R01 PROPOSAL CHECKLIST
PA-18-345: NIH Research Project Grant (Parent R01 Clinical Trial Required)

The following attachments should be uploaded as PDFs into Cayuse. Please check the complete SF424 Research Application Instructions and the Parent R01 Funding Opportunity Announcement.

Award Project Period | May not exceed 5 years.
Award Budget | If total direct costs exceed $500,000 in any year, Scientific/Research Contact permission is needed.

☐ COVER LETTER
☐ Addressed to the Division of Receipt and Referral.

☐ ABSTRACT
☐ Does not exceed 30 lines.

☐ NARRATIVE
☐ Does not exceed 3 sentences.

☐ BIBLIOGRAPHY & REFERENCES CITED
☐ Include any references cited in Research Plan Form and in the Human Subjects and Clinical Trials Information form.
☐ Citing interim research products allowed.
☐ Articles authored/co-authored by applicant that arose from NIH support formatted as one of the following:
  - NIHMS97531 (NIH Manuscript Submission reference number)
  - PMCID234567 (PubMed Central reference number)
  - PMC Journal – In Process (PMCID not yet available)

☐ FACILITIES AND OTHER RESOURCES
☐ No quantifiable financial information provided.
☐ If there are multiple performance sites, describe the resources available at each site.

☐ EQUIPMENT
☐ If appropriate, equipment’s location and pertinent capabilities identified, including subawards.

☐ BIOSKETCH
☐ Use the sample format page that is approved through 03/31/2020.
☐ Does not exceed 5 pages.
☐ 4 complete sections:
  ☐ A. Personal Statement.
    ☐ Up to 4 publications or research products cited.
    ☐ Interim research products allowed.
  ☐ B. Positions and Honors.
  ☐ C. Contributions to Science.
    ☐ Up to 5 described.
    ☐ Each entry does not exceed ½ page.
☐ Up to 4 publications or research products cited.
Interim research products allowed.

D. Additional Information: Research Support and/or Scholastic Performance.

**RR BUDGET (detailed)**

**OR**

**MODULAR BUDGET**
- If you are applying for $250,000 or less per budget period
- Request total direct costs in modules of $25,000
- Include consortium direct costs (not indirect costs) if applicable
- Enter Consortium Indirect (F&A) in section A

**BUDGET JUSTIFICATION (detailed)**

**OR**

**PERSONNEL JUSTIFICATION (modular)**
- No individual salary information provided

**SPECIFIC AIMS**
- Does not exceed 1 page.

**RESEARCH STRATEGY**
- Does not exceed twelve pages.
- Organize sections with headings in order: Significance, Innovation, Approach.
- Do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form.

**LETTERS OF SUPPORT**
- Attached as single PDF.

**RESOURCE SHARING PLAN**

**PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION**
- See the “If Yes to Human Subjects” section for instructions.
- You must include at least one human subjects study record by selecting “Add New Study.”
  - If any of your human subjects studies meet the agency definition of delayed onset human subject study, use “Add New Delayed Onset Study.”
  - Justification attachment required for delayed onset study
- Add a separate study record for each protocol.
- Do not duplicate studies within your applications.
- Each study record is divided into numbered sections:
  - Section 1 – Basic Information
    - Study Title max 30 characters.
    - Answer the Clinical Trial Questionnaire based on the study you are describing in this study record.
    - If a clinical trial has already been entered into ClinicalTrials.gov, enter the identifier (e.g., NCT87654321) for this trial.
    - If you are building on an existing study, enter the identifier only for the ancillary study, not the parent study.
  - Section 2 – Study Population Characteristics (includes Inclusion Enrollment Report)
Conditions or Focus of Study
- At least 1 entry is required
- Use appropriate descriptors from NLM's Medical Subject Headings

Eligibility Criteria
- 15,000 characters max
- To provide a bulleted list, use a dash followed by a space “- ”

