# Q:\Website\ORA Logos\ORA Stack2.pngPre-Award Proposal Checklist

# **NIH R01 (per SF 424 form D)**

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**Deadline(s): NEW:** Feb. 5; Jun 5; Oct. 5

**RENEWAL/RESUBMISSION:** Mar. 5, Jul. 5, Nov. 5

**Anticipated Project Start Date(s):** December 1; April 1; July 1

**Budget:** Unlimited for up to 5 Years; however most typical is $250,000/year. Direct costs over $250,000/year require a **detailed R&R Budget and Budget Narrative**. Direct costs over $500,000/year require prior **NIH approval**.

## Please be sure to inform the Office of Sponsored Projects Services of your intent to submit as soon as possible.

The following checklist is for the Research Project Grant (Parent R01), PA‐13‐302. When applying for a program‐specific R01, please make sure that you review the guidelines thoroughly for any additional requirements and/or variations. Your [Sponsored Projects Services](http://www.buffalo.edu/research/about-us/staff-directory/contact-grant-expert.html) contact will download the Grants.gov package. The completed application package is due to SPS 5 business days prior to submission for their review.

## Applicants are encouraged to identify a participating Institutes and Centers (IC) that supports their area of research via the [R01 IC-Specific Scientific Interests and Contact](http://grants.nih.gov/grants/guide/contacts/parent_R01.html) website and contact Scientific/Research staff from relevant ICs to inquire about their interest in supporting the proposed research project.

## Formatting (from the [SF 424 Form D](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/research-forms-d.pdf) Guide)

**Font size**:  Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, or Verdana; 11 pt. font or larger; black ink only.

Color text and smaller text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible when the page is viewed at 100%.

**Type density**:  Must be no more than 15 characters per linear inch (including characters and spaces)

**Line spacing**: Must be no more than six lines per vertical inch.

**Margins:** Minimum one-half inch.

**Filenames:** File name is limited to 50 characters or less (including spaces). Avoid us ampersand (&) since it requires special formatting.

Save documents as PDF files. Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.

**Headers/Footers:** Do not use headers, footers or page numbers.

**Title:**  The NIH limits title character length to 200 characters, including spaces.

Additional formatting details may be found at: <http://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm>

## Basic Required Documents

For specific section requirements, see the [SF 424 (R&R) Application Guide](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf)  and the program announcement.

### SF424 (R&R)

**Cover Letter:** 1 page maximum. Required for Changed/Corrected Application submitted after the deadline and/or if video to be sent and/or large-scale genomic data to be collected. Otherwise not required, but strongly encouraged. SF424: G-44

### RESEARCH & RELATED Other Project Information

**Project Summary:** 30 line maximum, self‐contained description of the project which includes a statement of objectives and methods to be employed (not a summary of accomplishments). State the application’s broad, long‐term objectives and specific aims, making reference to the mission of the agency. Will be public domain. SF424: G-61

**Project Narrative:** In 2-3 sentences, describe in language for lay audience the relevance of this research to public health. Will be public domain. SF424: G-61

**Bibliography & References Cited:** No page limit; list **all** authors in the sequence appearing in the publication. SF424: G-62

**Facilities & Other Resources:** No page restriction. Identify and describe facilities to be used (laboratory, animal, computer, office, clinical, and other). Describe only those resources that are directly applicable to the proposed work. Also describe how the scientific environment in which the research will be done contributes to the probability of success. If there are multiple sites, describe resources available at each site. For Early Stage Investigators (ESIs), describe institutional investment in the success of the investigator. SF424: G-63

**Equipment:** No page restriction. List of major equipment already available for the project; list location and pertinent capabilities. SF424: G-64

**Other Attachments:** Attach a file only to provide any other project information not provided above or in accordance with the funding announcement and/or agency-specific instruction. SF424: G-65

### R&R Senior/Key Person Profile (Expanded) Form

**Biographical Sketch:** 5 page maximum/person. Required for senior/key personnel and Other Significant Contributors. Please note that as of May 25, 2016, there are new requirements for the NIH Biosketch. A Template and sample are available at the [ORA](http://www.buffalo.edu/research/research-services/prepare-and-submit-your-grant-proposal/developing-your-proposal/ProposalChecklistsandTemplates.html) Website.

