NIH Standard Proposal Content

The following standard **Forms** and **Document** uploads apply to most NIH proposal submissions. The Cayuse 424 module should be used to pull the correct proposal into your submission package. All forms/file uploads should be completed in 424, and your proposal will be submitted, system-to-system, through this Cayuse portal. If you need help with Cayuse 424, please contact OSP@memphis.edu

Please note that you must READ the specific solicitation or parent announcement to which you will submit to be certain there are no additional requirements or modifications to the standard documents identified below. Document formatting instructions and excerpts of specific document instructions from the NIH proposal guide follow this listing/brief description.

All documents must be uploaded in PDF format.

CHECKLIST OF FORMS AND DOCUMENTS

SF 424 Form *(form)*
Research & Related Project Performance Site Locations *(form)*
Research & Related Other Project Information *(upload section)*
　　　Project Summary: 30 line maximum self-contained description of the project which includes a statement of objectives and methods to be employed.
　　　Project Narrative (Public Relevance Statement): 2 – 3 sentences for lay audience explaining "Relevance to Public Health".
　　　Bibliography & References Cited: No page limit; however, conciseness is recommended.
　　　Facilities & Other Resources: Identify and describe facilities to be used (lab, animal, computer, etc.). When appropriate, indicate capacities, pertinent capabilities, proximity and extent of availability.
　　　Equipment: List of major equipment already available for project; if appropriate, list location and pertinent capabilities.
Research & Related Senior/Key Person *(form)* All Key Personnel must be registered in eraCommons *prior to* submission. If you are not registered, contact OSP@memphis.edu right away.
　　　Biographical sketch for all key personnel The 5-page biosketch includes a personal statement and a section on contributions to science. Please see the sample section for ideas as to how to structure your NIH biosketch.
PHS 398 Cover Page Supplement *(form)*
PHS 398 Research Strategy
　　　Introduction *(upload for resubmissions or renewals only)* 1 page limit
　　　Specific Aims *(upload)* 1 page limit
　　　Research Strategy *(upload)* 6-12 page limit, depending on mechanism; must include sections on *significance, innovation, and approach*
　　　Human Subjects *(upload, if applicable)*
　　　Vertebrate Animals *(upload; if applicable)*
　　　Letters of Support/Consortium Letters *(upload, if applicable)* – *must have if you have subreceipients.*
　　　Resource Sharing Plan *(upload, if applicable)*. NIH currently only REQUIRES this if you are requesting more than $500k/year in funding.
　　　Appendix *(upload)* Please refer to specific NIH guidance on what is allowed. Appendices cannot be used to circumvent page limits.

DOCUMENT FORMATING NOTES

NIH documents should be prepared using minimum ½ inch margins and one of four approved fonts (Palatino, Georgia, Arial, or Helvetica) with minimum font size of 11 points. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.

The application must be single-sided and single-spaced. Pages must be consecutively numbered throughout the application. <u>Documents must be uploaded as PDF files</u>.

<u>EXCERPTS</u> OF DOCUMENT INSTRUCTIONS FROM NIH PROPOSAL GUIDE

The *NIH proposal guide* is available at http://grants.nih.gov/grants/funding/phs398/phs398.html by clicking the MS Word or PDF document link immediately under the' DOWNLOADABLE INSTRUCTIONS AND FORMS' heading. What follows is only intended to address common document content requirements.

1. Cover Letter (Optional, but encouraged)
The Cover letter is for internal agency use and should include the following on separate lines:
- Application title.
- Funding Opportunity Announcement # and Title
- Request of an assignment (referral) to a particular IC or Scientific Review Group (SRG).
- List of individuals (e.g., competitors) who should not review the application and why.
- Disciplines involved, if multidisciplinary.
- Statement that any required NIH approval documentation for the type of application submitted is enclosed. (e.g. approval for applications requesting $500,000 or more, approval for Conference Grant, Cooperative Agreement, etc.)

2. Biosketch (limit 5 pages; follow required format and use NIH provided template)

3. Specific Aims (limit 1 page)
State concisely the research goals and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. Succinctly list specific objectives the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

4. Research Strategy (Generally 6 or 12 pages; check solicitation)
Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

(a) Significance (or significance and background, if you prefer)
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation
- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

- **Preliminary Studies for New Applications.** For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application.

- **Progress Report for Renewal and Revision Applications.** For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in Progress Report Publication List.

5. Bibliography/References Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

6. Facilities and Other Resources. Identify and describe lab, clinical, animal, office, computer, other) relevant to the conduct of the proposed work. When appropriate, indicate capacities, pertinent capabilities, proximity and extent of availability.

7. Equipment. List of major equipment already available for project; if appropriate, list location and pertinent capabilities.

8. Resource Sharing Plan(s)

   A. *Data Sharing Plan*: **Investigators seeking $500,000 or more in direct costs** (exclusive of consortium F&A) in any year **are expected to include a brief 1-paragraph description of how final research data will be shared**, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level.

   B. *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.

   C. *Genome-Wide Association Studies (GWAS):* Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible.

9. Appendix
The following materials may be included in the appendix to New, Revision, Renewal and Resubmission applications (note, however, that some FOAs do not permit publications):
- **Up to 3 publications** of the following types. In each case include the entire document:
    o Manuscripts and/or abstracts **accepted for publication but not yet published**.
    o Manuscripts and/or abstracts published, but a free, online, publicly available journal link is **not** available.
    o Patents directly relevant to the project.

(**Do not include unpublished theses or abstracts/manuscripts submitted, (but not yet accepted), for publication**.)

Publications that are publicly accessible must not be included in the appendix. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References Cited/Progress Report Publication List section, and/or the Biographical Sketch section.