

PHS 398 Research Plan				
1. Application Type: From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan. *Type of Application: <input type="checkbox"/> New <input type="checkbox"/> Resubmission <input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision				
See following instructions for completing the research plan.				
2. Research Plan Attachments: Please attach applicable sections of the research plan, below.				
1. Introduction to Application <small>(for RESUBMISSION or REVISION only)</small>	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
2. Specific Aims	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
3. Background and Significance	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
4. Preliminary Studies / Progress Report	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
5. Research Design and Methods	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Human Subjects Sections Attachments 6-10 apply only when you have answered "yes" to the question "are human subjects involved" on the R&R Other Project Information Form. In this case, attachments 6-10 may be required, and you are encouraged to consult the Application guide instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.				
6. Protection of Human Subjects	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
7. Inclusion of Women and Minorities	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
8. Targeted/Planned Enrollment Table	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
9. Inclusion of Children	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
10. Data and Safety Monitoring Plan	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Other Research Plan Sections				
11. Vertebrate Animals	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
12. Consortium/Contractual Arrangements	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
13. Letters of Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
14. Resource Sharing Plan(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
15. Appendix	<input type="text"/>	<input type="button" value="Add Attachments"/>	<input type="button" value="Remove Attachments"/>	<input type="button" value="View Attachments"/>

A maximum of 10 attachments is allowed.

The research plan should not exceed 25 pages. All tables, graphs, figures, diagrams, and charts must be included within the 25 page limit. NOTE: SOME FOAs HAVE DIFFERENT PAGE LIMITATIONS.

Each section below will require an upload of a separate file in PDF format. When this application is received by NIH, they will compile the sections, generate a Table of Contents, and add headers, footers, and page numbers. It is suggested that PIs create a single document and then separate sections into distinct PDF files to attach to this document.

Tips for Completing the PHS 398 Research Plan

Applications found not to comply with the requirements may be delayed in the review process.

<u>Application Type</u>	This information is automatically populated from the SF 424 (R&R) Cover Page.
<u>Research Plan Attachments</u>	<p>Even though there are separate PDF attachments, the total research plan must follow the page limit referenced in the instructions or FOA. NIH will validate that page limits are adhered to, along with checking the other formatting restrictions.</p> <p>Reviewers will review the application as an electronic document. Therefore, applicants are encouraged to use only a standard, single-column format for the text. Full-sized glossary photographs of materials may be included in the Appendix; however, an image of each, which may be in reduced size, must also be included within the page limits of the Research Plan.</p>
<u>Separate Attachments</u>	<p>The separate attachments will allow for increased efficiency in the automatic validations conducted by the NIH eRA system. The Research Plan sections will be concatenated in the appropriate order so reviewers and agency staff will see a single cohesive Research Plan.</p> <p>When validating for page limits, the eRA Commons will not count the white space created by breaking the text into separate files for uploading.</p>
<u>Page Limitations</u>	<p>Do not exceed 25 pages for Items 2–5. Some FOAs will include further limitations. If there are limitations included in the FOA, always follow those limitations.</p> <p>All tables, graphs, figures, diagrams, and charts must be included within the 25-page limit. Be succinct and remember that there is no requirement to use all 25 pages allotted to items 2–5 of the Research Plan.</p>
<u>Inclusion of URLs</u>	Unless otherwise specified in an NIH solicitation, Internet website addresses may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that they should not directly access an Internet site as it could compromise their anonymity.
<u>Notice of Proprietary Information</u>	<p>Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. If the information is essential, applicants should mark “Yes” to question 3 on the Other Project Information page.</p> <p>Then, all pages in the application that contain proprietary information should be marked with an asterisk (*) in the left-hand margin. A legend should be included at the beginning of Section 2, similar to “The following sections marked with an asterisk contain proprietary/privileged information that (name of Applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.”</p>

Begin each text section of the Research Plan with a section title (e.g., Introduction, specific Aims, Background & Significance, etc)

<p><u>1. Introduction to Application (for Resubmission or Revision only)</u></p>	<p>Use only if you are submitting an R&R Resubmission or Revision (Cover Page Item 8). The Introduction may not exceed three pages for resubmissions (previously known as a revision or amendment) or one page for revisions (previously known as competing supplements). Deviations from these general guidelines will be noted in particular funding announcement.</p>
<p><u>2. Specific Aims</u></p>	<p>List the broad, long-term objectives and the goal of the specific research proposed, for example, 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. One page is recommended.</p>
<p><u>3. Background and Significance</u></p>	<p>Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. Two to three pages are recommended.</p>
<p><u>4. Preliminary Studies/Progress Report</u></p>	<p><i>Preliminary Studies.</i> For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.</p> <p>Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.</p> <p><i>Progress Report for Renewal (previously known as Competing Continuation) and Revision (previously known as Supplemental Applications).</i> A Progress Report must be provided for renewal and revision applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Discuss any changes in the specific aims as a result of budget reductions. Include the complete references to appropriate publications and manuscripts accepted for publication (not part of the page limitations).</p> <p>Provide a succinct account of published and unpublished results,</p>

	<p>indicating progress toward their achievement.</p> <p>List the titles and complete references to all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. As part of the Appendix material you may include up to 10 publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to this project. Do not include manuscripts submitted for publication.</p> <ul style="list-style-type: none"> • Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article. • Manuscripts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment. • Manuscripts published but an online journal link is not available: The entire article should be submitted as a PDF attachment. <p>In the Progress Report for the renewal and revision applications, the publications portion and/or any Target and Enrollment Reports/Tables are not included in the 25-page limit.</p> <p>Six to eight pages are recommended for the narrative portion of this section.</p>
<p><u>5. Research Design and Methods</u></p>	<p>Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 14, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.</p> <p>Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible.</p>
<p><u>15. Appendix</u></p>	<p>Only one copy of appendix material is necessary. Use the add attachments button to the right of this field to complete this entry. A maximum of 10 PDF attachments is allowed. If more than 10 are needed, combine the remaining information into attachment</p>

#10.

New, resubmission, renewal, and revision applications **may** include the following materials in the Appendix:

- Submit up to 10 publications or manuscripts **accepted** for publication. *Do not include abstracts, unpublished theses, or manuscripts **submitted** for publication.*
- **Publications in press:** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.
- **Manuscripts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
- **Manuscripts published but an online journal link is not available:** The entire article should be submitted as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Photographs or color images of gels, micrographs, etc., provided that the image (may be reduced in size) is also included within the 25-page limit of Items 2 - 5 of the Research Plan. No images may be included in the Appendix that are not also represented within the Research Plan.

Do not use the Appendix to circumvent the page limitations of the Research Plan. An application that does not observe these limitations will be withdrawn from review. These Appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications. Specific appendix requirements may also be listed in a specific funding opportunity announcement.

The Appendix will be sent only to certain members of the Scientific Review Group who will serve as the primary reviewers of the application.

For specific instructions on completing sections 6–14, refer to the NIH Grants.gov Application Guide p.I-88–I-93 of the April 7, 2006 version. This document can be downloaded from <http://grants.nih.gov/grants/funding/424/index.htm>.