National Institutes of Health (NIH) – R Series – GRAMS 424 Submission

Please review program specific solicitation for compliance and completeness. **Guidelines in the solicitation may** *supplement* or *deviate* **from guidelines below.**

GENERAL INFORMATION	
UNT Internal deadline	**6 business days prior to sponsor deadline**
Grant Application Guide	Review the NIH SF424 Application Guide for full detail on proposal preparation: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/research-forms-h.pdf
eRA Commons Registration	NIH requires <u>ALL</u> Senior/Key Personnel to have an eRA Commons User ID. Contact your GCA Specialist if you do not have one.
Budget Restrictions	See solicitation for restrictions

FORMATTING GUIDELINES	
Document formatting	✔ PDF attachments only ✔ No headers or footers ✔ Headings within the text of attachments are encouraged ✔ Complete NIH formatting guidance is here: Format Attachments
Font type/size	✔ Arial, Georgia, Helvetica, Palatino Linotype are recommended ✔ Size 11 or larger (smaller font may be used for figures, charts, graphs is acceptable, as long as it is legible when the page is viewed at 100%)
Line spacing/Type Density	✔ No more than 6 lines of type within a vertical space of 1 inch ✔ No more than 15 characters per linear inch (including spaces) ✔ Only single column formatting; Multi-column format is discouraged
Page size	✔ 8.5 x 11
Margins	✔ At least 0.5" all sides
URLs	✔ Most sections do not allow for the inclusion of URLs unless specified in the funding opportunity announcement.

GRAMS 424 PROPOSAL DOCUMENTS		
1	☐	**SF424 RR (Proposal Cover Page)** – fillable
		✔ Complete fields, including type of submission, proposed project dates, project title, etc. ✔ GRAMS 424 will auto-populate some of the sections for you.
a.	☐	**Pre-application** (not typically used for NIH or other PHS agencies)
b.	☐	**Cover Letter**
		✔ Cover letter is for NIH's internal use only and not shared with peer reviewers. Ensure it is attached in the appropriate location to ensure it is only made available to appropriate staff. ✔ <u>Cover Letter should not be used to communicate application assignment preference.</u> ✔ Letter should be addressed to the Division of Receipt and Referral, and should reference the Application Title and the Title of the Funding Opportunity (PA or RFA). ✔ Refer to the content list in the SF424 Guide, G.200, Section 21 for specific situations in which a cover letter should be included.
2	☐	**RR Performance Sites** – fillable
		✔ Information on Primary location and any additional sites at which the project will be performed ✔ GRAMS 424 will auto-populate UNT as the Primary Site Location ✔ Additional Locations can be added as needed

3	☐	**RR Other Project Information**
		✔ Complete RR Other Project Information section containing questions about this project.
		✔ Upload below listed documents. Refer to SF424 Guide, G.220 for additional information.
		✔ If you checked "Yes" to Question 6, you must include a "Foreign Justification" attachment in Field 12. Other Attachments.
a.	☐	**Project Summary/Abstract** – 30 lines of text maximum
		✔ State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project
		✔ Describe the research design and methods for achieving the stated goals
		✔ Do not include proprietary information; if funded the project summary will become public information
		✔ Avoid descriptions of past accomplishments and the use of first person.
b.	☐	**Project Narrative** – 3 sentences, max
		✔ Describe the relevance of this research to public health
		✔ If funded, this public health relevance statement will be combined with the Project Summary and will become public information.
c.	☐	**Bibliography & References Cited** – no page limit
		✔ For Research applications, include any references cited in the *Research Plan Form* and in the *PHS Human Subjects and Clinical Trials Information Form*.
		✔ When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, 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."
		✔ Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. Active hyperlinks are not allowed.
d.	☐	**Facilities & Other Resources** – no page limit
		✔ Review solicitation for requirements
		✔ Describe how the scientific environment in which the research will be done contributes to the probability of success (i.e.: institutional support, physical resources, intellectual rapport)
		✔ Discuss ways in which the proposed research will benefit from unique features of the scientific environment
		✔ Describe any special facilities used for working with biohazards and any other potentially dangerous substances.
e.	☐	**Equipment** – no page limit
		✔ List major items of equipment already available for this project and if appropriate, identify location and pertinent capabilities
f.	☐	**Other Attachments** – if applicable
		✔ Attach additional files only in accordance with the FOA and/or agency-specific instructions (i.e.: Foreign Justification)
4	☐	**RR Senior/Key Personnel**
		✔ All Senior/Key Personnel data should be entered into this section
		✔ eRA Commons username must be entered into the "Credential, e.g., agency login" field
		✔ For additional detail on who qualifies as Senior/Key Personnel refer to: SF424 Guide, G.240
a.	☐	**Biographical Sketch** – 5 page limit
		✔ Must be included for all senior/key personnel and other significant contributors (OSCs)

