NIH REQUIRED DOCUMENTS
R01/R03/R21 CHECKLIST FOR FORMS E

For All Documents

- Black or high-contrast text colors recommended
- 11 point or larger font, recommended fonts - Arial, Georgia, Helvetica, Palatino Linotype
- Use at least ½" margins
- Do not use headers, footers or page numbers.
- Save documents as PDF files. All file names may include letters, numbers, underscores and hyphens. No special characters Recommended naming convention: *PILastName_DocumentTitle*

Read all instructions in the Funding Opportunity Announcement (FOA) before completing the forms.

For specific document requirements, see the Forms Version E General (G) instructions (https://grants.nih.gov/grants/how-to-apply-application-guide.html) If you are proposing a clinical trial: https://grants.nih.gov/policy/clinical-trials/definition.htm , be sure your FOA accepts clinical trials.

Cover Page and Other Project Information

1) **Cover Letter** *PILastName_CoverLetter*
- Required for: a) Changed/Corrected Application submitted after the deadline; b) if subaward budget components not active for all budget periods; c) inclusion of agency approval documentation (i.e. budget request of $500,000 or more, approval of Conference Grant or Cooperative agreement); d) if video to be sent; and/or e) large-scale genomic data to be collected. *Otherwise not required*.
- Include application title, funding opportunity title, and information, explanation, and/or documentation of required items. See Research Instructions FORMS-E for details.

2) **Project Summary** *PILastName_Summary*
- Maximum of 30 lines of text

3) **Project Narrative** *PILastName_Narrative*
- Maximum of 3 sentences

4) **Bibliography & References Cited** *PILastName_References*
- Be careful with PubMed references; they can generate an error and prevent submission
- Should include any references listed in PHS 398 Research Plan Form and PHS Human Subjects and Clinical Trials Information Form

5) **Facilities & Other Resources** *PILastName_Facilities*
- Describe any special facilities used for working with biohazards and potentially dangerous substances
- For Early Stage Investigators (ESI) describe institutional investment in the success of the investigator

6) **Equipment** *PILastName_Equipment*

7) Other Attachments: Attach a file only in accordance with FOA and or agency specific instructions.

Key Person Profile and Budget

8) **Biographical Sketches** *KPLastName_Biosketch*
- Required for each PI, Co-I and senior/key person
- 5 page maximum. Template available at https://grants.nih.gov/grants/forms/biosketch.htm
- Figures, tables or graphics are not allowed
  - No more than 4 publications can be listed under the Personal Statement
  - No more than 5 Contributions to Science can be included and no more than 4 publications can be listed under each Contribution.
  - Research support should not include award amounts or effort

9) **Budget Justification** *(submit based on budget type)* *PILastName_Justification*

- Non-Modular Budgets (for budgets exceeding $250,000 direct costs in any year or as indicated by the FOA) – Detailed justification, 1 PDF file. See budget justification template for guidance.
- Modular Budgets – Request direct costs in modules of $25,000, no future year escalation. 3 PDF files *(may need only 1 PDF)*
  - Required for budgets with $250,000 or less in direct costs per year, excluding subcontract indirect costs (unless FOA states otherwise).
    1. Personnel Justification *PILastName_Personnel*
    2. Consortium Justification – *if a consortium is involved* *PILastName_Consortium*
    3. Additional Narrative Justification *PILastName_AdditionalJust*
       – *required if modules change from year to year*

Research Plan and Assignment Request

10) Introduction (*Required for Revisions and Resubmissions only or if FOA indicates*)

- Maximum of 1 page *PILastName_Introduction*

11) **Specific Aims** *PILastName_SpecificAims*

- Maximum of 1 page

12) **Research Strategy** *PILastName_ResearchStategy*

- R03/R21: Maximum of 6 pages
- R01: Maximum of 12 pages
- Sections – Must be labeled in this order and with each header: 1. Significance (including scientific premise); 2. Innovation; 3. Approach
- As applicable, also include preliminary studies for new applications and progress report for renewal and revision applications as part of the Research Strategy, keeping within the three sections listed above
  - Do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information Form
  - Include progress report for renewal and revision applications (included in the page limitation).

