NIH RESEARCH PROPOSAL CHECKLIST

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). It is important to remember that particular FOAs have specific requirements that may not be included in this checklist, or the checklist may have more than is required for your project.

This document is designed only to serve as a project management tool. It does NOT replace the detailed information available within the FOA, 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.**

FORMATTING BASICS
▪ Font Size: 11 pt or larger ▪ Recommended Fonts: Arial, Georgia, Helvetica, Palatino Linotype ▪ No headers or footers ▪ No page numbers ▪ Margins: Minimum of ½ inch margins on all sides ▪ **Hyperlinks: Typically limited to citing relevant publications in biosketches and publication lists only. All other links are not allowed and, if included, may result in the withdrawal of your proposal by NIH. See NOT-OD-20-174 and the NIH Format Attachments page.**
****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

RESOURCES	
SF424 Forms Version F (eff. 5/25/20)	https://grants.nih.gov/grants/how-to-apply-application-guide.html
Page Limits	https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm
Standard Due Dates	https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

CHECKLIST

Proposal Component	Elements to Complete	Notes	SF424 Guide Reference	✓
SF424 RR Form		Complete in ASSIST	G.200	
RR Other Project Information	1. Are Human Subjects involved?	Complete in ASSIST	G.220.1	
	2. Are Vertebrate Animals Used?	Complete in ASSIST	G.220.2	

	3. Is proprietary/privileged information included in the application?	Complete in ASSIST	G.220.3	
	4. Environmental Questions	Complete in ASSIST	G.220.4	
	5. Is the research performance site designated, or eligible to be designated, as a historic place?	Complete in ASSIST	G.220.5	
	6. Does this project involve activities outside of the United States or partnerships with international collaborators?	If "Yes," include a "Foreign Justification" attachment in Field 12, Other Attachments.	G.220.6	
	7. Project Summary/Abstract	30 lines of text	G.220.7	
	8. Project Narrative	2-3 sentences	G.220.8	
	9. Bibliography and References Cited	Must include PubMed Central or NIHMS reference #, if applicable	G.220.9	
	10. Facilities and other resources		G.220.10	
	11. Equipment		G.220.11	
	12. Other Attachments	Use only in accordance with the FOA and/or agency-specific instructions	G.220.12	
RR Performance Sites Form		▪ Complete in ASSIST ▪ Include primary and all other applicable performance sites	G.230	
RR Key Personnel Form	Key Personnel Form	▪ Complete in ASSIST ▪ Complete for PI/PD and all other Senior/Key personnel.	G.240	
	Biosketch	▪ https://grants.nih.gov/grants/forms/biosketch.htm ▪ Complete for PI/PD and all other Senior/Key personnel. ▪ 5 pages per biosketch. ▪ 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.**	G.240 – Biosketch Instructions	
Budget	**R&R (Detailed) Budget**	▪ Used when applying for more than $250,000 per budget period in direct costs. ▪ Refer to FOA for specific guidance.	G.300	

		▪ **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.		
	Budget Justification			
	R&R Subaward Budget	This form is required only when the prime grantee is submitting an R&R Budget Form and has subaward/consortium budgets.	G.310	
	PHS 398 Modular Budget	▪ Used when applying for less than $250,000 per budget period in direct costs. ▪ Refer to FOA for specific guidance. ▪ Direct costs are requested in modules of $25,000.	G.320	
	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.		
	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	▪ Use to explain any variations in the number of modules requested annually. ▪ Not required for FOAs with direct cost limits that do not spread evenly across budget periods		
PHS 398 Research Plan	1. Introduction	RESUBMISSION and REVISION or if the FOA specifies that one is needed. 1 page	G.400.1	
	2. Specific Aims	Required unless otherwise specified in the FOA. 1 page	G.400.2	
	3. Research Strategy	▪ Required ▪ Page limit varies by project type. Consult the NIH Table of Page Limits.	G.400.3	

		• Must address Significance, Innovation, and Approach • Start each section with the appropriate heading		
	4. Progress Report Publication List	Only for RENEWAL applications	G.400.4	
	5. Vertebrate Animals	Required if vertebrate animals are involved, or if you answered "Yes" to the question #2 "Are Vertebrate Animals Used?" on the **RR Other Project Information Form**.	G.400.5	
	6. Select Agent Research	Required if select agents are involved. No specific page limit but be succinct.	G.400.6	
	7. Multiple PI/PD Leadership Plan	Required for multi-PI projects. For background information, see the NIH Multiple Principal Investigators page.	G.400.7	
	8.Consortium/Contractual Arrangements	Required if subrecipients are included	G.400.8	
	9. 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**. This extends to substantial unfunded collaborations.**	G.400.9	
	10. Resource Sharing Plan	May be included for multiple reasons: • Data Sharing Plan – included when seeking $500,000 or more in direct costs in any budget period. • Sharing Model Organisms – when proposing to develop model organisms. Regardless of amount requested. • Genomic Data Sharing – when seeking funding for research that generates large-scale human or non-human genomic data. • Some FOA's request this document regardless of the requested amount. Please read the FOA.	G.400.10	
	11. Authentication of Key and/or Chemical Resources	If applicable to the proposed science. Max 1 page suggestion	G.400.11	
	12. Appendix	Include if applicable. Do not use to circumvent page limits. • See NOT-OD-17-089 regarding allowable appendix materials. • A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10.	G.400.12	

