

## 5.5 PHS 398 Research Plan Form

**PHS 398 Research Plan**

OMB Number: 0925-0001

<b>Introduction</b>			
1. Introduction to Application (Resubmission and Revision)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
<b>Research Plan Section</b>			
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. *Research Strategy	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
4. Progress Report Publication List	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
<b>Human Subjects Section</b>			
5. 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"/>
6. Data Safety Monitoring Plan	<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. Inclusion of Children	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
<b>Other Research Plan Section</b>			
9. Vertebrate Animals	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
10. Select Agent Research	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
11. Multiple PD/PI Leadership Plan	<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. Authentication of Key Biological and/or Chemical Resources	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
<b>Appendix</b>			
16. Appendix	<input type="button" value="Add Attachments"/>	<input type="button" value="Delete Attachments"/>	<input type="button" value="View Attachments"/> <input type="checkbox"/>

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.

### Research Plan Attachments (see also Section [2.3.2 Creating PDFs for Text Attachments](#))

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. In addition, be sure to save files with descriptive file names.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text.

Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Digital images of material such as electron micrographs or gels must only be included within the page limits of the Research Strategy. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.

Investigators must use image compression such as JPEG or PNG. Do not include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.

### **Separate Attachments**

Separate attachments have been designed for the Research Plan sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the Research Plan sections will be concatenated in the appropriate order so that reviewers and agency staff will see a single cohesive Research Plan.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you **must** delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

### **Page Limits**

Applicants must observe the page numbers given in the detailed Table of Page limits at [http://grants.nih.gov/grants/forms\\_page\\_limits.htm](http://grants.nih.gov/grants/forms_page_limits.htm) unless the FOA specifies otherwise. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. If PAs or RFAs contain specific page limits, those instructions always supersede the instructions in this application guide.

All applications and proposals for NIH funding must be self-contained within specified page limits. Agency validations will include checks for page limits. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may be delayed in the review process. Unless otherwise specified in an NIH solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are not obligated to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access a website (except to review publications cited in the Biographical Sketch or Progress Report publication list) as it could compromise their anonymity.

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>.

### **Notice of Proprietary Information**

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, make sure you have checked the “Yes” box of question #3 in the “Other Project Information” form.

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. However, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

**Begin each text section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc).**

**Introduction**

Field Name	Instructions
1. Introduction to Application (for Resubmission or Revision only)	<p>Use only if Type of Application is Resubmission or Revision. See specific instructions in <a href="#">Part I Section 2.7, Resubmission Applications</a> and <a href="#">Part I Section 2.8, Revision Applications</a> on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA.</p> <p>The Introduction is a required attachment for Resubmissions and Revisions. Follow the page limits for the Introduction in the Table of Page limits at <a href="http://grants.nih.gov/grants/forms_page_limits.htm">http://grants.nih.gov/grants/forms_page_limits.htm</a> unless otherwise specified in the FOA.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

**Research Plan Section**

Field Name	Instructions
2. Specific Aims	<p>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.</p> <p>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</p>

Field Name	Instructions
	<p>paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>The Specific Aims attachment is required unless otherwise specified in the FOA. Follow the page limits for the Specific Aims in the Table of Page limits at <a href="http://grants.nih.gov/grants/forms_page_limits.htm">http://grants.nih.gov/grants/forms_page_limits.htm</a> unless specified otherwise in the FOA.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
3. Research Strategy	<p>Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. 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 and References Cited section (<a href="#">Part I Section 4.4.9</a>).</p> <p>Follow the page limits for the Research Strategy in the table of page limits <a href="http://grants.nih.gov/grants/forms_page_limits.htm">http://grants.nih.gov/grants/forms_page_limits.htm</a>, unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.</p> <p>a. <i>Significance</i></p> <p>Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.</p> <p>Describe the scientific rationale for the proposed project, including consideration of the strengths and weaknesses of any prior research or preliminary data.</p> <p>Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.</p> <p>Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.</p> <p>b. <i>Innovation</i></p> <p>Explain how the application challenges and seeks to shift current research or clinical practice paradigms.</p> <p>Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.</p> <p>Explain any refinements, improvements, or new applications of</p>

Field Name	Instructions
	<p>theoretical concepts, approaches or methodologies, instrumentation, or interventions.</p> <p>c. Approach</p> <p>Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</p> <p>Describe how the experimental design and methods proposed will achieve robust and unbiased results.</p> <p>Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.</p> <p>If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.</p> <p>Explain how relevant biological variables, such as sex, are factored into research designs and analyses in vertebrate animal and human studies.</p> <p>Strong justification, e.g., scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.</p> <p>Please refer to NOT-OD-XXX for further consideration of NIH expectations about sex as a biological variable.</p> <p>Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 11, below.</p> <p>If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.</p> <p>If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.</p> <p><b>As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.</b></p> <p><b>Preliminary Studies for New Applications:</b> For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for</p>