13) **Progress Report Publication List** *PILastName_Publications*

- *Required for renewals*

14) **Vertebrate Animals** *PILastName_Vertebrate*

- Required if vertebrate animals involved

15) **Select Agent Research** *PILastName_SelectAgent*

- Required of activities involve use of select agents

16) **Multiple PI/PD Leadership Plan** *PILastName_LeadershipPlan*

- Required only if more than 1 PD/PI, not applicable to Co-Investigators

17) **Consortium/Contractual Arrangements** *PILastName_Contractual*

- Required if there is a subcontract

18) **Letters of Support** *PILastName_SupportLetters*

- All letters of support in a single PDF document
- Font and margin requirements do not apply to letters of support
  - Letters should stipulate expectations for co-authorship and whether cell lines, samples or other resources promised in the letter are freely available to other investigators or not.

19) **Resource Sharing Plan** *PILastName_ResourceSharing*

- *Strongly encouraged, required if $500,000 or more in direct costs in any one year, model organisms to be developed, large-scale genome data to be generated, or if FOA requirement.*

20) **Authentication of Key Biological and/or Chemical Resources** *PILastName_Authentication*

- Required only for established key biological and/or chemical resources. If not applicable, include a brief statement indicating that none will be used. See Forms E Research Instructions.

21) Appendix – *See NIH guidelines for acceptable appendix materials* and information required by the FOA

22) Assignment Request Form (optional)

- Use to communicate specific application assignment and review requests
- Do NOT include this information in Cover Letter

Humans Subjects and Clinical Trials

Refer to NIH's Forms E Guide: Section G. 500 for information on Exemptions (new categories as of 1/25/18).
All applicants must use the PHS Human Subjects and Clinical Trials Information Form regardless of your answer to the question "Are human subjects involved?" on the R&R Other Project Information Form. Follow instructions on the PHS Human Subjects and Clinical Trials Information form that are specific to your answer to the "Are Human Subjects Involved?" question.

23) **Human Specimens and/or Data** *PILastName_HumanSpecimenData*

- Required if no human subjects are involved, but human specimens and/or data will be used.

24) **Delayed Onset Study** *PILastName_DelayedOnset*

- Required only when human subjects research is anticipated within the period of award but definite plans cannot be described in the application.

25) Study Record and Attachments

- Required for any project involving Human Subjects and/or Clinical Trails that does not include only delayed onset studies.
- Each proposed protocol must have its own study record.
- Use unique file names for each form and document.
- See table below for requirements based on type of human subject or clinical trial research.

NIH Human Subjects (HS) and Clinical Trials (CT) Required Forms and Documents

	Type of Research			
HS/CT Forms and Documents	**Human Subjects, Exemption 4**	**Human Subjects, no Clinical Trial**	**Clinical Trial**	**File Name** *(if multiple study records, add _StudyRecord# to each file)*
Study Record Form	Required	Required	Required	*PILastName_StudyRecord*
Study Record Form: Section 1, 2, 3	Required	Required	Required	
Study Record Form: Section 4-5	Do not complete	Do not complete	Required	
Inclusion of Women, Minorities, & Children	Required	Required	Required	*PILastName_Inclusion*
Recruitment and Retention Plan	Not required	Required if study involves human participants	Required	*PILastName_RRPlan*
Study Timeline	Not required	Required if study involves human participants	Required	*PILastName_Timeline*
Inclusion Enrollment Report	Not required	Required	Required	
Protection of Human Subjects	Not required	Required for all non-exempt research. For exempt, provide justification for exemption.	Required	*PILastName_Protection*
Single IRB	Required only for Multi-site study	Required only for Multi-site study	Required only for Multi-site study	*PILastName_IRBPlan*
Data and Safety Monitoring Plan	Optional	Optional	Required	*PILastName_DataSafety*
Overall Structure of the Study Team	Optional	Optional	Required	*PILastName_StudyTeam*
Statistical Design and Power	Do not include	Do not include	Required	*PILastName_StatisticalMethods*
FDA Regulated Intervention	Do not include	Do not include	Required for FDA-regulated intervention study	*PILastName_FDA*
Dissemination Plan	Do not include	Do not include	Required	*PILastName_Dissemination*
Other Requested Information	Do not include	Do not include	As required by the FOA	*PILastName_OtherHS*

PHS Assignment Request Form

- Form is optional. Use only if you wish to communicate specific awarding component assignments or review preferences. You have flexibility to make a single entry or to provide extensive information using this form.

Refer to OHSP Policy and Guidelines document regarding Guidelines for Single IRB Plan in an NIH Grant Application.