

Outline for NIH Research Proposals

The following describes how the narrative should be structured for NIH. (See SF424.) Sections A – D below should not exceed 25 single-spaced pages.

A. Specific Aims (Introduction)

This section should be titled “Specific Aims.” It should be approximately **one single-spaced page** and include the following*:

It should express the PI’s research goals at three levels:

- 1) **Broad long-term objective of the research:** Here you express the broadest use of your findings. The objective should be broad enough to justify your research efforts, yet narrow enough that your research aims or objectives for this project (and others you will do) are applicable.
- 2) **Specific Aims or objectives:** This is a statement of the problem to be addressed and how findings of this research effort will be used. This is not a hypothesis or methodology, but rather a succinct statement of the anticipated research outcomes. From these outcomes, the hypotheses can be generated. In your proposal it might be this statement that begins like this: “The specific aim of this research is to determine...”
- 3) **Hypotheses or questions:** You should express a hypothesis or question that is testable here. This statement should direct the research design and data collection methods.
- 4) **Research Rationale:** This is a statement that places your research in a context that clarifies why it should be done (e.g. its importance or urgency). Provide some information about the current conditions or positive consequences of the proposed research. This can be done by explaining the contribution this research will make to general knowledge or the need for your research data to further work in this area, etc. Although you will have a more detailed history in the background and significance section, there should be a concise statement here that you can then elaborate upon in the background section.

*This section should state the project aims in a compelling, but objective way. Avoid exaggeration of the project’s importance because this may cause reviewers to question its validity.

B. Background and Significance (Literature Review or Conceptual Framework) – 2 or 3 pages

The literature review is a focused review of other research activities that have led to your application. It **includes only** references directly related to the project’s stated objectives and **excludes** references to other related research areas. Be sure to cite recent research and try to include the research of potential reviewers. The agency will have reviewers who are top researchers in the field. Reviewers are not interested in everything that the PIs know, but rather how current and previous work led to your proposed project.

C. Preliminary Studies

Describe the studies and add references to publications you have made related to this work if applicable. Write this section so it states the relationship between your prior work and the proposed research. Summarize highlights of the research. Presenting pilot data is very useful here. You should include here any pretests. If complicated instrumentation is used, provide evidence that pretests have been conducted and that back up support is available. The point of this section is to show the reader that the PIs are qualified and have the resources to conduct the research. A complete list of publications (either submitted or accepted) resulting from these studies should be included in the appendix.

D. Research Design and Methods

In this section you clearly describe the design, procedures, and any statistical analyses that will be used to accomplish the specific aims of the study. Include how data is to be gathered, analyzed, and interpreted.

It should include the following:

Project Design: The design whether experimental or other needs to be explicitly stated and clearly described. A statement such as a “focus group will be used” is insufficient. You must give enough detail for reviewers to determine the appropriateness of the design in terms of its applicability to the project hypotheses. Simpler designs are preferable. Whether qualitative or quantitative, the design needs to be carefully described.

Subjects:

For Human Subjects: Here describe relevant characteristics about the sample population(s) to be used. Identify them by age, gender, and number. Describe how you will select your sample. Provide information on projected attrition and if significant, the corrective procedures you will use. It is important to defend the appropriateness of the sample and any anticipated benefits to the population.

For Animal Subjects: (Not applicable)

Instruments: Describe data collection instruments, including reliability and validity information when appropriate. Do not supply diagrams for equipment, but rather the name (full name and make) and why this one is appropriate (if this might be questioned). Provide information on measurement level of variables. If your data will be collected over time, both short-term and long-term data collection procedures should be provided. When data collection is going to be conducted over a long period of time, incentives for participants to continue as part of the study should be described.

Procedures: Describe data collection procedures. Include enough detail so that someone unfamiliar with the procedures could duplicate major aspects and be able to envision the environment. Also, describe how you plan to record initial data, enter them for data analysis, and store them. Surveys will be administrated to collect data on....” is insufficient. Instead describe the procedure in enough detail so that anyone reading the proposal could envision what and how this will be undertaken, by whom, and when. If there are alternative ways to your procedure that are cited in the literature, explain why you’ve chosen this procedure instead. If data collection requires training, explain how the training will be conducted and by whom.

Methods of Analysis: Describe statistical approach and related data analyses in as much detail as possible. Associating the method of analysis with the hypothesis and specific aims is recommended. Spell out these associations carefully so that there are no misunderstandings. The same issue is important when multiple data sets are analyzed. Present any specific statistics to be used. Also discuss the results you expect and how they will be interpreted.

Research Timeline: Describe the timeframe for the procedure presented in the research plan. This is a template for what you have requested in your budget.

E. Human Subjects

Here you need to provide additional information on human subjects being used. You will describe (among other things) why these subjects were chosen, recruitment plans and informed consent procedures, and an explanation of how risks will be minimized.

NIH requires the following information for research using human subjects.

1. Provide a detailed description of the proposed involvement of human subjects in the work previously 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, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

2. 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.

3. Describe plans for the recruitment of subjects and the consent procedures to be followed. Include 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. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the PHS only if requested.

4. Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

G. Literature Cited

List all references here. Use a standard style.

H. Consortium/Contractual Arrangements

Include a signed statement from an authorized official at the consortium institution(s) if applicable.

I. Consultants

Attach letters from non-Marist individuals confirming their roles in the project.

Abstract: Write this part last. It should be a summary for what is being proposed and how it will be done. Include the project's long-term objectives and specific aims. The PIs current work can be mentioned if it has lead to the current proposal. A statement of the proposal's relationship to the mission of the NIH program is important to include.