NIH R21 Guide – Forms D

This checklist is meant to be used as a tool and does not replace the detailed requirements for submission information, which are found in the Funding Opportunity Announcement (FOA) and the SF424 (R&R) Application Packages – Research Instructions for NIH and Other Agencies

http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/research-forms-d.pdf

PI Name: _____

Title: _____
A "new' application must have a different title from any other PHS project submitted for the same application due date with the same PD/PI. A "resubmission" or "renewal" application should normally have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A "revision" application must have the same title as the currently funded grant. NIH and other PHS agencies limit title character length to 200 characters, including the spaces between words and punctuation.

Project Dates: _____
Standard Due Dates for Competing Applications: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm

Solicitation: _____
Parent Announcements (For Unsolicited or Investigator-Initiated Applications):
http://grants.nih.gov/grants/guide/parent_announcements.htm

Format Attachments Requirements

- must be in PDF format
- font size must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible)
- text color must be black with the following recommended fonts: arial, garamond, georgia, helvetica, palatino linotype, times new roman, verdana
- do not include headers or footers in attachments
- use paper size no larger than standard letter paper size (8.5'' x 11'')
- provide at least one-half inch margins (top, bottom, left, right) for all pages

Additional formatting information can be found here: http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm

SF424 (R&R) Forms

☐ **Cover Letter Attachment** *(no page limit but generally 1 – 2 pages)*
Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the announcement and/or the agency specific instructions. Applicants are encouraged to include a cover letter with the competing application. The cover letter should no longer be used for assignment requests. The new PHS assignment form is used for that purpose. Instead the cover letter should be used to relay information such as:

- Reason for late application
- Explanation of why a Subaward isn't active in all periods of the proposed project
- Statements regarding agency approval documents (e.g., requests over $500,000)
- Intent to submit a video as part of the application (NOT-OD-12-141)
- Indication that the proposed study will generate large-scale human or non-human genomic data (NOT-OD-14-111 and NOT-OD-15-027)

Full instructions pages R-25 & R-26

☐ **Project Summary/Abstract** *(30 lines of text maximum)*
State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Full instructions pages R-36

☐ **Project Narrative** *(2 or 3 sentence maximum)*
Using no more than two or three sentences, describe the relevance of this research to public health. Full instructions page R-36

☐ **Bibliography & References Cited** *(no page limit)*
Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number for each article. Full instructions page R-36 & R-37

☐ **Facilities & Other Resources** *(no page limit)*
Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements. If there are multiple performance sites, describe the resources available

at each site. Describe any special facilities used for working with biohazards or other potentially dangerous substances. Full instructions page R-37

☐ **Equipment**
List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Full instructions page R-37

☐ **Other Attachments**
Not generally used for R21. Attach a file only to provide other project information in accordance with the funding opportunity announcement and/or agency-specific instructions.

R&R Senior/Key Person Profile

Unless otherwise specified in an agency announcement, senior/key personnel are the program director/principal investigator (PI/PD) and other individuals who contribute to the scientific development or execution of the project in a substantive, measureable way whether or not salaries are requested.

Also use this section to list any Other Significant Contributors (OSCs), who are those individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of "zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). OSCs should be listed after all senior/key persons. A biosketch is required for all senior/key persons and Other Significant Contributors.

☐ **Biographical Sketch** *(5 page limit)*
              see Appendix B for biographical sketch reference sheet

R&R Budget Form

Modular budgets are applicable for the R21 funding mechanism. Applicants request funds in $25K increments up to cap of $275K direct costs over a two year period. No more than $200K may be requested in any one year. Note that consortium/contractual F&A costs are not factored into the direct cost limit. Modular budgets are simplified, therefore detailed categorical information is not needed. A modular budget justification should include:

☐ **Personnel Justification**
List all personnel, including names, percent of effort and roles on the project. Do not include salary and fringe benefit rate in the justification.

☐ **Consortium Justification** *(if applicable)*

Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort using the metric of person months, and roles on the project. No individual salary information should be provided.

☐ **Additional Narrative Justification** *(if applicable)*

Additional justification should include explanation for any variations in the number of modules requested annually.

PHS 398 Research Plan Form

☐ **Introduction to Application** *(for resubmission or revision only, 1 page limit)*

NIH allows a thirty-seven month window for resubmission (only one resubmission is allowed for each new, unfunded application). Include an introduction for all resubmissions that summarizes substantial additions, deletions, and changes to the application and responds to the issues and criticism raised in the summary statement. Full instructions page R-72 and http://grants.nih.gov/grants/policy/amendedapps.htm

☐ **Specific Aims** *(1 page limit)*

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Full instructions page R-73

☐ **Research Strategy** *(6 page limit)*

Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography & References Cited section. Full instructions pages R-73 – R75

☐ **Protection of Human Subjects**

Complete this section is you answered "yes" to the question "Are human subjects involved?". If the answer is "no" to the question but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved. Full instructions page R-76 and Supplemental Instructions, Part II Section 4.1, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ **Data Safety Monitoring Plan**

Complete this section if you answered "yes" to Item 1, Clinical Trial. Refer to Supplemental Instructions, Part II Section 4.1.5, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ **Inclusion of Women and Minorities**

