

**Title Page:** Use fp1. Irrelevant sections have already been typed in N/A.

**Abstract:** Use fp2. Follow instructions at the top of the page.

### **Research Plan:**

The Research Plan should include sufficient information needed for evaluation of the project. Be specific and informative, and avoid redundancies. Organize Items a-c of the Research Plan to answer these questions:

1. What do you intend to do?
2. Why is the work important?
3. What has already been done?
4. How are you going to do the work?

### Page Limitations

Do not exceed 10 pages for Items a-c. All tables, graphs, figures, diagrams, and charts must be included within the 10-page limit.

### Research Plan Format and Page Distribution

The PHS recommends the following format and page distribution.

#### a. Specific Aims

List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology. One page is recommended. **(JS: I would recommend 2 – 4 specific aims, stated as questions or hypotheses).**

#### b. Background and Significance

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Two to three pages are recommended. **(JS: this is basically a literature review, leading up to the questions you want to address. It should be carefully referenced.)**

### c. Research Design and Methods

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as the data sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. **(JS: This is the heart of your proposal. I recommend a highly structured format that explicitly addresses potential problems.)**

Although no specific number of pages is recommended for the Research Design and Methods section, the total for Items a-c may not exceed 10 pages, including all tables and figures.

### d. Human Subjects Research (not included in the 10 page limit; should be a page or less)

If you marked "Yes" for Item 4 on the Face Page of the application and did not claim any exemptions from the regulations, create a section entitled "Protection of Human Subjects." In this section, you must provide information to address all four evaluation criteria below as they apply to the research you are proposing.

#### 1. RISKS TO THE SUBJECTS

**Human Subjects Involvement and Characteristics:** Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.

Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations.

Sources of Materials: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks: Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

## 2.ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

Protection Against Risk: Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. In studies that involve clinical trials (biomedical and behavioral intervention studies), describe the plan for data and safety monitoring of the research to ensure the safety of subjects.

## 3.POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

## 4.IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

e. Vertebrate Animals. (not included in the 10 page limit; should be a page or less)

If you have marked Item 5 on the Face Page of the application "Yes," create a section heading entitled "Vertebrate Animals." Place it immediately following the "Research Design and Methods" section of the application (or after Item d, if applicable.)

Under the Vertebrate Animals heading address the following five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods 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 reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

f. Literature Cited (JS: I expect about 10-15 references; not included in the 10 page limit;)

List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference 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.