates should expand upon, but not duplicate information found in the Facilities and Other Resources section or in the Sponsor(s) section describing the Research Training Environment.
- ii. **Research Training Project — Aims and Strategy** - For most types of applications, the Research Training Project should include the following: Specific aims and objectives; Methods, approaches, and techniques for each aim and objective; Discussion of possible challenges and how they will be managed; and Alternative approaches that might be tried if the initial approaches do not work.
 1. **Research Training Project — Specific Aims (1 page)** –
 - a. State concisely the broader goals of the proposed research training project (for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a barrier to progress in the field, or develop new technology).
 - b. List succinctly the specific objectives or aims of the research training project to be completed by the candidate during the funding period. Summarize the expected outcome(s). Include the potential impact that the results of the proposed research training project will have on the research field(s) involved.
 2. **Research Training Project — Strategy (6 pages)** - Although the fellowship research training project may fall within the larger funded research program of the sponsor(s), the research training project strategy must be written in the candidate's own words. Using language written by others is not allowed in this section because the application is intended to provide information regarding the candidate's understanding of the research training project and ability to communicate the scientific rationale and approaches. Additionally, this section will provide information to evaluate the training potential of the research training project. Candidates may solicit feedback and incorporate suggestions from the sponsor(s) and other scientists into the research training project strategy, but the text must be written by the candidate. * Note for Candidates with Multiple Specific Aims: Candidates may address the Significance and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.
 - a. **Scientific Foundation and Rationale**
 - i. Provide the context for the proposed research training project. Include information on published and unpublished findings serving as the scientific foundation for the proposed research training project. Describe the strengths and weaknesses in the rigor of the prior research that serves as the key support for the proposed project.
 - ii. Describe the rationale for the research training project, including unaddressed areas for research and why this area of research is interesting and important.

- iii. Describe how achieving the proposed research training project goals will advance biomedical research in the candidate's chosen field.
- b. Approach
 - i. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan attachment, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans, as appropriate. Resources and tools for rigorous experimental design can be found at the Enhancing Reproducibility through Rigor and Transparency website.
 - ii. For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources webpage.
 - iii. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
 - iv. 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.
 - v. Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.
 - vi. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. If applicable, a full discussion on the use of select agents should appear in the Select Agent Research attachment below.
 - vii. If research on Human Embryonic Stem Cells (hESCs) is proposed, but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.
 - viii. If you are proposing to gain clinical trial research experience, briefly describe your role on the clinical trial.
- c. Progress Report Publication List (**for Renewal applications**)
- d. **Training in the Responsible Conduct of Research (1 page)** - The plan must address the five required instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research (RCR), as more fully described in the NIH Grants Policy Statement, Section 11.2.3.4: Responsible Conduct of Research:
 - i. Format: Describe the required format of instruction (i.e., face-to-face lectures, coursework, and/or real-time discussion groups). A plan with only on-line instruction is not acceptable.
 - ii. Subject Matter: Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, and research ethics).
 - iii. Faculty Participation: Describe the role of the sponsor/mentor(s) and other faculty involvement in the instruction.

- iv. Duration of Instruction: Describe the total number of contact hours of instruction, taking into consideration the duration of the program.
- v. Frequency of Instruction: Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the candidate's current career stage, including the inclusive dates instruction was last completed.

