FORM PAGE 1: FACE PAGE

Complete entire form while noting the following:

Q2 Number: N/A Title: Yale Liver Center Pilot Project Program

Q6 From: 09/01/2020 Through: 08/31/2021

Q7 7a. Direct Costs $25,000 7b. Total Costs $25,000

Q8 8a. Direct Costs $25,000 8b. Total Costs $25,000

Q9 Name: Yale University

Address: 150 Munson Street, 3rd Floor

PO Box 208327

New Haven, CT 06520-8327

Q10-13 Does not need to be completed

FORM PAGE 2: SUMMARY, RELEVANCE, PROJECT/PERFORMANCE SITES, SENIOR/KEY PERSONNEL, OTHER SIGNIFICANT CONTRIBUTORS, AND HUMAN EMBRYONIC STEM CELLS

Complete entire form

FORM PAGE 3: RESEARCH GRANT TABLE OF CONTENTS

Complete entire form

FORM PAGE 4: 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 (research assistant, technical assistant)
- Requests for funds for travel or publications is **not** allowed
- Budget should make use of entire $25,000

FORM PAGE 5: BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD

Complete entire form

BIOSKETCHES

Biosketches of all key personnel should be included following NIH guidelines here.

OTHER SUPPORT

Other Support of all key personnel should be included following NIH guidelines here.

RESOURCES FORMAT PAGE

One-page limit

RESEARCH PLAN (must use continuation format page to complete)

1. Specific Aims (½ page limit)
   - **a.** 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.
   - **b.** 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).

2. Research Strategy (6 page limit)
   - **a. Significance**
     - Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
     - Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
     - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
     - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
   - **b. Innovation**
     - Explain how the application challenges current research or clinical practice paradigms.
     - 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. Approach – include information on preliminary studies**
     - 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. Unless addressed separately in the Resource Sharing Plan section, include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate.
     - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
     - 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.
     - 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.
3. Bibliography
4. Select agent research (not allowed)
5. Multiple PD/PI leadership plan (not allowed)
6. Consortium/contractual agreements (not needed)
7. Letters of support (not required but will be accepted)

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

Include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.)

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 should contact Christine Abu-Hanna for appropriate forms.