R21 Grant Checklist – Forms F

Cover Letter  ..................................................  Don’t add study or award preferences
Abstract/Project Summary  ...............................  30 lines maximum
Narrative/Relevance  ......................................  2-3 sentences
Introduction  .....................................................  1 page (Resubmission/Revision Only)
Specific Aims  ....................................................  1 page
Research Strategy  .............................................  6 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
Appendix  ..........................................................  Only if PA instruct to add (survey, questionnaires)
Biosketch  ..........................................................  5 page maximum
Budget Justification  ............................................  no limit
Facilities and Resources  .....................................  no limit if applicable
PHS Assignment Request Form  ....................  Add study or award preference
Foreign Justification  ........................................  If foreign subgrantee on project (no-limit)

**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
R21 Grant Checklist – Forms F (Continued)

Study Timeline ........................................... no limit if applicable
Cumulative Inclusion/Planned Enrollment Report ........ form page if applicable

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
Subawards 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