Include a personal statement, positions, and honors, contributions to science (also recommend including a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography), and ongoing/completed research support from the past three years. SF424: G-77

### R&R Budget Form

**Budget:** Please work directly with your Sponsored Projects contact to draft/finalize your budget. As a general rule, R01 application budgets are not limited but need to reflect the actual needs of the proposed project. However, R01s can be limited in a specific FOA.

For requests of more than $500,000 in direct costs in any year, the PD/PI must contact the NIH Institutes and Centers (IC) program staff at least six weeks prior to submission to obtain an agreement that the IC will accept the application. Include cover letter, identify staff member and IC who agreed to accept application.

Allowable Costs

* Salary and fringe benefits for Principal Investigator, key personnel, and other essential personnel
* Equipment and supplies
* Consultant costs
* Alterations and renovations
* Publications and miscellaneous costs
* Contract services
* Consortium costs
* Facilities and Administrative costs (indirect costs)
* Travel expenses

**Budget Justification:** List all personnel, effort, project role, and contribution, no salary information. Additional Narrative Justification required if modules change from year to year. SF424: G-104

Personnel template available at the ORA Website.

### PHS 398 Research Plan Form

**Introduction:** Required only if type of application is Resubmission or Revision. 1 page limit. SF424: G-123

**Specific Aims:**  1 page limit. Concisely state the project goals and summarize expected outcome. SF424: G-123

**Research Strategy:** 12 page limit. Sections must be labeled in this order and with each header: a) Significance; b) Innovation; c) Approach; d) Preliminary Studies for new applications or Progress Report for renewal/revision applications. SF424: G-124

**Progress Report Publication List:** For renewal applications only. List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. SF424: G-127

Human Subjects Section (no page limits on this section; if applicable) SF424: G-128:

Protection of Human Subjects: Complete this section only if you answered “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form. Refer to [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 of the section PHS 398 Cover Page Supplemental Form. 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:** Complete this section only if you answered “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form and the research does not fall under Exemption 4. Please refer PHS Inclusion Enrollment Report of these instructions as well as the Supplemental Instructions, Part II Section [4.2](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf), [4.3,](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf) and [5.6](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf).

**Inclusion of Children:** Complete this section only if you answered “yes” to the question “Are human subjects involved?” on the R&R Other Project Information form. Refer to [Supplemental Instructions, Part II, Section 4.4 and 5.8](http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf).

Other Research Plan Sections (no page limits on this section; if applicable) SF424: G-130:

**Vertebrate Animals:** Complete this section if you answered “yes” to the question “Are Vertebrate Animal Used? On the R&R Other Project Information Form. Recommend sections to be labeled in this order and with each header: 1) Description of Procedures; 2) Justification; 3) Minimization of Pain and Distress. For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf> SF424: G-130

**Select Agent Research:** Complete this section if you have hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. A list of agents can be found at: <http://www.selectagents.gov/> SF424: G-131

**Multiple PI/PD Leadership Plan:** Only required when applications have designated multiple PD/PIs. No page restriction. SF424: G-132

**Consortium/Contractual Arrangements:** Required if there are subawards/subcontractors. Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). SF424: G-132

**Letters of Support:** Compile and 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. Font and margin requirements do not apply to letters of support. SF424: G-134

**Resource Sharing Plan:** Strongly encouraged, required if $500,000 or more in direct costs in any one year, model organisms to be developed, or large-scale genome data to be generated. SF424: G-135

**Authentication of Key Biological and/or Chemical Resources:**  If applicable, briefly describe methods to ensure the identity and validity of key biological and/or chemical rescores used in the proposed studies. 1 page limit is suggested. SF424: G-135

**Appendix:** Maximum of 10 PDF attachments is allowed. Note some FOAs do not permit publications. Refer to the SF424: G-136 for a complete list of allowable materials.

**For complete detailed instructions of each required component, it is recommended that you consult the SF\_424 Guide. Note there may be variations from the guide, based on the Program Announcement.**