NIH Checklist

Note this checklist is a general guide for "R01" type grants. Please always refer to the official NIH SF424 application guide and funding opportunity announcement for specific instructions.

	Proposal Requirements	Notes
☐	**Title**	Up to 200 characters including spaces
☐	**PHS Assignment Request Form**	Assignment of Institute/Center; study section, etc.
☐	**Budget**	Application budgets are not limited but need to reflect the actual needs of the proposed project. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/ Research Contact at least 6 weeks before submitting the application.
☐	**Budget Justification**	Application budgets are not limited but need to reflect the actual needs of the proposed project
☐	**Project Summary & Abstract**	30 lines of text maximum. Provide a concise description of project objectives and methodologies suitable for dissemination to the public.
☐	**Project Narrative**	2 – 3 sentences explaining the relevance to Public Health; Use simple language
☐	**References**	No page limit; be concise and select relevant references
☐	**Facilities & Other Resources**	The following categories should be addressed: • Laboratory • Clinical • Animal • Computer • Office • Other Resource Requires description of scientific environment, and how it will contribute to the success of the project. Include: • Unique features of the environment • For Early Stage Investigators, the institutional investment in the success of the investigator
☐	**Equipment**	List major items of equipment already available for this project and, if appropriate, identify location and pertinent capabilities
☐	**Other Attachment**	(if applicable) Foreign Justification
☐	**PI Biosketch**	**5 Page Limit** A. Personal Statement B. Positions and Honors C. Contributions to Science D. Research Support and/or Scholastic Performance
☐	**Other Key Personnel Biosketch(es)**	
☐	**Introduction**	Introduction to application is for Resubmission or Revision only
☐	**Specific Aims**	**1 Page Limit** 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.
☐	**Research Strategy**	**12 page limit** Research Strategy: a. Significance b. Innovation c. Approach Approach includes: • Preliminary Studies for New Applications • Progress Report for Renewal/Revision Applications
☐	**Vertebrate Animals**	if live vertebrate animals are to be used, federal policy requires applicants to address the following criteria: 1. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals. 2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro). 3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

☐	**Select Agent Research**	If applicable; 1. Identify the select agent(s) to be used in the proposed research. 2. Provide the registration status of all entities where select agent(s) will be used. 3. Provide a description of all facilities where the select agent(s) will be used. • Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s). • Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s). • Describe the biocontainment resources available at all performance sites.
☐	**Multiple PD/PI Leadership Plan**	If applicable; required for applications designating multiple PDs/PIs. Leadership Plans should address the following administrative processes and PI responsibilities: 1. Roles/areas of responsibility of the PIs 2. Fiscal and management coordination 3. Process for making decisions on scientific direction and allocation of resources 4. Data sharing and communication among investigators 5. Publication and intellectual property (if needed) policies 6. Procedures for resolving conflicts
☐	**Consortium/Contractual Arrangements**	If Applicable; Include Letters of Intent to establish a Consortium
☐	**Letters of Support**	e.g., consultants; institutional letters
☐	**Resource Sharing Plan(s)**	Data Sharing Plan Sharing Model Organisms Genomic Data Sharing (GDS)
☐	**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**	Allowable Appendix Materials: For applications proposing clinical trials (unless the funding opportunity announcement (FOA) provides other instructions for these materials): • Clinical trial protocols • Investigator's brochure from an Investigational New Drug (IND) application, as appropriate for the goals of the research proposed in the application. For all applications: • Blank informed consent/assent forms • Blank surveys, questionnaires, and/or data collection instruments • Other items only if they are specified in the FOA as allowable
☐	**Human Subjects and Clinical Trials Information**	1. Human Specimens/or Data • Required if Human Subjects are involved, but human specimens and/or data will be used. 2. 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. 3. Study Record and Attachments • Required for any project involving Human Subjects and/or Clinical Trials.

FORMAT SPECIFICATIONS FOR ATTACHMENTS

- PDF files only – file names are 50 characters or less and use only standard characters - A through Z, a through z,
- 0 through 9, underscore (_), hyphen (-), space ( ), and period (.). Do not use any other special characters (e.g.,
  "&", "*", "%", "/", or "#") in the file name.
- Margins are ½" all around
- Font = black; Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, or Verdana typeface are recommended; size 11 or larger; must be no more than 15 characters per linear inch (including characters and spaces)
- Do not include headers or footers
- Use section headings

General Subrecipient Checklist (documents required for submission)

1. Letter of Commitment (signed by the Institution Authorized Organizational Representative)
2. Statement of Work
3. Budget
4. Budget Justification

5. F&A Agreement
6. Biosketch(es) (Key Personnel)
7. Facilities and Resources
8. Equipment
9. Authentication of Key Resources (if applicable)