Field Name	Instructions
	<p>Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.</p> <p><b>Progress Report for Renewal and Revision Applications.</b> For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment; do not include that information here.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
4. Progress Report Publication List (Renewal Applications Only)	<p>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. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, or arose from AHRQ support after the publication date of the AHRQ public access policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: <a href="http://publicaccess.nih.gov/submit_process_journals.htm">http://publicaccess.nih.gov/submit_process_journals.htm</a>.</p> <p>Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material, see Part I Section 5.5.15 for more information).</p>

### Human Subjects Section

Field Name	Instructions
5. Protection of Human Subjects	<p>Refer to <a href="#">Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Training Plan</a>.</p> <p>Complete this section if you answered “yes” to the question “Are human subjects</p>

Field Name	Instructions
	<p>involved?” on the R&amp;R Other Project Information form. 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. Follow the instructions provided in the Application Guide and the FOA regarding the Protection of Human Subject attachment.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
6. Data Safety Monitoring Plan	<p>Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.</p> <p>Complete this section if you answered “yes” to Item 2 Clinical Trial of the Cover Page Supplement Form. Follow the instructions provided in the Application guide and the FOA regarding the attachment.</p>
7. Inclusion of Women and Minorities	<p>Refer to <a href="#">Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>. This section is required if you answered for applicants answering “yes” to the question “Are human subjects involved?” on the R&amp;R Other Project Information form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p> <p>Also, please refer to <a href="#">Section 5.8</a> of these instructions as well as the <a href="#">Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan (Section 4.3)</a> for more information on the PHS Inclusion Enrollment Report form as part of your application.</p>
8. Inclusion of Children	<p>Refer to <a href="#">Sections 4.4</a> and <a href="#">5.7</a> of the <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>. Complete this section if you answered “Yes” to the question “Are human subjects involved” on the R&amp;R Other Project Information Form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

## Other Research Plan Section

Field Name	Instructions
<p>9. Vertebrate Animals</p>	<p>Complete this section if you answered “yes” to the question “Are Vertebrate Animals used?” on the R&amp;R Other Project Information Form.</p> <p>If Vertebrate Animals are involved in the project, address each of the criteria below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the criteria below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following criteria will result in the application being designated as incomplete and it will not be considered.</p> <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, the grantee must submit to the NIH awarding office detailed information as required in points 1-5 below and verification of IACUC approval prior to the involvement of animals. If the grantee does not have an Animal Welfare Assurance, then an applicable Animal Welfare Assurance will be required (see Part III, <a href="#">Section 2.2 Vertebrate Animals</a> for more information).</p> <p>The criteria are as follows:</p> <ol style="list-style-type: none"> <li>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, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.</li> </ol> <p>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).</p> <p>For additional information, see <a href="http://grants.nih.gov/grants/olaw/VASchecklist.pdf">http://grants.nih.gov/grants/olaw/VASchecklist.pdf</a>. Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>10. Select Agent Research</p>	<p>Select agents are 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. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See</p>



Field Name	Instructions
	<p><a href="http://www.selectagents.gov/">http://www.selectagents.gov/</a>.</p> <p>If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions is available at <a href="http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html">http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html</a>.</p> <p>If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, 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. Although no specific page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> <li>1. Identify the select agent(s) to be used in the proposed research.</li> <li>2. Provide the registration status of all entities* where select agent(s) will be used. <p style="margin-left: 40px;">If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.</p> <p>*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”</p> </li> <li>3. Provide a description of all facilities where the select agent(s) will be used. <p style="margin-left: 40px;">Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).</p> <p style="margin-left: 40px;">Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).</p> <p style="margin-left: 40px;">Describe the biocontainment resources available at all performance sites.</p> </li> </ol> <p>If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.</p> <p>Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.</p> <p>Save this file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
11. Multiple PD/PI	For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the

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Leadership Plan	<p>PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. 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 procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.</p> <p>If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.</p> <p>Save this file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
12. Consortium/Contractual Arrangements	<p>Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&amp;R) form (Item 17) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p style="padding-left: 40px;">The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
13. Letters of Support (e.g., Consultants)	<p>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. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Do not place these letters in the Appendix. Consultant biographical sketches should be in the Biographical Sketch section.</p>

