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


R21
- The combined budget for direct costs for the two-year project period may not exceed $275,000. No more than $200,000 may be requested in any single year.
- Max 2 year project
- **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.

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 (6 pages)
- Progress Report Publication List (Renewal applications only)
- Budget Justification

If no to human subjects:
- Human Specimen justification (if applicable) – would be needed if “No” to question if are human subjects involved; but must include if “Yes” is marked for the question that your Proposed research does involve human specimens and/or data?

If yes to human subjects:
- Other Requested Information (if applicable; see FOA)
- Study Record (1 for each proposed study; max 150 separate Study Records)
  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