11. Commitment To Candidate, Mentoring and Training Environment

- a. **Sponsor(s) Commitment (6 pages)** - Complete these items as comprehensively as possible so that a meaningful evaluation of the commitment to the research training can be made by the reviewers. Create a heading at the top of the first page titled "Sponsor(s) Commitment" and organize each statement in the specified order. Each sponsor and co-sponsor statement must address these sections.
 - i. Mentoring Approach and Candidate Mentoring Plan – Effective mentorship is critical to the development and retention of scientists and the advancement of research. Sponsors and co-sponsors must describe their mentoring approach and the specific mentoring plan for the candidate to ensure career advancement in the biomedical research workforce. The mentoring plan should be tailored to the overall training goals outlined by the candidate and go beyond simply providing access to research environments. Effective mentoring plans may include areas such as enhancing the candidate's understanding of scientific research, promoting the candidate's professional development, maintaining effective communication, aligning expectations and fostering independence.
 - ii. Prior Commitment to Training and Mentoring - This section may be used to demonstrate the sponsor(s) past commitment to effective training, mentoring, and career development. Previous experience is not a pre-requisite to serve as a sponsor. Sponsor(s) may provide examples from no more than 2-5 recent trainees at the level of the candidate and describe the individualized training and mentoring offered. Simply listing former trainees and their career outcomes does not provide evidence of effective mentoring. The sponsor(s) should describe the impacts of the individualized training and mentoring on each former trainee's scientific, educational, or career development. For early-stage sponsor(s), examples may include informal training and mentoring activities conducted as a student or postdoctoral fellow.
 - iii. Commitment to the Candidate's Research Training Plan
 - 1. This section should contain confirmation of the sponsor(s) commitment to the candidate's research training plan and that sponsor(s) have sufficient time to devote to the training and mentoring given their other professional and supervisory obligations. The sponsor(s) should provide:
 - a. A description of the frequency, duration, and nature of meetings with the candidate throughout the training plan timeline.
 - b. A listing of how many other scientists in the research team will be supervised during the proposed fellowship award period and how the candidate will receive consistent, individualized attention.
 - iv. Research Training Environment - The sponsor should describe the research training environment and how it will meet the needs of the candidate to achieve the outlined goals. The co-sponsor may include information if different from the sponsor's description. Include any additional relevant items to promote the development of the candidate not listed elsewhere in the application. For example, describe:
 - 1. The sponsor(s) research training environment and how the environment will support the candidate's development and attainment of the defined career goals. Sponsor(s) are encouraged to describe efforts to create safe, supportive, and accessible research environments. Describe the day-to-day research environment with special attention to training and how the candidate will benefit from the environment.
 - 2. Organizational research training environments such as available centralized research facilities or equipment needed to complete the research training project not listed elsewhere in the application.
 - 3. Relevant and accessible organizational research training program(s) related to the candidate's area of interest.

4. Opportunities for professional development and intellectual interactions, for example, scientific meetings, journal clubs, seminars, and opportunities for presentations. Include items such as classes, opportunities for interaction with other scientists and any professional skills development opportunities. Describe how the sponsor will work with the candidate to develop and publish rigorous scientific products such as publications and presentations.
 - v. Candidate's Potential - The section is intended to provide information about the candidate's main areas for development during the training as well as their potential to benefit from the research training plan and to have a productive career in the biomedical research workforce. Sponsor(s) should provide the following for the candidate:
 1. Examples of personal characteristics (for example, skills, abilities, traits, attitudes) that are likely to significantly contribute to further advancement in the candidate's defined career path. Take into consideration relevant indicators for success, such as scientific curiosity, resourcefulness, and persistence.
 2. Areas for development to improve the candidate's prospects of transitioning into a productive career in the biomedical research workforce. Areas may include, but not limited to the following skills: technical (e.g., new techniques or technical methods, quantitative or computational approaches), operational (e.g., practices that promote rigorous, reproducible, and responsible research) or professional (e.g., management, leadership, communication, teamwork). Indicate whether the proposed training plan will address these areas and contribute to the candidate's development and attainment of the stated career goals.
 3. An overall assessment of the candidate's preparedness and likelihood for success in the proposed research training plan. Provide examples, such as scientific or intellectual contributions, that highlight the likelihood of achieving the training goals and advancing to a career in the biomedical research workforce.
 - vi. Clinical Trial Training (if proposed) Note: If the candidate is proposing to gain experience in a clinical trial as part of the research training plan, then the sponsor or co-sponsor should include information in the statement to document leadership of the clinical trial. Include the following:
 1. A statement/attestation that the sponsor or co-sponsor will be responsible for the clinical trial.
 2. Source of funding;
 3. ClinicalTrials.gov Identifier (e.g., NCT87654321), if applicable;
 4. A description of how the expertise available to guide the candidate in the proposed clinical trials research experience;
 5. The sponsor(s) must have primary responsibility for leading and overseeing the trial and must describe the level of oversight .
 6. Include details on the specific roles/responsibilities of the fellow and sponsor, keeping in mind that the terms of a fellowship award do not permit the fellow to lead a clinical trial.
 - b. **Letters of Support from Collaborators, Contributors, and Consultants (6 pages)** - If any collaborators, consultants, or advisors are expected to contribute to the scientific development or execution of the candidate's research training plan, attach letters of support from those individuals here, describing their anticipated role and contributions.
12. 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** - (if applicable, no page limit): describe use of hazardous biological agents/toxins
- c. **Resource Sharing Plans** - (if applicable, no page limit):
 - i. **Sharing Model Organisms**: only if creation of a new model is proposed. Outline plan to make findings available to qualified individuals within the scientific community.
 - ii. **Research Tools**: sharing of unique research resources developed through NIH sponsored research. For more information, see the [Research Tools Policy on the NIH Scientific Data Sharing Website](#)
- d. **Authentication of Key Biological and/or Chemical Resources** - (if applicable, 1 page max recommended): briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies
13. **Assignment Request Form** – this is a form page, available from ORSP, used to identify the preferred institute, study section and expertise needed for review.
14. **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
15. **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.