		▪ PIs should ensure that they have read the guidance, FOA, and General Application Guide, as disallowed material can be the basis of a **noncompliant** application!		
PHS Human Subjects and Clinical Trials Information Form	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**. Does any of the proposed research in the application involve human specimens and/or data? Select "Yes" or "No" ▪ If "No," skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your FOA. ▪ If "Yes," provide an explanation for any use of human specimens and/or data not considered to be human subjects research. This is a PDF attachment.	G.500	
	Other Requested Information	Content is limited to what is described in the FOA or the SF424 Application Guide only.	G.500	
	Study Record	If you answered "Yes" to question #1 "Are Human Subjects Involved?" on the RR Other Project Information Form, add a Study Record for each proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.	G.500	
Study Record: PHS Human Subjects and Clinical Trials Information	***Section I: Basic Information***	▪ Required for all studies involving human subjects. ▪ Answer the following questions in ASSIST: 1.1 Study Title 1.2 Is this Study Exempt from Federal Regulations? 1.3 Exemption Number 1.4 Clinical Trial Questionnaire 1.5 ClinicalTrials.gov Identifier, if applicable	G.500	
	Section II: Study Participation Characteristics	Required unless Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number.	G.500	
	2.1 Conditions or Focus of Study	Complete in ASSIST.	G.500	
	2.2 Eligibility Criteria	Complete in ASSIST.	G.500	
	2.3 Age Limits	Complete in ASSIST.	G.500	

	2.3.a. Inclusion of Individuals Across the Lifespan	See the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects for additional information.	G.500	
	2.4 Inclusion of Women and Minorities	See the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page for additional information.	G.500	
	2.5 Recruitment and Retention Plan	Required unless Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number.	G.500	
	2.6 Recruitment Status	▪ Complete in ASSIST. ▪ Required unless Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number.	G.500	
	2.7 Study Timeline	Required unless either of the following apply: ▯ Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number. ▯ If you answered "No," to any question in the Clinical Trial Questionnaire.	G.500	
	2.8 Enrollment of First Participant	▪ Complete in ASSIST. ▪ Required unless Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number.	G.500	
	2.9 Inclusion Enrollment Report(s)	▪ Complete in ASSIST. ▪ Required unless Exemption 4 and no other exemptions are selected for question 1.3 Exemption Number.	G.500	
	Section III: Protection and Monitoring Plans	Required for all studies involving human subjects	G.500	
	3.1 Protection of Human Subjects	PDF Attachment	G.500	
	3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	Select "Yes" or "No" ▪ If "Yes," a Single IRB Plan is required for AHRQ but is not required for NIH. The Single IRB Plan is a PDF attachment.	G.500	
	3.3 Data and Safety Monitoring Plan	▪ Required if you answered "Yes," to all questions in the Clinical Trial Questionnaire.	G.500	

		▪ Optional for all other humans subjects research. ▪ For AHRQ applicants, see the AHRQ Data and Safety Monitoring Policy.		
	3.4 Will a Data and Safety Monitoring Board be appointed for this study?	▪ Required if you answered "Yes," to all questions in the Clinical Trial Questionnaire. ▪ Optional for all other humans subjects research.	G.500	
	3.5 Overall Structure of the Study Team	Optional - refer to the FOA for specific instructions.	G.500	
	Section IV: Protocol Synopsis	Required if you answered "Yes," to all questions in the Clinical Trial Questionnaire.	G.500	
	4.1 Study Design	Complete in ASSIST	G.500	
	4.2 Outcome Measures	Complete in ASSIST	G.500	
	4.3 Statistical Design and Power		G.500	
	4.4 Subject Participation Duration	Complete in ASSIST	G.500	
	4.5. Will the study us an FDA-regulated intervention?	Select "Yes" or "No" ▪ If "Yes," include an attachment that describes the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status	G.500	
	4.6 Is this an applicable clinical trial under FDAAA?	Complete in ASSIST	G.500	
	4.7 Dissemination Plan	Although one Dissemination Plan per application is sufficient, you must include a file for each study within your application. All filenames within your application must be unique. You may either attach the same Dissemination Plan to different studies or attach a file that refers to the Dissemination Plan in another study within your application.	G.500	
	Section V: Other Clinical Trial-related Attachments	▪ Only include attachments if specified by the FOA ▪ A max of 10 attachments is allowed.	G.500	
PHS 398 Cover Page Supplement	1. Vertebrate Animals Section	▪ Complete in ASSIST	G.210	

		▪ Required if you answered "Yes" to question #2 " Are Vertebrate Animals Used?" on the RR Other Project Information Form.		
	2. Program Income Section	Select "Yes" or "No" If "Yes," complete the remainder of the section.	G.210	
	3. Human Embryonic Stem Cells Section	▪ Select "Yes" or "No" If "Yes," complete the remainder of the section. ▪ See NIH Grants Policy Statement, Section 4.1.13: Human Stem Cell Research	G.210	
	4. Human Fetal Tissue Section	Does the proposed project involve human fetal tissue from elective abortions? If "Yes," upload the HFT Compliance Assurance. The file name must be named HFTComplianceAssurance.pdf	G.210	
	5. Inventions and Patents Section	Only for RENEWAL applications	G.210	
	6. Change of Investigator/Change of Institution Section	Complete in ASSIST, if applicable	G.210	
PHS Assignment Request Form		▪ Complete in ASSIST ▪ Optional	G.600	