Age Limits

Inclusion of Women, Minorities, and Children
- Upload as PDF attachment
- Two Sections: “Inclusion of Women and Minorities” and “Inclusion of Children”
- Complete Inclusion Enrollment Report(s) (IER)
  - Max 20 IERs per study record
  - If you selected Exemption 4 only, IERs not required
  - Comments limited to 500 characters
  - Complete Cumulative (Actual) if study uses existing dataset/resource and complete Planned if study will not

Recruitment and Retention Plan
- Recruitment Status
- Study Timeline
- Enrollment of First Subject
  - 2.5 – 2.8 NOT required if you selected Exemption 4 or selected “No” to human participants

Section 3 – Protection and Monitoring Plans
- Protection of Human Subjects
  - Address: Risks to Human Subjects; Adequacy of Protection Against Risks; Potential Benefits of the Proposed Research to Research Participants and Others; and Importance of the Knowledge to be Gained
- Is this a multi-site study?
  - If yes, use sIRB

Data and Safety Monitoring Plan
- Overall Structure of the Study Team
  - Do not include biosketch information

Section 4 – Protocol Synopsis if applicable
- Do not complete this section if you answered “no” to any of the questions in the Clinical Trial Questionnaire.
- Brief Summary
  - 5,000 characters max
- Study Design
  - Narrative Description 32,000 characters max
- Interventions
  - Add up to 20
  - Name 200 characters max
  - Description 1,000 characters max
- Outcome Measures
  - Add up to 50
  - Brief Description 999 characters max
- Statistical Design and Power
- Subject Participation Duration
  - 255 characters max
Will the study use an FDA-regulated intervention?
  □ If yes, attach PDF
  □ Dissemination Plan
    □ Must include for each study within your application
  □ Section 5 – Other Clinical Trial-related Attachments if applicable
    □ This section only required if specified in the FOA.
    □ No page limits.

IF APPLICABLE

□ CONSORTIUM JUSTIFICATION (modular budget)
  □ Round to nearest $1,000 of total costs (direct and indirect)
  □ No individual salary information provided
  □ List the organizations and whether they are foreign or domestic
  □ List names of personnel, effort, and roles

□ ADDITIONAL NARRATIVE JUSTIFICATION (modular budget)
  □ Only necessary if variation in number of modules requested

□ SUBAWARD BUDGET ATTACHMENT FORM
  □ Included only if you have a sub and are using the Detailed (R&R) Budget Form.
  □ Separate subaward Budget Justification must be submitted.

□ OTHER RESEARCH PLAN SECTIONS
  □ VERTEBRATE ANIMALS
    □ Address: Description of Procedures, Justifications, Minimization of Pain and Distress
  □ SELECT AGENT RESEARCH
  □ MULTIPLE PD/PI LEADERSHIP PLAN
  □ CONSORTIUM/CONTRACTUAL ARRANGEMENTS
  □ AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES
  □ APPENDIX
    □ Max 10 attachments.
    □ Only allowable materials:
      □ Blank informed consent/assent forms
      □ Blank surveys, questionnaires, data collection forms
      □ Simple lists of interview questions

□ PHS ASSIGNMENT REQUEST FORM
  □ This section included when communicating specific application assignment and review requests. This information was previously collected in the Cover Letter.

□ INTRODUCTION TO APPLICATION if resubmission/revision
  □ Does not exceed 1 page.

□ PROGRESS REPORT PUBLICATION LIST if renewal
PAGE FORMATTING

- Page Size | 8½ x 11
- Margins | 0.5+ top, bottom, right, left | No page numbers | No headers or footers
- Font | 11+ | Arial | Georgia | Helvetica | Palatino Linotype recommended fonts
- Type Density | Up to 15 characters per linear inch
- Line Spacing | Up to 6 lines per vertical inch
- Figures | Max size 1200 x 1500 pixels | JPEG or PNG
- Headings | Highly encouraged (e.g., Significance, Innovation) within attachments
- Hyperlinks | Limited to publications in biosketches & publication list