NIH Application Guide for Applications
Due on or after January 25, 2018

Tour the new Application Guide!

How to apply – application guide

R01

- Clinical Trial
  - FOA must accept clinical trial if project proposes a clinical trial (FOA may indicate clinical trial optional or required)
- Total costs (direct and indirect) are limited to $499,999 annually over a 5-year period
- Format Attachments:
  - Font: Arial, Helvetica, Palatino Linotype or Georgia; size 11 points or larger
  - At least one-half inch margins (top, bottom, left, and right) for all pages.
  - Do not include headers or footers in your attachments; no page numbers

Required Attachments

- ☐ Project Summary/Abstract (30 lines of text)
- ☐ Project Narrative (2-3 sentences)
- ☐ Bibliography and References Cited
- ☐ Facilities and Resources
- ☐ Equipment
- ☐ Other Attachments
- ☐ Biosketch for senior/key personnel *(5 pages per bio)*
- ☐ Introduction *(for resubmission or revision applications only)*
- ☐ Specific Aims *(1 Page)*
- ☐ Research Strategy *(12 pages)*
- ☐ Progress Report Publication List *(Renewal applications only)*
- ☐ Budget Justification

If no to Human Subjects:

- Human Specimen justification *(if applicable)*

If yes to human subjects:

- ☐ Other Requested Information *(if applicable; see FOA)*
- ☐ Study Record *(1 for each proposed study; max 150)*
  1. *Clinical trial questionnaire required for each study section*
- ☐ Delayed Onset Study Record *(If applicable; 1 for each proposed study; max 150)*
  1. Justification document

- ☐ Inclusion of Women, Minorities, and Children *(if applicable; now one document two headings)*
- ☐ Recruitment and Retention Plan *(if applicable)*
- ☐ Study Timeline *(if applicable)*
- ☐ Inclusion Enrollment Report *(max 20 per study record)*
- ☐ Protection of Human Subjects
- ☐ sIRB Multi-Site Ethical Review *(if applicable)*
- ☐ Data Safety Monitoring Plan *(if applicable; clinical trial required, otherwise optional)*
- ☐ Overall Structure of the Study Team *(if applicable)*

Clinical Trial

- ☐ Protocol Synopsis *(section applicable if yes to clinical trial)*
    1. Brief Summary *(5,000 characters max)*
    2. Study Design
        1. Narrative Study Description *(32,000 characters max)*
    3. Statistical Design and Power
    4. FDA Regulation Plan *(if applicable)*
    5. Dissemination Plan *(if applicable)*
    6. Other clinical trial related documents *(if applicable, max 10 attachments)*

If yes to vertebrate animals:

- ☐ Vertebrate Animals

Other Documents *(if applicable)*:

- ☐ Select Agents Research
- ☐ Multiple PD/PI Leadership Plan
- ☐ Consortium/Contractual Arrangements
- ☐ Letters of Support
- ☐ Resource Sharing Plan
- ☐ Authentication of Key Biological and/or Chemical Resources
- ☐ Assignment Request Form *(optional)*
- ☐ Cover Letter

Subcontractors *(if applicable)*:

- ☐ Performance Site
- ☐ Key Personnel Profile
- ☐ Biosketch for senior/key personnel *(5 pages per bio)*
- ☐ Facilities and Resources
- ☐ Equipment
- ☐ Detailed Budget
- ☐ Budget Justification