| Field Name | Instructions |
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| | research will exert on the research field(s) involved.<br><br>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.<br><br>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 http://grants.nih.gov/grants/forms_page_limits.htm unless specified otherwise in the FOA.<br><br>Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**. |
| 3. Research Strategy | 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 (Section 4.4.9).<br><br>Follow the page limits for the Research Strategy in the table of page limits http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. Note that the page limit for this attachment will be validated as a single file.<br><br>1. *Significance*<br>• Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.<br>• Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.<br>• Explain the project's potential to lead to a marketable product, process or service.<br>• For Phase II, Fast-Track, and Phase IIB Competing Renewals, explain how the commercialization plan demonstrates a high probability of commercialization. |

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| | 2. *Innovation*<br>• Explain how the application challenges and seeks to shift current research or clinical practice paradigms.<br>• 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.<br>• Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.<br>3. *Approach*<br>• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. 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.<br>• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.<br>• 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.<br>• Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.<br>• If your study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample.<br>• Please refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable. |

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| | • 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.<br>• 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.<br><br>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.<br><br>**As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.**<br><br>**Preliminary Studies for New Applications:** 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 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.<br><br>**Progress Report for Renewal and Revision Applications**. 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. For any studies meeting the NIH definition for clinical research, discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children etc.) as part of the progress report, particularly if relevant to studies proposed in the renewal or revision application. You should **not** submit a Cumulative Inclusion Enrollment Report form unless the enrollment is part of the renewal or revision application.<br><br>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. |