R21 Submission Checklist

All written attachments are identified below with an asterisk (*). Other components may include PDF forms or form fields. Additional guidance on the content and format of all documents is located in the SF424 Research Instructions for NIH and Other PHS Agencies.

Font must be 11 pt. or larger; preferred fonts are Arial, Helvetica, Palatino, Georgia. Use half-inch margins (minimum). Use headings. Do not use headers or footers. Colored font is allowed, however, no hyperlinks are allowed except government approved links in a biosketch. Guidance on format and page limits is found at NIH Format Attachments and NIH Page Limits.

Project Information

- □ *Cover Letter - Optional. Only use the cover letter to address items outlined on page 28 of the SF424 instructions. The cover letter is separated from the rest of the proposal and not seen by reviewers.
- □ Assignment Request Form – Optional. This form is used to communicate specific awarding component assignments or review preferences. If you want to include it, you can fill out the attached PDF, and I will add it to the application.
- □ *Project Summary/Abstract (30 lines of text maximum)
- □ *Project Narrative (2-3 sentences)
- □ *Bibliography & Reference Cited
- □ *Facilities and Other Resources
- □ *Equipment
- □ *Other Attachments - These are identified in the funding opportunity or by the IC when required. They are not part of most applications.
- □ *Biographical Sketches
- □ Budget
- □ *Budget Justification

Research Plan

- □ *Introduction To Application (1 page maximum) – Only required for resubmissions, revisions, or if specified in FOA.
- □ *Specific Aims (1 page maximum)
- □ *Research Strategy (6 pages maximum)
- □ *Progress Report Publication List – Only required for renewal applications.
- □ *Vertebrate Animals – Include if applicable.
- □ *Select Agent Research – Include if applicable.
- □ *Multiple PD/PI Leadership Plan – Include if applicable.
- □ *Consortium/Contractual Agreement – Include if applicable.
- □ *Letters of Support – Include if applicable.
- □ *Resource Sharing Plan
- □ *Authentication of Key Biological and/or Chemical Resources (1 page maximum) – Include if applicable.
- □ *Appendix (10 page maximum). Include if applicable. Only several documents are allowed in the appendix

Human Subjects and Clinical Trials Documents

If your project involves human subjects research as defined by NIH guidelines, you must provide at least one Human Subjects Study Record or at least one Delayed Onset Study Record. These are described below. The Human Subject Study Record is most common, but the PI should review the research instructions to determine which is required for the study.

If your study meets the definition of human subjects research, the required sections of the Study Record: PHS Human Subjects and Clinical Trials Information form will depend on (1) whether or not your study falls under one of the

exemptions and (2) whether or not it meets the definition of a clinical trial. NIH provides tools to make these determinations here information here.

- □ Complete a **Human Subjects Study Record** for **each** proposed study involving human subjects, using the Study Record: PHS Human Subjects and Clinical Trials Information form. This form contains a combination of text fields, narrative text boxes and attachment fields. Fill out the attached form and provide the attachments separately in word documents. See SF 424 page 95 for guidance on completing this form, including which fields and attachments are required for your project, the content of written attachments, and if you should include more than one study record.
    - Section 1: Basic Information
        - □ Complete questions on the Study Record: PHS Human Subjects and Clinical Trials Information form
    - Section 2: Study Population Characteristics
        - □ Complete questions on form and the following documents
        - □ *Inclusions of Individuals Across the Lifespan
        - □ *Inclusion of Women and Minorities
        - □ *Recruitment and Retention Plan
        - □ *Study Timeline
        - □ Inclusion Enrollment Report, complete page 2 of the Study Record: PHS Human Subjects and Clinical Trials Information form
    - Section 3: Protection and Monitoring Plans
        - □ Complete questions on form and the following documents
        - □ *Protection of Human Subjects
        - □ *Data and Safety Monitoring Plan – (required for clinical trials, optional for non-clinical human subjects research. for details.)
        - □ *Overall Structure of Study Team – (required for clinical trials, optional for non-clinical human subjects research. for details.)
    - Section 4: Protocol Synopsis
        - □ Only required for clinical trials. Do not provide information in this section if this is not a clinical trial.
        - □ Complete questions on form and the following documents
        - □ *Statistical Design and Power
        - □ Will the study use an FDA-regulated intervention? (If yes, include attachment)
        - □ *Dissemination Plan
    - Section 5: Other Clinical Trial Related Attachments
        - □ *Only required for clinical trials. Do not provide information in this section if this is not a clinical trial.

- □ **Delayed Onset Study Record**
    - Delayed Onset Study definition: Human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application.
    - Delayed onset does NOT apply to a study that can be described but will not start immediately.
    - If you have multiple delayed onset studies, you can include them together in a single Delayed Onset Study.
    - For each Delayed Onset Study, address the following:
        - □ Study Title
        - □ Anticipated Clinical Trial?
        - □ *Justification: Attach as a PDF