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

Upload the following attachments as PDFs into Cayuse. Check the complete SF424 Research Application Instructions and the Parent R01 Funding Opportunity Announcement for more specific information.

Award Project Period | Max 5 years.
Award Budget | If total direct costs exceed $500,000 in any year, Scientific/Research Contact permission is needed.

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

☐ ABSTRACT
☐ Max 30 lines of text.

☐ NARRATIVE
☐ Max 3 sentences.

☐ BIBLIOGRAPHY & REFERENCES CITED
☐ Include any references cited in Research Plan Form and in the Human Subjects and Clinical Trials Information form.
☐ May cite interim research products.
☐ Format articles authored/co-authored by applicant that arose from NIH support 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
☐ Do not provide quantifiable financial information.
☐ If there are multiple performance sites, describe the resources available at each site.

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

☐ BIOSKETCH
☐ Use the sample format page that is approved through 03/31/2020.
☐ Max 5 pages.
☐ 4 complete sections:
  ☐ A. Personal Statement.
    ☐ Cite up to 4 publications or research products.
    ☐ May cite interim research products.
    ☐ No figures, tables, or graphics.
  ☐ B. Positions and Honors.
  ☐ C. Contributions to Science.
    ☐ Describe up to 5 contributions.
    ☐ Max ½ page per entry.
☐ Cite up to 4 publications or research products per contribution.
☐ May cite interim research products.
☐ D. Additional Information: Research Support and/or Scholastic Performance.
☐ Do not include person months or direct costs.

☐ RR BUDGET (detailed)

OR

☐ MODULAR BUDGET
☐ Use when 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)
☐ Do not provide individual salary information.

☐ SPECIFIC AIMS
☐ Max 1 page.

☐ RESEARCH STRATEGY
☐ Max 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
☐ Upload as single PDF file.

☐ 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.”
☐ Include a single justification attachment for all delayed onset studies.
☐ 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
  - Max 15,000 characters.
  - 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 max 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
  - Max 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
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).
Do not provide individual salary information.
List the organizations and whether they are foreign or domestic.
List names of personnel, effort, and roles.

ADDITIONAL NARRATIVE JUSTIFICATION (modular budget)
Include only if you requested a variation in number of modules.

SUBAWARD BUDGET ATTACHMENT FORM
Include only if you have a sub and are using the Detailed (R&R) Budget Form.
Must submit separate subaward Budget Justification.

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, surveys, questionnaires, data collection forms
Simple lists of interview questions
FOA-specified items

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

INTRODUCTION TO APPLICATION if resubmission/revision
Max 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
- 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