NIH R01 General Guidelines

SF 424 Guidelines Form F for Research	Unlimited up to 5 years (requests >$500,000 direct costs require 6 week prior approval letter)
PA-20-185 for non clinical trials PA-20-184 for Clinical Trials	

UPLOADED DOCUMENTS	
LOI - due date	As applicable
OTHER PROJECT INFORMATION	
Project Abstract/Summary	30 lines of text
Project Narrative (Public Relev)	3 sentences
Bibliography & References	As applicable
Facilities & Other Resources	REQUIRED
Equipment [major equipment already available]	As applicable
Other Attachments	N/A
KEY PERSONNEL [BIOSKETCH]	5 pages each
BUDGET	**ORSP will prepare budget forms**
Budget Justification	**detailed budget justification if >$250,000 DC/YR**
RESEARCH PLAN	
Specific Aims	1 page - REQUIRED
Res Strategy	12 pages
Significance (incl Scientific Premise)	
Innovation	
Approach (Incl Scientif Rigor & Biological variables)	
OTHER	
Vertebrate Animals	As applicable
Select Agent	As applicable
Multi PI Leadership Plan	As applicable
Consortium/Contractual agr's	As applicable
Letters of support	As applicable
Resource Sharing	Required if amount =$500k/more
Authentication of key Biological and/or Chemical Resources	As applicable
Appendix	As applicable
PHS Assignment Request Form (previously included in cover letter)	Optional
HUMAN SUBJECTS	**Click here for instructional video**
Justification for no human subjects if human specimens/data	As applicable
Section 2 -Study Population Characteristics -complete online and attach required docs.	All required if "yes" to human subjects
Inclusion of Individuals Across the Lifespan	
Inclusion of Women and Minorities	
Recruitment and Retention Plan	
Study Timeline	
Inclusion Enrollment Report -complete online	
Section 3 -Protection and Monitoring Plans -complete online and attach required docs.	All sections required if clinical trial
Protection of Human Subjects Document	Required for clinical trials
Data and Safety Monitoring Plan	Required for clinical trials
Overall structure of study team	Required for clinical trials
Sections 4 and 5: Protocol Synopsis -complete online and attach required docs.	Only for clinical trials
Statistical Design and Power	Required for clinical trials
Dissemination Plan	Required for clinical trials
Other Clinical Trial-related attachments	if required in specific guidelines

Guideline specific requirements

NIH Standard Due Dates for Competing Applications

http://grants.nih.gov/grants/funding/submissionschedule.htm

NIH Submission Policies

https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/submission-policies.htm

NIH Table of Page Limits

http://grants.nih.gov/grants/forms_page_limits.htm

NIH Senior/Key Personnel Definitions

http://grants.nih.gov/grants/policy/senior_key_personnel_faqs.htm#1658

Special Requirements or Unallowable Costs:

Does your human subjects research study meet the NIH Definition of a clinical trial?

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral **outcome?**

If the answer is "Yes" to all four of these questions, this study meets the definition of a NIH clinical trial and Sections 3, 4 and 5 are required.