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