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-21-05JE1pst/7JgrEmesleenih.gov/7grantsagrv/wapply

publication and if applicable, NIH Manuscript Submission or PubMed Central reference numbers.

- 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.
- 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:

- a. Introduction summarize changes made to application based on reviewer comments
- b. Specific Aims : 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
 - i. Significance
 - 1. Explain the importance of the problem or critical barrier to progress in the field that the

training at either their doctorate institution or at the institution where they have been training

- 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
 - a. Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc. Relevant

- 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. Data Sharing Plan for projects with more than \$500,000/yr direct costs
 - ii. 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.
- d. Authentication of Key Biological and/or Chemical Resources
- 20. <u>Assignment Request Form</u> this is a form page, available here http://www.marquette.edu/orsp/documents/PHSAssignmentRequestForm_April2016.pdf
- 21. Referee Letters Selecting a Referee

a.

- 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.
- The sponsor/co-sponsor(s) of the appl ET/S2-5.9 (e)-615 (h)-0.8 (e)-6 (s)-4.3 (p)-0.a0 Tw6 0 Td()4582.487 (l)-3j/TT

iv. Will a Data and Safety Monitoring Board be appointed for this study –