

GRANT LOGISTICS & SUBMISSION PLANNING - R01

PI:	
Funding Mechanism (Provided by Faculty):	
Funding Period:	
Grant Title:	
Submission Due Date:	
Due to UC Office:	
Clinical Trial (Yes/No):	<u>No</u>
Animals (Yes/No):	<u>Yes</u>
Human Subjects (Yes/No):	
	Animal Protocol #:
	Human Subjects Protocol #:

	COMPONENT	REQUIRED	PAGE LIMIT	NOTES
1	Cover Letter	Determine if Needed		
2	Biosketches	All Key Personnel	5 pages	
3	Project Summary (Abstract)	Required	No Longer than 30 Lines	
4	Project Narrative	Required	2 - 3 Sentences	
5	Bibliography & References Cited	Required		
6	Facilities & Other Resources	Required		
7	Equipment	Required		
8	Introduction to Application	Required (if Resubmission)	1 Page	
9	Specific Aims	Required	1 Page	
10	Research Strategy	Required	12 pages	
11	*PHS Human Subjects and Clinical Trials Information Form	Required (if Humans)		
12	Progress Report Publication List	Required (if Renewal)		
13	Vertebrate Animals	Required (if have Animals)		
14	Select Agent Research	Determine if Needed		
15	Multiple PI Leadership Plan	Required (if Multi-PI)		
16	Consortium/Contractual Arrangements	Subcontracts Only		
17	Letters of Support	Determine if Needed		
18	Resource Sharing Plans	Required		
19	Authentication of Key Biological and/or Chemical Resources	Determine if Needed		
20	Appendix	Only allowed if requested in NOA		
21	Assignment Request Form	Use to request study section (No longer done in cover letter)		
22	Budget Justification	Required		

NOTES:

PI is responsible for preparing and submitting required documents to COM O&F in pdf.

Final review of the entire proposal packet is the responsibility of the PI

NIH PROPOSALS:

No Headers or Footers - these are system generated
 Fonts - Palatino, Georgia, Arial, Times New Roman and Helvetica (11 points or larger)
 Margins - at least one-half margins (top, bottom, left, and right)

***Always read the RFP and refer to agency guidelines if not NIH.**

NIH DEFINITION OF A CLINICAL TRIAL:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

Changes as of January 25, 2018

*Inclusion Enrollment Report, Protection of Human Subjects, Inclusion of Women & Minorities, and Inclusion of Children attachments have been combined into the new PHS Human Subjects and Clinical Trials Information Form

**The Data Safety Monitoring Plan attachment has been removed