Research Plan attachment is required - 5 page limit, unless otherwise specified

**SPECIFIC AIMS**

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 have 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).

**PRELIMINARY STUDIES**

Include information on preliminary studies. Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application.

**SIGNIFICANCE**

Explain the importance of the problem or critical barrier to progress that the proposed project addresses.

Describe the strengths and weaknesses in the [rigor](https://grants.nih.gov/grants/glossary.htm#ScientificRigor) of the prior research (both published and unpublished) that serves as the key support for the proposed project.

Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

**INNOVATION**

Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

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.

Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

**APPROACH**

Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, and reference any Resource Sharing Plans as appropriate. Resources and tools for rigorous experimental design can be found at the [Enhancing Reproducibility through Rigor and Transparency](https://grants.nih.gov/reproducibility/index.htm) website.

For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the [Research Methods Resources](https://researchmethodsresources.nih.gov/) webpage.

Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

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.

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. Refer to the NIH Guide Notice on [Sex as a Biological Variable in NIH-funded Research](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html) for additional information.

Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH [hESC Registry](https://grants.nih.gov/stem_cells/registry/current.htm) cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.