

Instructions for Proposed Budget

(Expense categories may include personnel such as technician salary, supplies, small equipment, and other costs. The budget cannot include faculty salaries, travel expenses, or funds for consultants). Indirect costs are not allowable. Up to \$40,000 may be requested.

Instructions for the Research Plan

The Research Plan consists of the following items, as applicable. Begin each section of the Research Plan with a section header (e.g., Introduction, Specific Aims, Research Strategy, etc.).

1. Introduction **(Resubmission or Revision Applications only)**

An Introduction must be included that summarizes the substantial additions, deletions and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Reviewers' Summary Statement. (1/2 - 1 page)

2. Specific Aims

Provide a brief statement of the problem and your hypotheses. List the most important objectives of your work. (1 page)

3. Research Strategy

Organize the Research Strategy in the specified order, using the instructions provided below. 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 (item 5).

(a) Significance (2 pages)

Briefly describe the background of this proposed work and indicate how it will fill gaps in the existing knowledge. Also, indicate any preliminary work that is pertinent to this project

(b) Innovation (1 page)

- 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 intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach (3 pages)

Briefly describe the research design and methods that will be used to accomplish the specific aims of the project.

4. Expected Results and Future Plans to Secure Extramural Funding:

Describe any previous attempts to obtain funding for this project (1 page).

- Give the review score from the prior submission(s)
- Detail how this submission addresses prior review(s):
- Include any reviews and review scores from external funding agencies or the OCMDC for prior submissions.

5. Bibliography and References Cited

Provide a bibliography of any references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application.

The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

6. Protection of Human Subjects (if applicable)

Refer to Part II of the PHS 398: [Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#) if the proposed research will involve human subjects.

If the proposed research will not involve human subjects but involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

7. Inclusion of Women and Minorities (if applicable)

To determine if Inclusion of Women and Minorities applies to the application, see [Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#), Sections 4.2 and 5.6.

8. Targeted/Planned Enrollment Table (if applicable)

If this application involves the Inclusion of Women and Minorities, complete the attached Targeted/Planned Enrollment Table for each protocol; see [Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#), Section 4.3.

9. Inclusion of Children (if applicable)

To determine if Inclusion of Children applies to the application, see [Part II Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan](#), Sections 4.4 and 5.7.

10. Vertebrate Animals (if applicable)

If vertebrate animals are involved in the project, address each of the five points below.

The five points are as follows:

1. Provide a detailed description of the proposed use of the animals for the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association

(AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.