YALE LIVER CENTER

Yale SCHOOL OF MEDICINE

Memorandum

To: Liver Center Members and other research faculty of the Medical School

From: Michael H. Nathanson, M.D. Ph.D., Director, Yale Liver Center
Mario Strazzabosco, M.D., Ph.D., Co-Director, Yale Liver Center
Wajahat Z. Mehal, MD, PhD, Pilot Project Program Director, Yale Liver Center

CC: Christine Abu-Hanna, Program Manager

Date: July 10, 2023

Re: SUBMISSION OF APPLICATIONS FOR YALE LIVER CENTER PILOT FUNDING

The NIH/NIDDK P30 Liver Center grant provides for the annual submission of pilot projects (up to $40,000 direct costs each) from both Liver Center and non-Liver Center investigators.

The purposes of the pilots are to fund new initiatives, not ongoing research, and to support new investigators to pursue liver related research that should lead to future R01-type funding or other support. Projects utilizing Core Facilities and supporting young investigators or applying new methodologies or approaches to the study of liver pathophysiology are given priority.

Investigators should meet one of the following criteria, in order of priority:

1. Senior fellows or junior faculty at Yale, currently not funded by NIH grants and in need of funds to help prepare for R01-type applications.
2. Established University investigators not currently funded for work related to the Center's focus on liver related research, but who wish to apply their areas of expertise to subjects of Center interest.
3. Funded Center investigators who wish to pursue a project that is different from their current focus of interest, and who needs to develop preliminary data to apply for new R01-type funding.

Pilot grants will undergo two levels of review: first from Center executive committee and then from our External Advisory Board. The Board will convene at Yale in December or January to determine a priority score for each request and can approve or disapprove the project or modify the budget. No pilot projects can be submitted for more than two consecutive years. All current pilot project recipients must follow the same guidelines to request a second year of funding.

Please note the following dates on your calendar

Friday, August 18, 2023: Deadline for submission of Letter of Intent (one electronic copy) emailed to Christine Abu-Hanna at Christine.abu-hanna@yale.edu by 5:00pm.

The letter of intent **must include** the following:
1) Academic position, VISA status and future scientific plans regarding liver-related research
2) Title of pilot project and
3) A sentence as to the applicability of the pilot project to the Liver Center. **Projects must make use of the Center's facilities.**

Upon Letter of Intent review by the Executive Committee, applicants will be notified whether they can submit a full application.

Friday, September 29, 2023: Deadline for submission of full applications (one electronic copy) emailed to Christine Abu-Hanna by 5:00pm. This should include all documents listed below. Due to pilot projects being internally funded, ***a TranSum and Office of Sponsored Projects approval/signature is not required.***

Friday, October 20, 2023: Internal reviews of the most competitive applications are returned to investigators for revisions.

Friday, November 24, 2023: Receipt of revised application deadline (one electronic copy) emailed to Christine Abu-Hanna by 5:00pm.

December 2023 or Jan 2024: External Advisory Board meets to make final decisions on awards. Applicants will be expected to present their pilot project to the Board on this date (approximately 15 minutes).

March 1, 2024: Approved projects will begin funding.

Application Instructions:
The general format of the NIH research project applications on fillable individual PHS 398 forms Rev. 3/20 approved through 02/28/2023 must be used to request pilot funding. Please only use forms listed below and submit in the order listed. To download forms, please click here. If using the PDF forms, Adobe Acrobat Professional software is required to save/edit your application on the forms required when submitting your application.

Only the pages listed are required for this application. Pilot project applications should not exceed the page limits and format instructions. Please read the instructions carefully.

If you have any questions, please contact Program Manager, Christine Abu-Hanna at 203-785-5610 or email.

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: 03/01/2024 Through: 02/28/2025

Q7 7a. Direct Costs $40,000 7b. Total Costs $40,000

Q8 8a. Direct Costs $40,000 8b. Total Costs $40,000

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 include only direct costs and make use of entire $40,000

FORM PAGE 5: BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD & BUDGET JUSTIFICATION

Complete entire form

BIOSKETCHES

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

OTHER SUPPORT

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

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 (5 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.
     - In keeping with current NIH guidelines describe plans to address weakness in the rigor of prior research that serves as support for the proposed project, methods to ensure robustness and unbiased results, validation of key biological resources and explain how relevant biological variables (i.e. sex) are factored into the research design and analysis for studies involving vertebrate animals or humans.
   - **d. Additional required information**
     - Describe how this project is related to the Center's themes and goals (Immunobiology and Inflammation, Hepatic Metabolism Epithelial Biology and Pathobiology)

- How will this project benefit from specific collaborations with Center members?
- What are your plans for follow-up upon the successful completion of the project?
- Briefly describe which Liver Center cores you will be using.

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 must follow guidelines and complete appropriate forms listed here.