NIH Proposal Checklist—R01 New Applications Clinical Trials Required December 2017

This document does not replace the NIH guidelines –please read the guidelines and solicitation thoroughly before preparing your proposal. This Funding Opportunity Announcement can be found at https://grants.nih.gov/grants/guide/pa-files/PA-18-345.html, and the NIH SF424 Application Guide can be found at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

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 COMPONENTS – Shaded sections require a narrative attachment or text box entry. Samples and Templates for attachments are available on ORSP's website at http://www.marquette.edu/orsp/ProposalWriting.shtml

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. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other).
    b. Describe only those resources that are directly applicable to the proposed work.
    c. Also describe how the scientific environment will contribute to the probability of success of the project.
    d. If there are multiple sites, describe resources available at each site.
5. Equipment (if applicable; no page limit): Provide list of major equipment items already available. If appropriate, identify their locations and pertinent capabilities.
6. Biosketch (5 pages /person): Required for senior/key personnel and Other Significant Contributors
    a. Include personal statement, positions and honors, **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.), and ongoing/completed research support from past three years.
    b. 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
9. Assignment Request Form – this is an optional form page, available here - http://www.marquette.edu/orsp/documents/PHSAssignmentRequestForm_April2016.pdf
10. 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.
11. Research Strategy (12 pages): **[Must be organized in following order. Use section headings]**
    a. Significance
    b. Innovation
    c. Approach
12. Other Research Plan Sections (if applicable) **[Create separate attachments for each]**:
    a. Vertebrate Animals (if applicable, no page limit).
    b. Select Agent Research (if applicable, no page limit)
    c. Multi PI Leadership Plan (if applicable, no page limit)
    d. Consortium/Contractual Agreements - (if there is/are subcontractor(s)) – ORSP will prepare
    e. Letter(s) of Support (if applicable) collaborator and consultant letters
    f. Resource Sharing Plans (if applicable)
        i. Data Sharing Plan (1 paragraph): for project over $500,000/yr direct costs
        ii. Sharing Model Organisms (no page limit): only if the creation of a new mouse model is proposed. Outline a plan to make research findings available to qualified individuals within the scientific community.
        iii. Genomic Data Sharing (no page limit)
    g. Authentication of Key Resources Plan (if applicable, 1 page):
        i. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.
13. Human Subjects and Clinical Trials Information **[Create separate documents for each attachment]**
    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, available here - http://www.marquette.edu/orsp/documents/PHS-Inclusion-Enrollment-Report_April2016.pdf
    c. 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)
        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. Protocol Synopsis
        i. Brief Summary (limited to 5,000 characters): text box
        ii. Narrative Study Description (limited to 32,000 characters): text box

iii. Primary Purpose – drop down choices
iv. Interventions – drop down choices
v. Study Phase – drop down choices
vi. Intervention Model - drop down choices
vii. Masking – select yes or no
viii. Allocation – drop down choices
ix. Outcome Measures
    1. Name (limited to 255 characters): text box
    2. Type – drop down choices
    3. Time Frame (limited to 255 characters): text box
    4. Brief Description (limited to 999 characters): text box
x. Statistical Design and Power (no page limit)
xi. Subject Participation Duration (limited to 255 characters): text box
xii. Will the study use an FDA-regulated intervention – select yes or no
    1. Availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status (no page limit) if yes to above
xiii. Dissemination Plan (no page limit)

e. 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

14. Introduction (1 page): if resubmission or revision, include an introduction section detailing the reviewer comments addressed in the application.

UNIVERSITY FORMS/SUPPLEMENTARY DOCUMENTATION NEEDED: Forms generated by ORSP when project title and budget are finalized and then routed to the faculty in order to obtain institutional review and approval (reviewed/signed by department chair and college dean and others making commitments, if any).

1. Marquette University Proposal Registration Form
2. Disclosure of Financial Interests Form
3. ORSP Budget Form
4. List of all Project Sites
    a. 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.
5. List of all 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).
    a. Letters of support/verification of key personnel's commitment to the project should be given to ORSP
6. Letters of support/verification of commitment from any other Marquette resources needed.