Office of Contracts and Grants
UNIVERSITY OF COLORADO **BOULDER**

NIH REQUIRED DOCUMENTS R01/R03/R21 CHECKLIST

We are noticing extra scrutiny of proposal requirements by NIH's Division of Receipt and Referral, including returning proposals without review for things that have previously passed initial review.
We recommend strictly following NIH proposal guidelines.

For All Documents

- **E-mail all documents to grantgov@colorado.edu AND Proposal Analyst**
- 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*

For specific document requirements, see the Forms Version E General (G) instructions (https://grants.nih.gov/grants/how-to-apply-application-guide.html) and the funding opportunity announcement (FOA).

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.
- Do not use cover letter for requesting institute or review assignment. Requests should be made with the Assignment Request Form.

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

3) Project Narrative *PILastName_Narrative*
- Maximum of 2-3 sentences

4) Bibliography & References Cited *PILastName_References*
- Be careful with PubMed references; they can generate an error and prevent submission

5) Facilities & Other Resources *PILastName_Facilities*

6) Equipment *PILastName_Equipment*

Key Person Profile and Budget

7) Biographical Sketches *KPLastName_Biosketch*
- Required for each PI, Co-I and senior/key person
- 5 page maximum.
- Use most current template. Template available at *https://grants.nih.gov/grants/forms/biosketch.htm*.
- Research support should not include award amounts or effort

8) Budget Justification *(submit based on budget type)* *PILastName_Justification*
- Non-Modular Budgets – Detailed justification, 1 PDF file.
  - See OCG budget justification template for guidance.
  - Itemize and provide details for any materials and supplies categories (i.e. glassware, chemicals, animal costs, etc.) that are $1,000 or more.

- Modular Budgets – 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 – *required if modules change from year to year* — *PILastName_AdditionalJust*

Research Plan and Assignment Request

9) Introduction (*Required for Revisions and Resubmissions only*) — *PILastName_Introduction*
- Maximum of 1 page

10) Specific Aims — *PILastName_SpecificAims*
- Maximum of 1 page

11) 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; 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

12) Progress Report Publication List — *PILastName_Publications*
- *Required for renewals*

13) Vertebrate Animals — *PILastName_Vertebrate*
- Required if vertebrate animals involved

14) Select Agent Research — *PILastName_SelectAgent*
- Required of activities involve use of select agents

15) Multiple PI/PD Leadership Plan — *PILastName_LeadershipPlan*
- Required only if more than 1 PI, not applicable to Co-Investigators

16) Consortium/Contractual Arrangements — *PILastName_Contractual*
- Required if there is a subcontract

17) 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

18) 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.*

19) 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.

20) Appendix

See NIH guidelines for acceptable appendix materials, current notice NOT-OD-18-126: *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html*

Allowable Appendix Items for Inclusion:
- Blank data collection forms, blank survey forms and blank questionnaire forms (Do not include instruction pages)
- Simple lists of interview questions
- Blank informed consent/assent forms
- Other items only if they are specified in the FOA as allowable Appendix materials
- Additional FAQs on the Appendix Policy located here: *https://grants.nih.gov/grants/policy/appendix_policy.htm*

21) Assignment Request Form (optional)
- Use to communicate specific application assignment and review requests
- Do NOT include this information in Cover Letter
- Ensure the institution you're requesting is accepting proposals for the program you're applying to. This information is usually detailed in the funding opportunity announcement.

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).

22) Human Specimens and/or Data *PILastName_HumanSpecimenData*

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

23) 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.

24) Study Record and Attachments

- Required for any project involving Human Subjects and/or Clinical Trails that does not include only delayed onset studies.
- Study Record Form available on OCG Forms webpage.
- One Study Record form required for each study.
- Use unique file names for each form and document.
- See table below for requirements based on type of human subject or clinical trial research.

25) 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	Required	Required	Required	
Study Record Form: Section 2	Not required	Required	Required	
Study Record Form: Section 3	Required – only justification of exemption document	Required	Required	
Study Record Form: Section 4-5	Do not complete	Do not complete	Required	
Inclusion of Women, Minorities, & Children	Not 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	Required – only justification of exemption document	Required for all non-exempt research. For exempt, provide justification for exemption.	Required	*PILastName_Protection*
Single IRB	Select N/A	For all exempt research, select N/A For non-exempt research, 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*