**RESEARCH STRATEGY**

Delete all purple text from final version before converting to PDF:

The “Research Strategy” attachment is required. Must be 11 points or larger (Recommended: Arial, Georgia, Helvetica, Palatino Linotype).

**Format:**

Please following the limits for the Research Strategy in the [NIH Table of Page Limits](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm), unless otherwise specified in the FOA. Although multiple sections of information are required in the Research Strategy detailed below, the page limit applied to the entirety of the single “Research Strategy” attachment. Attach this information as a PDF file.

**Content:**

Organize the Research Strategy in the specified order and use the instructions provided below unless otherwise specified in the FOA. Start each section with the appropriate heading – Significance, Innovation, Approach.

Cite published experimental details in the Research Strategy attachment and provide the full reference in the “Other Project Information Form” in the “Bibliography and Reference Cited” attachment.

Note for applications proposing the use of human fetal tissue:

* If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the [*NIH Grants Policy Statement*](https://grants.nih.gov/policy/nihgps/index.htm)) is included in the proposed application you must include specific information in the Approach section of the Research Strategy attachment
* Applications proposing HFT that do not address these requirements will be administratively
* withdrawn.

Note for applications proposing the involvement of human subjects and/or clinical trials:

* Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of your proposed research, but do not duplicate information collected in the PHS Human Subjects and Clinical Trials form.
* The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and children; protection and monitoring plans; and statistical design and power.
* You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy.

Note for applicants with multiple specific aims:

* You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all the Specific Aims collectively.

**Significance:**

* Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
* 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.
* Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

**Additional Instructions for Research:** Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

**Additional Instructions for Multi-project:** Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

**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 the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
* 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/?AspxAutoDetectCookieSupport=1) 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*](https://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. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.
* 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.

**As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.**

**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 can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.

**Progress Report for Renewal and Revisions Applications:**

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. In the Progress Report, you should:

* 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 resulting from significant budget reductions.
* Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH definition for [*clinical research*](https://grants.nih.gov/grants/glossary.htm#ClinicalResearch). Use the Progress Report section to discuss, but not duplicate information collected elsewhere in the application.
* Do not include a list of publications, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.