Part I. Specific aims

Format:
- 1 page, narrow margin, Arial, 11 font size

Content:
- 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/aims 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). Typically, 3 specific aims are expected.

Part II. Research Strategy

Format:
- 6-12 pages, narrow margin, Arial, 11 font size

Content:
- Significance (2-5 pages)
  a) Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
  b) 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 proposed project.
  c) Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Innovation (0.5-1 page)
  a) Explain how the proposed project challenges and seeks to shift current research or clinical practice paradigms.
  b) 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.
  c) Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- Approach (3-6 pages)
  a) For each specific aim, describe the overall strategy, methodology, and analyses to be used to accomplish the proposed work. 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.
  b) For each specific aim, discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aim.
  c) 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.

d) 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.

e) 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.