NIH FORMS VERSION H
RESEARCH PROPOSAL CHECKLIST
(Updated 10.5.23)

The following checklist is designed for most National Institutes of Health research (e.g., R01, R21, etc.) proposals. The checklist is designed to assist PIs in responding to a NIH funding opportunity announcement (FOA). Kindly note that particular FOAs (Fellowships, STTR/SBIR, Training, etc.) have specific requirements that may not be included in this checklist. ***This document is designed only to serve as a project management tool. It does NOT replace the detailed information available within the FOA, and the funding agency's forms, instructions, and review criteria.*** **For any questions, please refer to the FOA, contact your program officer, or contact your ORA Contract Administrator.**

When submitting NIH proposals, complete in ASSIST

FORMATTING BASICS	
- Font Size: 11 pt or larger - Recommended Fonts: Arial, Georgia, Helvetica, Palatino Linotype - No headers or footers - No page numbers - Use section headings ****This list is not exhaustive. All formatting requirements are here:** https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm	- File names are 50 characters or less (no special characters: "&", "*", "%", "#", or "/" in file name) - Margins: Minimum of ½ inch margins on all sides - Hyperlinks: Typically limited to citing relevant publications in biosketches and publication lists only. See **NOT-OD-20-174** and the **NIH Format Attachments page.**

RESOURCES	
SF424 Application Guide	Standard Due Dates
Page Limits	UMD Standard Institutional Information

✔	Proposal Component	Notes	SF424 Guide Reference
	SF424 (R&R) Form	**Title**: limited to 200 characters, including spaces and punctuation EIN: 1520710851-A1	G.200
	PHS 398 Cover Page Supplement	**Includes human fetal tissue (HFT) from elective abortions:** upload the HFT Compliance Assurance. The file name must be named HFTComplianceAssurance.pdf	G.210

	RR Other Project Information	▪ **Human Subject Assurance Number:** IRB FWA: 00005856
		   ➤ **Need help determining whether your application includes human subjects?** Check out the NIH Research Involving Human Subjects website for information, including a Decision Tool to help make the determination.
		▪ **Animal Welfare Assurance Number:** IACUC OLAW: D16-00172
		▪ **International Collaborators:** Include a "Foreign Justification" attachment in Field 12 - Other Attachments.
		▪ **Project Summary/Abstract:** 30 lines of text
		▪ **Project Narrative:** limited to three (3) sentences
		▪ **Bibliography/Reference Cited:** Must include PubMed Central or NIHMS reference #, if applicable (when applicant (PI) is the author or co-author of the article)
		▪ **Facilities and Other Resources:** The following categories should be addressed: Laboratory | Clinical | Animal | Computer | Office | Other Resources
		Requires description of scientific environment, and how it will contribute to the success of the project.
		▪ **Equipment:** List major items of equipment already available for this project and, if appropriate, identify location and pertinent capabilities.
		▪ **Other Attachments**: Use <u>only</u> in accordance with the FOA and/or agency-specific instructions. Upload foreign justification for international collaborators.
		   ➤ **Plan for Enhancing Diverse Perspectives (PEDP):** Required by BRAIN Initiative FOAs. Limited to 1 page. Must include: Summary of strategies | Timeline and
			G.220
			
			G.220.7
			G.220.8
			G.220.9
			
			G.220.10
			
			G.220.11
			
			G.220.12

		milestones for the PEDP | Approaches to assessing progress towards meeting the PEDP defined goals. For more information, see the PEDP Overview, FAQs, and Key Elements & Examples.	
	RR Performance Sites Form	Include primary and all other applicable performance sites (e.g., subaward locations, fieldwork sites)	G.230

	RR Key Personnel Form	▪ **Key Personnel Form**: Complete for PI/PD and all other Senior/Key personnel (as outlined in the FOA). Enter the highest degree/credentials and year obtained for each personnel listed.
		▪ **Biosketch:** Complete for PI/PD and all other Senior/Key personnel.
		   ➢ Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications.
		   ➢ You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). **Hyperlinks to personal websites are not allowed. Follow the hyperlink guidance in NOT-OD-20-174 and the NIH Format Attachments page**
		▪ **Current & Pending Support:** Not applicable unless required by the FOA.
			G.240

	Budget	▪ **R&R (Detailed) Budget:** Used when applying for <u>more</u> than $250,000 per budget period in direct costs. ▪ **R&R Subaward Budget:** Required when the prime grantee is submitting an R&R Budget Form and has subaward/consortium budget(s). ▪ **PHS 398 Modular Budget:** Used when applying for <u>less</u> than $250,000 per budget period in direct costs. Direct costs are requested in modules of $25,000.	G.300 G.310 G.320
Special Budget Protocols		▪ **If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting the application. For more information, see the NIH Grants Policy Statement. ▪ Budget adheres to all NIH and FOA requirements - including the salary cap ▪ **For Applications on or BEFORE October 4, 2023: If a Data Management and Sharing (DMS) Plan is required in the proposed application**, costs to support these activities, including personnel costs (e.g., personnel who will be curating data for the project) must be noted as a <u>single</u> line item in Section F. Other Direct Costs in the R&R Budget Form. The line item must be titled "Data Management and Sharing Costs" (without quotation marks but following exact phrase and spacing). The line item must only be used for DMS costs and cannot include or be combined with any "Other" costs. If no cost will be incurred, enter "0" in the "Funds Requested" column. ▪ **For Applications on or AFTER October 5, 2023: If a Data Management and Sharing (DMS) Plan is required in the proposed application,** costs to support these activities may be requested in the appropriate cost category. Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment (L), pursuant to the instructions.	

