NIH Proposal Checklist—R01/R03/R21 Clinical Trial Required **Dec 2024**

This document does not replace the NIH guidelines –please read the guidelines and solicitation thoroughly before preparing your proposal. The NIH SF424 Application Guide can be found at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general-forms-h.pdf and more specifically for R grants: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/research-forms-h.pdf . Not all NIH Institutes participate in the parent or other programs. Please make sure that the institute you are interested in is participating in the specific PA, PAR or RFA you are applying through. Pre-proposal contact with an appropriate program officer is highly recommended for all NIH applications and is required for some. Here is the parent solicitation for each:

- R01 - NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
- R03 – NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
- R21 – NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)

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

APPLICATION CONTENTS – Underlined information denotes a separate document that must be submitted as a PDF.

1. Project Summary/Abstract **(no more than 30 lines)**: Provide a concise description of project objectives and methodologies suitable for dissemination to the public.
2. Project Narrative **(2-3 sentences)**: Describe the relevance of this research to public health in lay terms.
3. Bibliography & References Cited **(no page limit)**: Each reference must include the names of all authors, article and journal title, book title, vol#, pg.#, year of publication. When citing articles that fall under the Public Access Policy (peer-reviewed, accepted for publication since April 7, 2008, and are a result of NIH funding) and were authored or co-authored by the applicant, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process."
4. Facilities and Other Resources (no page limit):
    a. Instructions, sample and template can be found on the ORSP NIH website.
    b. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other).
    c. Describe only those resources that are directly applicable to the proposed work.
    d. Also describe how the scientific environment will contribute to the probability of success of the project.
    e. If there are multiple sites, describe resources available at each site.
5. Equipment (no page limit): Provide list of major equipment items already available. If appropriate, identify their locations and pertinent capabilities. Sample available on the ORSP website.
6. Biosketches **(5 page maximum/person)**: Required for senior/key personnel and Other Significant Contributors. We encourage using SciENcv to develop your biosketch and automatically format it.
    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 (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.
    c. When citing articles that fall under the Public Access Policy (peer-reviewed, accepted for publication since April 7, 2008, and are a result of NIH funding) and were authored or co-authored by the applicant,

provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process."

7. Budget Forms and Justification **[Note: ORSP liaison will create shell and route to faculty for editing.]**
    a. For requests of more than $500,000 in direct costs in any year, the PD/PI must contact the NIH IC program staff at least six weeks before submission to obtain an agreement that the IC will accept the application. Include cover letter with application, identifying staff member and IC who agreed to accept application.
8. Cover Letter (as applicable, see below): This should be on university letterhead and should include only the following as applicable. Institute and study section information should no longer be included here.
    a. Application title
    b. Funding Opportunity title
    c. As applicable: For late applications include specific information about the timing and nature of the cause of the delay; 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; Explanation of any subaward budget components that are not active for all periods of the proposed grant; Statement that you have attached any required agency approval documentation for the type of application submitted; 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; OR 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.
9. Assignment Request Form: this is a form page. Ask ORSP for the most recent version of the document.
10. Introduction (1 page, as applicable): If resubmission or revision, include an introduction section detailing the reviewer comments addressed in the application.
11. Specific Aims **(**1 page): Concisely state goals and specific objectives of the proposed research and summarize expected outcomes, including the impact the results will exert on the research field.
12. Research Strategy **(R01=12 pages, R03=6 pages, R21=6 pages)**: [Must be organized in following order. Use section headings]
    a. Significance
    b. Innovation
    c. Approach
13. Vertebrate Animals - (as applicable**,** no page limit).
14. Multi PI Leadership Plan - (as applicable, no page limit).
15. Consortium/Contractual Agreements - (if there is/are subcontractor(s) – ORSP will provide)
16. Letter(s) of Support – collaborator and consultant letters (not a requirement, try to keep to one page each)
17. Data Management and Sharing (DMS) Plan – (recommended to be no more than 2 pages)
    a. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a DMS Plan.
    b. A DMS Plan should reflect the proposed approach at the time the application is prepared. For some programs and data types, NIH and/or NIH Institutes, Centers, Offices, or programs have developed additional data sharing requirements.
    c. You should address these Elements of an NIH DMS Plan: data type; related tools, software and/or code; standards; data preservation, access and associated timelines; and access, distribution, or reuse considerations. A sample format is provided on the Data Management and Sharing Plan Format Page. Additional resources and information about MU's recommended online program, DMPTool, is available on Marquette's Data Management Planning webpage. Do not include hyperlinks in this attachment.
    d. The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan (a single plan addressing both).
18. Resource Sharing Plans (as applicable, no page limit)

