

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.
- Only 4 products under Personal Statement, 4 Products per Contribution, & 5 total Contributions
- 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 *PILastName\_AdditionalJust*
      - *required if modules change from year to year*

**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\_ResearchStrategy*
  - 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 if 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](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**

HS/CT Forms and Documents	Type of Research			File Name (if multiple study records, add _StudyRecord# to each file)
	Human Subjects, Exemption 4	Human Subjects, no Clinical Trial	Clinical Trial	
Study Record Form	Required	Required	Required	<i>PILastName_StudyRecord</i>
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	<i>PILastName_Inclusion</i>
Recruitment and Retention Plan	Not required	Required if study involves human participants	Required	<i>PILastName_RRPlan</i>
Study Timeline	Not required	Required if study involves human participants	Required	<i>PILastName_Timeline</i>
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	<i>PILastName_Protection</i>
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	<i>PILastName_IRBPlan</i>
Data and Safety Monitoring Plan	Optional	Optional	Required	<i>PILastName_DataSafety</i>
Overall Structure of the Study Team	Optional	Optional	Required	<i>PILastName_StudyTeam</i>
Statistical Design and Power	Do not include	Do not include	Required	<i>PILastName_StatisticalMethods</i>
FDA Regulated Intervention	Do not include	Do not include	Required for FDA-regulated intervention study	<i>PILastName_FDA</i>
Dissemination Plan	Do not include	Do not include	Required	<i>PILastName_Dissemination</i>
Other Requested Information	Do not include	Do not include	As required by the FOA	<i>PILastName_OtherHS</i>