

R01 Grant Checklist

Cover Letter	
Abstract/Project Summary	30 lines maximum
Narrative/Relevance	2-3 sentences
Introduction	1 page (Resubmission/Revision Only)
Specific Aims	1 page
Research Strategy	12 pages
References	no limit if applicable
Progress Report Publication List	(Renewal Only)
Vertebrate Animals	no limit if applicable
Select Agent Research	no limit if applicable
Multiple PI Leadership Plan	no limit if applicable
Consortium Contractual Arrangements	no limit if applicable
Letters of Support	no limit
Resource Sharing Plan	no limit if applicable
Authentication of Key Biological/Chemical Resources	1 page if applicable
Biosketch	5-page maximum
Budget Justification	no limit
Facilities and Resources	no limit if applicable
Equipment	required (no limit)
PHS Assignment Request Form	form page
Foreign Justification	no limit if applicable

Human Subjects Research Form (mandatory, see HSR Form)

Section 2 – Study Population Characteristics

Inclusion of Individuals Across the Lifespan	no limit
Inclusion of Women and Minorities	no limit
Recruitment and Retention Plan	no limit if applicable
Study Timeline	no limit if applicable
Cumulative Inclusion/Planned Enrollment Report	form page if applicable



R01 Grant Checklist (continued)

Section 3- Protection and Monitoring Plans

Protection of Human Subjects	no limit
Single IRB plan	no limit if applicable
Data Safety Monitoring Plan	no limit if applicable
Overall Structure of the Study Team	no limit applicable

Section 4 on HSR- (only required if you answered “Yes” to all questions on the Clinical Trial Questionnaire). If you have a Clinical Trial, please provide the documents below:

Study Design	32000 Characters
Statistical Design and Power	no limit if applicable
FDA – regulated intervention	no limit if applicable
Dissemination Plan	no limit if applicable

Section 5 – Clinical Trial Attachments

Sub awards documents (Pre-award will request. Please see sub contact information):

- Letter of Intent and 398 face page signed by institutional official
- Detailed Budget and Justification
- Scope of work
- R&R budget form
- Biosketch and profile information for all senior key personnel
- Facilities & Resources
 - 5 question certification form for all senior key personnel