This section is required for applicants answering "yes" to the question "Are human subjects involved?" and the research does not fall under Exemption 4. Refer to Supplemental Instructions, Part II (Section 4.2, 4.3, 5.6), http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ **Inclusion of Children**

This section is required for applicants answering "yes" to the question "Are human subjects involved?" and the research does not fall under Exemption 4. Refer to Supplemental Instructions, Part II (Section 4.4, 5.8), http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ **Vertebrate Animals**

Complete this section if you answered "yes" to the question "Are Vertebrate Animals Used?" If Vertebrate Animals are involved in the project, address each of the following criteria listed below:

1. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Research Strategy section. Identify the species, stains, ages, sex, and total numbers of animals by species, to be used in the proposed work.
2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

Full instructions page R-77, additional information http://grants.nih.gov/grants/olaw/VASchecklist.pdf

☐ **Select Agent Research**

If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period (list of agents: http://www.selectagents.gov/), either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place:

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities where select agent(s) will be used.

3. Provide a description of all facilities where the select agent(s) will be used.

Full instructions page R-78

☐ **Multiple PD/PI Leadership Plan**
For applications designated multiple PD/PIs, a leadership plan must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedure for resolving conflicts. Full instructions page R-78-79

☐ **Consortium/Contractual Arrangements**
Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s) The Letter of Intent from the Consortium site is uploaded here. Full instructions page R-79

☐ **Letters of Support**
Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. Full instructions page R-79

☐ **Resource Sharing Plan**
When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions, Part III 1.5, http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

☐ **Authentication of Key Biological and/or Chemical Resources** *(limit 1 page)*
If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics. Full instructions page R-80

☐ **Appendix**
A maximum of 10 PDF attachments is allowed in the appendix. Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. Full instructions page R-80 and R-81

PHS Inclusion Enrollment Report

The PHS Inclusion Enrollment Report form is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. Full instructions page R-80, additional information Supplemental Instructions, Part II Section 4.3, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf

PHS Assignment Request Form

The optional Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs). This information was previously collected in the Cover Letter Attachment, but now this optional information must be provided on the Assignment Request Form and not in the Cover Letter Attachment. Full instructions pages R-83 and R-84

NIH R21 Checklist – Forms D

☐ Cover Letter *(generally 1 – 2 pages)*

☐ Project Summary/Abstract *(30 lines of text maximum)*

☐ Project Narrative *(2 or 3 sentences maximum)*

☐ Bibliography & References Cites

☐ Facilities & Other Resources

☐ Equipment

☐ Biographical Sketch *(5 page limit)*

☐ Personnel Justification (*required*) / Consortium Justification (*if applicable*) / Additional Narrative Justification (*if applicable*)

☐ Introduction to Application *(for resubmission or renewal only, 1 page limit)*

☐ Specific Aims *(1 page limit)*

☐ Research Strategy *(6 page limit)*

☐ Protection of Human Subjects *(if human subjects involved)*

☐ Data Safety Monitoring Plan *(if clinical trial)*

☐ Inclusion of Women and Minorities *(if human subjects involved)*

☐ Inclusion of Children *(if human subjects involved)*

☐ Vertebrate Animals *(if vertebrate animals used)*

☐ Select Agent Research *(if application involves the use of select agents)*

☐ Multiple PD/PI Leadership Plan *(if designated multiple PD/PI application)*

☐ Consortium/Contractual Arrangements

☐ Letters of Support

☐ Resource Sharing Plan

☐ Authentication of Key Biological and/or Chemical Resources *(1 page limit)*

☐ Appendix

☐ Inclusion Enrollment Report

☐ Assignment Request Form

Appendix A – Additional Items Required For Subcontractors

☐ Official organization name, DUNS number, address

☐ Administrative contact information for Institution

☐ Contact information from PI

☐ NIH biographical sketch for Subaward PI

☐ Letter of Intent to collaborate/consortium letter from Authorized (OSP) Official

☐ Letter of Support from collaborating Senior/Key Personnel

☐ COI Disclosure from PI (or evidence that their Institution is in compliance)

☐ Information about Facilities/Equipment/Resources to add to Brown application

☐ Budget on R&R Budget Pages and budget justification

☐ Scope of Work (describes the actual work being completed by the Collaborator)

Appendix B – NIH General Biographical Sketch Reference Sheet

NIH General Biographical Sketch Reference Sheet

The biographical sketch may not exceed five pages and follows the format below:

A. Personal Statement
- Briefly describe why you are well-suited for your role in the project described in this application
- Identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project
- May explain impediments to your past productivity and include a description of factors such as family care responsibilities, illness, disability, and active military service

B. Positions and Honors
- List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science
- Briefly describe up to five of your most significant contributions to science
- For each contribution, reference up to four-peer reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) *note: applicants may use 'et al' in lieu of listing all authors in a citation*
- The description of each contribution should be no longer than one half page including figures and citations
- May provide a URL to a full list of published work – this URL must be to a Federal Government website (a .gov suffix). NIH recommends using My Bibliography. Providing a URL to a list of published work is not required, and reviewers are not required to look at the list.

D. Research Support
- List both selected ongoing and completed research projects for the past three years (Federal or non-Federally supported)
- Begin with the projects that are most relevant to the research proposed in the application
- Do not include number of person months or direct costs