Yale Liver Center Pilot Project Application Instructions

Please read the instructions carefully and use the attached template for your application.
If you have any questions, please email Program Manager, Christine Abu-Hanna.

FORMAT INSTRUCTIONS

Use attached template to complete application

Submit documents in the order listed below as a single PDF

Font: Arial, Size:11, Margins: 0.5" (narrow setting)

Figures may be included in the research strategy

PAGE 1: FACE PAGE

Complete entire form

PAGE 2: FACE PAGE CONTINUED

PROJECT SUMMARY: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the Liver Center/NIDDK). Describe the research design and methods for achieving the stated goals.

RELEVANCE: (aka Project Narrative) Describe the relevance of this research to public health in, at most, three sentences. For example, NIH applicants can describe how, in the short or long term, the research would contribute to fundamental knowledge about the nature and behavior of living systems and / or the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

PAGE 3: DETAILED BUDGET FOR INITIAL BUDGET PERIOD

Complete entire form while noting the following:

- PI salary is **not** allowed
- Salary may only be requested for project support personnel such as a research assistant or technical assistant. Support for postdocs is not allowed.
- Requests for funds for travel or publications are **not** allowed
- Budget should include only direct costs and make use of the entire $40,000

PAGE 4: BUDGET JUSTIFICATION

BUDGET JUSTIFICATION: Use the Budget Justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request.

BIOSKETCHES

Biosketches of all key personnel should be included following NIH guidelines here. Use new format FORMS-H.

OTHER SUPPORT

Other Support of all key personnel should be included following NIH guidelines here. Use new format FORMS-H.

PAGE 5: SPECIFIC AIMS (1 page limit)

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 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).

PAGE 6-9: RESEARCH STRATEGY (4 page limit)

1. **Significance**
   a. Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
   b. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
   c. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   d. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
2. **Innovation**
   a. Explain how the application 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.
3. **Approach – include information on preliminary studies**
   a. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. 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, and reference any Resource Sharing Plans and the Data Management and Sharing (DMS) Plan, as appropriate.
   b. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
   c. 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.
   d. 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.
4. **Additional required information**
   a. Describe how this project is related to the Center's themes and goals (Immunobiology and Inflammation, Hepatic Metabolism, Liver Biology and Pathobiology)
   b. Alignment of the P and F project with the P and F program's vision/mission
      i. The purpose of the pilot is to provide support for investigators to collect preliminary data sufficient to support a grant application for independent research support and/or to test a novel, even high-risk, hypothesis.
   c. Relevance of the P and F project to NIDDK's scientific mission
   d. How will this project benefit from specific collaborations with Center members?
   e. What are your plans for follow-up upon the successful completion of the project?
      i. Briefly describe the long-term goals of the research project that you hope to develop, if the pilot project is successful. Indicate your plans for future grant submissions to the NIH or other national organizations. If you have not previously had an extramural grant, you should identify a mentor and outline a mentoring plan.
   f. Briefly describe which Liver Center cores you will be using. Specifically, outline how the cores will facilitate this research.

PAGE 10: BIBLIOGRAPHY/REFERENCES CITED

LETTERS OF SUPPORT *Not required but will be accepted*

After we receive your grant application, it will be distributed to internal reviewers. Based on internal reviews, you will be notified if you can submit a revised application and present to our External Advisory Board

If you are invited to present to our External Advisory Board, you will be required to submit the information below with your grant revisions

VERTEBRATE ANIMALS

If live vertebrate animals are involved in the project, address each of the following criteria:

1. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Each of the criteria must be addressed. In addition to the 3 criteria above, you should also:

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.
- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

RESOURCE SHARING PLAN

Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible.

Research Tools: NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

DATA MANAGEMENT AND SHARING PLAN

Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens. Please complete the DMS Plan format page here.

AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

Key biological and/or chemical resources are characterized as follows:

- Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION

Projects proposing clinical trials will **not** be considered. All other projects involving human subjects must follow guidelines and complete appropriate forms listed here.