	✔	Use NIH biosketch template and follow instructions found on NIH Biosketch Page

5 ☐ **RR Budget OR PHS 398 Modular Budget**

✔ Review solicitation for specific budget requirements. Below are general guidelines.

☐ RR Budget (Non-Modular)	PHS 398 Modular Budget
o Requesting more than $250,000 per budget period in direct costs. o Required for applications proposing the use of human fetal tissue o Requires prior approval for budget with $500k or more in direct costs for any budget period. o **Detailed Budget** information is entered for each budget period	✔ Requesting less than $250,000 or less per budget period for direct costs ✔ Budget request must be made in **modules of $25,000** (direct costs). ✔ Detailed budget information is not submitted.
☐ o **Budget Justification** o Provide detailed cost breakdown and justification for each budget category in your budget request. o May include quotes in attachment o Include a justification for any significant increases/decreases from the initial budget period. o Costs for Data Management and Sharing must be clearly labeled as "Data Management and Sharing Justification" in the within the budget justification attachment. Refer to SF424 Guide G.240, L. Budget Justification for content requirements. Specify if no costs are incurred. o **RR Subaward Budget (if applicable)** o Includes budget detail on subaward o Must be included for each subaward o **Subaward Budget Justification** must be included for each subaward budget	o **Personnel Justification** o List all personnel including names, number of *person months* (not % effort) devoted to the project. Do not provide individual salary information. o **Consortium Justification (if applicable)** o Estimate of consortium/subaward costs (direct & indirect) rounded to the nearest $1,000 o List individuals/organizations and indicate foreign or domestic o List all personnel, including names, person months, and role on the project o **Additional Narrative Justification (if applicable)** o Provide explanation for any variations in the number of modules requested annually. o **"Data Management & Sharing Justification"** should be included here o If budget requires any additional justification or quotes, you may include it here

6 ☐ **PHS Human Subjects and Clinical Trials Information**

✔ Complete this form after you have completed the questions on the RR Other Project Information section.

✔ Required to be completed even if no human subjects are involved.

✔ Answer the question "Does the proposed research in the application involve human specimens and/or data? If you answer "yes", provide explanation. Refer to SF424 Guide G.500, Human Specimens and/or Data for additional information and content requirements

✔ If you answered "No" to "Are Human Subjects Involved?", skip the rest of the form

✔ If you answered **"Yes"** to "Are Human Subjects Involved?", proceed in completing the form as required and attach all required documents. Refer to SF424 Guide, G.500 when completing this section and the **separate checklist** for HSCTI content and documents.

7 ☐ **PHS 398 Cover Page Supplement**

✔ Complete RR Cover Page Supplement section containing questions about this project. If needed, refer to SF424 Guide, G.210 for additional guidance.