Field Name	Instructions
	<p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>14. Resource Sharing Plan(s)</p>	<p>NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. 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 <a href="#">Part III, 1.5 Sharing Research Resources</a>.</p> <ol style="list-style-type: none"> <li>1. <i>Data Sharing Plan:</i> Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&amp;A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific funding opportunity announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See <a href="#">Data-Sharing Policy</a> or <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html</a>.</li> <li>2. <i>Sharing Model Organisms:</i> Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See <a href="#">Sharing Model Organisms in Part III, 1.5.2</a>, and <a href="#">NIH Guide NOT-OD-04-042</a>.</li> <li>3. <i>Genomic Data Sharing:</i> Applicants seeking funding for research that generates large-scale human or non-human genome data are expected to provide a plan for sharing of these data or an appropriate explanation why data sharing is not possible. Large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS Policy provides examples of genomic research projects that are subject to the Policy. For further information see the NIH GDS Policy, <a href="#">NIH Guide NOT-OD-14-124</a>, and the GDS website at <a href="http://gds.nih.gov/">http://gds.nih.gov/</a>.</li> <li>4. AHRQ Policy for Public Access to Scientific Publications and Scientific Data requires all applicants to provide progress to date with sharing of publication and data in digital format arising from AHRQ funding after the publication date of the AHRQ policy. AHRQ applicants must also provide a data management plan that includes (1) a plan for protecting confidentiality and personal privacy, and (2) a description of how scientific data in digital format will be shared, including a plan for long-term preservation and access to the data and the associated costs, or explanation of why data sharing is not possible. See Part III, 1.5.4</li> </ol> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

Field Name	Instructions
	<p>Note that an Institutional Certification for applications including GDS is not required at the time of submission, but will be requested as Just-in-Time (JIT) information prior to award. If an award is made and the application includes a GDS plan the Institutional Certification must be submitted and accepted before the award can be issued.</p>
<p>15. Authentication of Key Biological and/or Chemical Resources</p>	<p>Briefly describe methods to be used in ensuring the identity and validity of key biological and/or chemical resources used in the proposed studies.</p> <ul style="list-style-type: none"> <li>• Key biological and/or chemical resources are those that: 1) may differ from laboratory to laboratory or over time; and 2) whose qualities and/or qualifications could influence the research data. These include, but are not limited to, cell lines, antibodies and specialty chemicals.</li> <li>• Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.</li> </ul> <p>Include brief, one-paragraph descriptions of how you will ensure the identity and integrity of each class of key resources (e.g., cell lines, antibodies, etc.) you plan to use in your studies. Describe how the effects of resources known to vary in activity, such as serum used in tissue culture, will be monitored and reported in such a way that the experiments can be repeated by other researchers. If authentication of one or more key resources is not possible, explain why this is the case and how the effects on the reproducibility of the experiments and the rigor of the conclusions drawn from them will be mitigated.</p> <p>If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.</p> <p>Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.</p> <p>Save this information in a single file. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>16. Appendix</p>	<p>Only one copy of appendix material is necessary. Use the <b>Add Attachments</b> button to the right of this field to complete this entry.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details <b>and check the FOA</b> for any specific instructions), though not all grant activity codes allow publications to be included in the appendix.</p> <p>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. For additional information regarding Appendix material and page limits, please refer to the NIH Guide</p>

Field Name	Instructions
	<p data-bbox="391 285 1393 348">Notice NOT-OD-11-080, <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html</a>.</p> <p data-bbox="391 373 1422 569">Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Reviewers are not required to consider any additional materials included in the Appendix. Only those materials listed below will be reviewed.</p> <p data-bbox="391 594 1414 657">New, resubmission, renewal, and revision applications may include the following materials in the Appendix (note, however, that some FOAs do not permit publications):</p> <p data-bbox="472 682 1373 779"><b>Publications – No longer allowed as appendix materials except in the circumstances noted below.</b> Applicants may submit up to 3 of the following types of publications:</p> <p data-bbox="548 793 1385 856"><b>Manuscripts and/or abstracts accepted for publication but not yet published:</b> The entire article should be submitted as a PDF attachment.</p> <p data-bbox="548 871 1390 968"><b>Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:</b> The entire article should be submitted as a PDF attachment.</p> <p data-bbox="548 982 1409 1045"><b>Patents directly relevant to the project:</b> The entire document should be submitted as a PDF attachment.</p> <p data-bbox="391 1077 1373 1140">Do not include unpublished theses, or abstracts/manuscripts <b>submitted</b> (but not yet accepted) for publication.</p> <p data-bbox="472 1165 1425 1228">Surveys, questionnaires, and other data collection instruments; clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.</p> <p data-bbox="472 1243 1386 1402">For videos, including those demonstrating devices, see information in <a href="#">Post-Submission Application Materials section</a> and <a href="#">NOT-OD-12-141</a>. When submitting a video as part of the application the cover letter must include information about the intent to submit it, if this is not done, a video will not be accepted.</p> <p data-bbox="391 1434 956 1465">Items that must <b>not</b> be included in the appendix:</p> <p data-bbox="472 1491 1422 1587">Digital photographs or color images of gels, micrographs, etc. <b>are no longer accepted as Appendix material.</b> These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.</p> <p data-bbox="391 1619 1390 1749">Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.</p>

Once all data have been entered, use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a form from your application, uncheck the box next to the form name in the Optional document section.

**5.6 (Reserved)**

**5.7 (Reserved)**