a. Sharing model organisms plan (no page limit): only if the creation of a new animal model is proposed. Outline a plan to make research findings available to qualified individuals within the scientific community.
b. Research Tools (no page limit) - When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, they are to be made readily available for research purposes to qualified individuals within the scientific community. For more information, see the Research Tools Policy on the NIH Scientific Data Sharing Website.

19. Authentication of Key Chemical and Biological Resources Plan (if applicable**, 1 page recommended**):
    a. briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.
20. Human Subjects and Clinical Trials Information - a Study Record will be uploaded for each proposed study involving human subjects – ask ORSP for the most recent version of the study record form. (Instructions for all attachments can be found on the ORSP website.)
    a. Study Title (must be unique for each study record)
    b. Clinical Trial Questionnaire
    c. Study Population Characteristics
        i. Conditions or focus of study
        ii. Study eligibility criteria
        iii. Age limits (minimum and maximum)
        iv. Inclusion of Individuals Across the LifeSpan (no page limit)
        v. Inclusion of Women and Minorities (no page limit)
        vi. Recruitment and Retention Plan (no page limit)
        vii. Recruitment Status (select not yet recruiting, recruiting, enrolling by invite, active, not recruiting, completed, suspended, terminated, withdrawn)
        viii. Study Timeline (no page limit)
        ix. Estimated date of Enrollment of First Subject
        x. Inclusion Enrollment Report – this is a form page built into the study record.
    d. Protection and Monitoring Plans
        i. Protection of Human Subjects (no page limit)
        ii. Is this a multi-site project – select yes or no
            1. Applicants who check "Yes" are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research.
            2. If “Yes” describe the single IRB plan – no page limit)
        iii. Data Safety Monitoring Plan – (no page limit) – required for clinical trials, recommended for all human subjects research.
        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) – required for clinical trials, recommended for all human subjects research.
    e. Protocol Synopsis
        i. Detailed Description – text box - limited to 32,000 characters, but typically needs only 5,000 characters and should be written in layperson’s terms.
        ii. Primary Purpose – drop down choices
        iii. Interventions – drop down choices
        iv. Study Phase – drop down choices
        v. Intervention Model - drop down choices
        vi. Masking – select yes or no
        vii. Allocation – drop down choices
        viii. Outcome Measures – text boxes
            1. Name – limited to 255 characters
            2. Type – drop down choices
            3. Time Frame – limited to 255 characters
            4. Brief Description – limited to 999 characters

ix. Statistical Design and Power – (no page limit)
x. Subject Participation Duration – text box limited to 255 characters
xi. Will the study use an FDA-regulated intervention – select yes or no
    1. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status – (no page limit)
xii. Dissemination Plan – (no page limit)

f. Section 5 - Other Clinical Trial-related Attachments
    i. Provide additional trial-related information only if your FOA specifically requests it. Include only attachments requested in the FOA, and use requested file names. If a specific file name is not given in the FOA, use a meaningful file name since it will become a bookmark in the assembled application image – up to 10 PDF attachments are allowed

SUPPLEMENTARY DOCUMENTATION THAT MAY ALSO BE NEEDED:

1. Project Sites - If collaborating with another site, a letter of intent, along with a scope of work and budget will need to be provided by the other institution.
2. Key Personnel (those who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested).
3. Letters of support/verification of key personnel's commitment to the project should be given to ORSP
4. Letters of support/verification of commitment from any other Marquette resources needed.

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 – designate Recognition and Allocation contributions for all key personnel.
4. Certification- PI's and key personnel should click on their names in the Key Personnel section to access the proposal person certification tab and answer the questions.
5. Questionnaire- answer all questions.
6. Conflict of Interest (COI) - update annual disclosure.