	Budget Justification	▪ **R&R (Detailed Budget):** Budget Justification should explain detailed categorical information and any exclusions applied to the F&A base calculation.
		   ➢ **UPDATED!** **If a DMS Plan is required in the proposed application**, include a brief justification of the proposed activities that will incur costs. The Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" within the budget justification attachment followed by the estimated dollar amount (total direct costs). Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page. For more information, see Budgeting for Data Management & Sharing on the NIH Scientific Data Sharing website and additional details to help Develop Your Budget.
		
		▪ **PHS 398 Modular Budget:** Detailed categorical information is not to be submitted with the application, but include the following (if applicable):
		   ➢ Personnel Justification: List all personnel, including names, percent effort (use the Person Months metric), and roles on the project. Do not include salaries or information on other costs.
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			G.310
			
			G.320

		➢ Consortium Justification: Provide estimate of total consortium/subaward costs for each budget period, rounded to the nearest $1,000. ▪ List the individuals/organizations with whom consortium or contractual arrangements have been made and indicate whether the collaborating institution is foreign or domestic. Used for any proposed subaward/consortium partners. Provide personnel justification for each. ➢ Additional Narrative Justification: **Required**. If the requested budget requires any additional justification (e.g., variations in the number of modules requested annually, applications submitting a DMS plan, direct costs that were excluded from the total direct costs, off site work, or off-site F&A rate, quotes), include that information in the Additional Narrative Justification attachment. ▪ <mark>UPDATED!</mark> If a Data Management and Sharing Plan is required in the proposed application, the Data Management and Sharing justification must be clearly labeled as "Data Management and Sharing Justification" followed by the estimated dollar amount (total direct costs). If no cost will be incurred, enter "0" for the estimated dollar amount. Also include a brief justification of the proposed activities that will incur costs. Provide a brief summary of the type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management considerations, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. The recommended length of the justification should be no more than half a page.	
	PHS 398 Research Plan	▪ **Introduction:** For resubmission or renewal applications only. Limit one page. ▪ **Specific Aims:** State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved. Limit one page. ▪ **Research Strategy:** Page limit varies by project type. Consult the NIH Table of Page Limits. Must address Significance, Innovation, and Approach (includes Preliminary Studies for New Applications and Progress Report for Renewal/Revision Applications). Start each section with the appropriate heading. ▪ **Progress Report Publication List**: Only for renewal applications. ▪ **Vertebrate Animals:** Required if vertebrate animals are involved, or if you answered "Yes" to the question #2 "Are Vertebrate Animals Used?" See Section G.400.5 for additional guidance. ▪ **Select Agent Research:** Required if select agents are involved. See section G.400.6 for additional guidance. ▪ **Multiple PI/PD Leadership Plan:** Required for multi-PI projects. For background information, see the NIH Multiple Principal Investigators page. ▪ **Consortium/Contractual Arrangement:** Required if subrecipients are included. ▪ **Letters of Support:** Attach all appropriate letters of support, including 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. ▪ **Resource Sharing Plan:** This section should include the following. The Data Management and Sharing and Genomic Data sharing Plans are now included in Other Plans (see below). ➢ Sharing Model Organisms – Required when proposing to develop model organisms regardless of amount requested. ▪ <mark>UPDATED!</mark> **Other Plans: (Data Management and Sharing Plan)** Refer to the list of NIH activity codes subject to the DMS Policy and your Funding Opportunity Announcement to determine if your application is required to provide an attachment and address a Data Management and Sharing (DMS) Plan. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a DMS Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses,	G.400.1 G.400.2 G.400.3 G,400.4 G.400.5 G.400.6 G.400.7 G.400.8 G.400.9 G.400.10 G.400.11

		completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens. ➢ Genomic Data Sharing – Include as a part of the DMS Plan when seeking funding for research that generates large-scale human or non-human genomic data. See the NIH Developing Genomic Data Sharing Plans page. ▪ **Authentication of Key Biological and/or Chemical Resources:** Generally, 1 page; briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. ▪ **Appendix:** Include if applicable. Do not use to circumvent page limits. See NOT-OD-17-089 regarding allowable appendix materials.	G.400.12 G.400.13
PHS Human Subjects and Clinical Trials Information Form	▪ For detailed information, visit the NIH Research Involving Human Subjects website. ▪ **Use of Human Specimens and/or Data:** Required regardless of response to question #1 "Are Human Subjects Involved?" on the **RR Other Project Information Form**. ▪ **Delayed Onset Study**: Required only when human subjects research is anticipated within the period of award but definite plans cannot be described in the application. ▪ **Study Record and Attachments:** Required for any project involving Human Subjects and/or Clinical Trials.		G.500
PHS Assignment Request Form	Optional		G.600