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