Deadline:
- Internal Application: October 1, 2020
- Full Application: December 1, 2020

Estimated Award Amount: $1,000,000 (initial direct costs)
JHU Nomination Limit: 1
For More Detailed Information Click Here

Opportunity Summary:
The NIDDK is proposing the establishment of the Liver Cirrhosis Network through this FOA which is seeking a single Scientific Data Coordination Center; and in conjunction with RFA-DK-20-003 seeking Clinical Research Centers, in order to promote clinical and translational research on cirrhosis of the liver in adults.

To accelerate the purpose of this FOA through the establishment of the Liver Cirrhosis Network, the NIDDK is proposing two broad approaches to be undertaken. First is the establishment of a Longitudinal Cohort of patients with cirrhosis. Second is the development and implementation of an intervention trial using an HMG-coenzyme A reductase inhibitor (“statin”). All studies undertaken by the Liver Cirrhosis Network will be performed with adult subjects. The findings and results emanating from these two approaches should advance the understanding about the pathophysiological mechanistic aspects of liver fibrosis from both pro- and anti-fibrotic processes; improve the assessment of clinical risk factors associated with advancement or recession of liver fibrosis; an opportunity to assess noninvasive measures of liver fibrosis and cirrhosis in conjunction with clinical measures; and determine the safety and efficacy of statin therapy in preventing disease progression and adverse clinical outcomes of cirrhosis.

The SDCC will abide by the NIDDK Regulatory Policies and Guidance document at https://www.niddk.nih.gov/research-funding/human-subjects-research/policies-clinical-researchers; and additionally will support protocol development, provide sample size calculations, statistical advice, questionnaires, and data analysis; coordinate implementation, training, and logistical and management support for the conduct of the studies; support manuscript preparation; organize committee meetings; assist in the establishment, coordination, and management of a central or single Institutional Review Board for the Liver Cirrhosis Network; and provide overall study coordination and quality assurance, including coordination of the logistical activities of the Data and Safety Monitoring Board, the Steering Committee and other standing committees; coordination of the biospecimens, tracking, distribution, and eventual depositing of both data and biospecimens into the NIDDK Data and Biospecimen Repository as per NIDDK policy (https://repository.niddk.nih.gov/home).

Eligibility & Requirements:
None.

Internal Nomination Process:
Interested applicants should submit the following documents:
1. JHU Limited Submission Cover Sheet
2. Proposal (maximum of two pages of text only, single spaced: 12-pt font and one-inch margins) (Note: figures, tables, and other reference material may be included in addition to the 2 pg. text limit)
3. Curriculum Vitae of investigator, including current external research support and publications
4. Budget (two pages maximum)

Questions? Comments? Email the Research Development Team at resapp@jhu.edu.