8	☐	**PHS 398 Research Plan**

✔ Upload documents listed below as applicable

a.	☐	**Introduction to Application (for resubmissions or revisions only)** – 1 page limit

✔ Summarize substantial additions, deletions and changes to application, as well as a rationale for change in PI/PIs

✔ Respond to issues and criticism raised in the summary statement

b.	☐	**Specific Aims** – 1 page limit

✔ State concisely the goals of the research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

✔ List succinctly the specific objectives of the research proposed

c.	☐	**Research Strategy** – see solicitation for page limits

✔ Organize the Research Strategy in the specified order and use instructions provided in the SF424 Guide G.400, Section 3 unless otherwise specified in your specific solicitation.
  o **Significance**
  o **Innovation**
  o **Approach**

✔ Cite published experimental details in the Research Strategy attachment and provide the full reference in the Bibliography and References Cited document

d.	☐	**Progress Report Publication List (for renewal applications only)** – no page limit

✔ List titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

e.	☐	**Vertebrate Animals (if applicable)** – no page limit

✔ Required if you answered "yes" to vertebrate animal use in the "Other Project Information" section

✔ If live vertebrate animals are involved in the project, address each of the criteria below as described in the SF424 Guide, G.400 Section 5
  o Description of Procedures
  o Justifications
  o Minimization of Pain and Distress

✔ Additionally, you should also:
  o Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
  o Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

f.	☐	**Select Agent Research (if applicable)** - no page limit

✔ Required if your proposed activities involve the use of select agents at **any** time during the proposed project period, either at the applicant organization or at any performance site.

✔ If activities involve a select agent that which have been excluded from the list per 42 CFR 73.3, use this attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list.

✔ Refer to the SF424 Guide, G.400 Section 6 for document content requirements

g.	☐	**Multiple PD/PI Leadership Plan (if applicable)** – no page limit

✔ Required if multiple PD/PIs are designated

✔ Document should address:
  o Rationale for choosing multiple PI structure
  o Governance and organizational structure of leadership team and project
  o Communication plans
  o Process for making decisions on scientific direction

		o Procedures for resolving conflicts
h.	☐	**Consortium/Contractual Arrangements (if applicable)** – no page limit
		✔ Required if you have consortiums/contracts (subcontracts) in your budget ✔ Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s)
i.	☐	**Letters of Support (if applicable)**
		✔ Letter should be combined into a single PDF file for attachment ✔ Attach any letters necessary to demonstrate the support of consortium participants and collaborators such as senior/key personnel and Other Significant Contributors included in the grant application. ✔ Letters should not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy ✔ Letters should serve to describe terms of collaboration or consultation and not letters of reference from persons not actively participating in project ✔ For consultants, letters should include rate/charge for consulting services.
j.	☐	**Resource Sharing Plan** – no page limit
		✔ Individuals are required to comply with the instructions for the Resource Sharing Plans (Sharing Model Organisms) as provided in the SF424 Guide, G.400, Section 10 ✔ 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
k.	☐	**Other Plan(s)** – 2 page limit (recommended)
		✔ Required for all Research Projects. Does not apply to Conference Grants (R13), unless otherwise indicated in the solicitation. ✔ Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing (DMS) Policy and must attach a DMS Plan. ✔ The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan. ✔ Sample DMS Plan format can be found on the Data Management and Sharing Plan Format Page. Refer to SF424 Guide, G.400, Section 11 for full guidance.
l.	☐	**Authentication of Key Biological and/or Chemical Resources (if applicable)** – 1 page limit
		✔ If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. ✔ See SF424 Guide, G.400, Section 12 for key biological/chemical resources characterization
m.	☐	**Appendices (if applicable)** - 10 PDF attachments max
		o Review your solicitation for special appendix instructions o If more than 10 attachments are needed, combine remaining into attachment #10 o File names should be descriptive of content o Summary sheet is encouraged to be included in first appendix attachment summarizing items included in the Appendix. o Review SF424 Guide, G.400, Section 13 for allowable appendix material (i.e., blank data collection forms, blank informed consent forms)
9	☐	**PHS Assignment Request** - optional
		✔ Allows selection of a suggested awarding component assignment or review preference to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs). ✔ Also allows for identification of specific individuals who should not review your application and up to 5 types of expertise needed for the review of your application