


NIDDK: Priorities and Perspectives


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NIDDK: Support of Fatty Liver Disease Research

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\$30,142,653,000

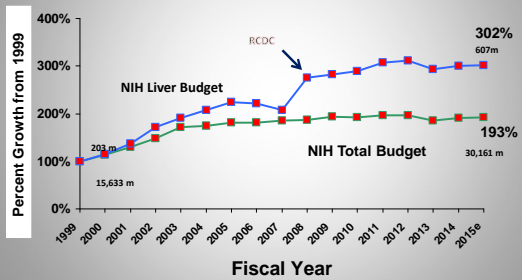
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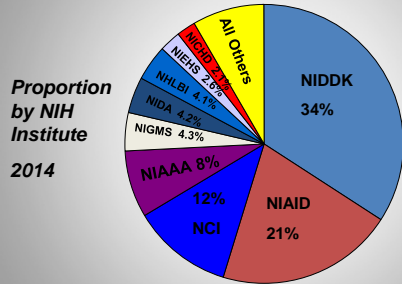
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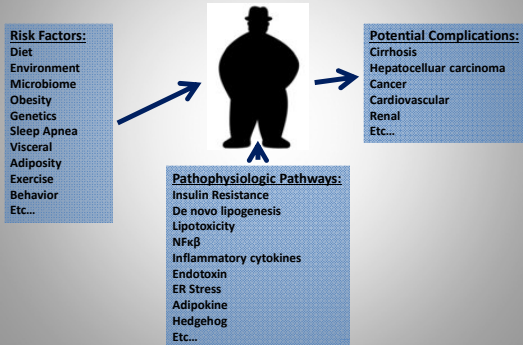
**Growth in NIH Liver Disease Research Funding:
FY 1999-2015**



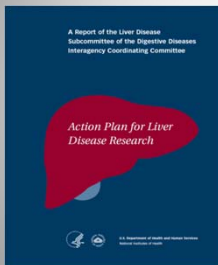
NIH Support of Liver Disease Related Research



STOPNASH: A Brief Summary



The Trans-NIH Action Plan for Liver Disease Research



- Released in early 2005
- Initiated with the establishment of the Liver Disease Research Branch, NIDDK
- To advance research on liver and biliary diseases

Research Goals: Fatty Liver Disease

	Short Term (0-3 years)	Intermediate Term (4-6 years)	Long Term (7-10 years)
High Risk	A3. Develop more accurate animal models of nonalcoholic fatty liver disease (including secondary forms) and define molecular characteristics.	B3. Develop rapidthroughput systems to evaluate potential therapies of fatty liver disease. Develop therapy of acute alcoholic hepatitis that promotes recovery and decreases permanent injury.	C3. Identify genetic markers for development of steatohepatitis and its complications. Develop screening programs for early detection and intervention with preventive or therapeutic regimens.
Intermediate Risk	A2. Conduct phase I and II clinical trials of candidate therapies for NASH, TPN associated liver disease, and alcoholic liver disease (e.g., silymarin, cytokines, anti cytokines, antifibrotic agents).	B2. Delineate the hepatic pathways of lipid metabolism and how they are altered in alcoholic and nonalcoholic liver disease. Develop noninvasive means of distinguishing steatosis from steatohepatitis and for grading and staging disease.	C2. Establish the prevalence and incidence of NASH in the general population as well as special populations in the United States, such as children, minority groups, and patients with diabetes and other dysmetabolic syndromes. Better define the safe amounts of alcohol intake in terms of liver disease for different populations.
Low Risk	A1. Establish cohort study to prospectively analyze the natural history of the full spectrum of nonalcoholic fatty liver disease.	B1. Elucidate the clinical, metabolic, proteomic, and gene expression patterns associated with various stages of nonalcoholic and alcoholic fatty liver disease. Evaluate role and effects of bariatric surgery on NASH.	C1. Establish the efficacy and safety of therapy with insulin sensitizing agents and vitamin E in NASH. Establish the efficacy and safety of therapy with SAMe in ALD.

Funding Mechanisms for Basic and Translational Research

- Vast majority of NIDDK funded projects are investigator initiated
- Mechanisms for basic/translational research
 - R01 Research Project Grant
 - P01 Project Program Grant
 - R24 Collaborative Interdisciplinary Team Science
 - Don't forget Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)

NIDDK Program Project P01

- PAR-13-266
- P01 proposals should define a central scientific theme as the foundation for the application
- A minimum of 3 projects that may address a range of scientific questions that are complementary with the central scientific theme
- At least one research core that provides services to at least two of the research projects

NIDDK Program Project P01

- Points to consider for P01 proposals:
 - In general, these are large budgetary commitments by the NIDDK
 - Strongly encouraged to initiate a dialogue with NIDDK program staff at least 6 months prior to anticipated application submission
 - Invitation to present P01 proposal to NIDDK staff
 - Permission is necessary by NIDDK program staff in order to submit a P01 application

NIDDK Collaborative Interdisciplinary Team Science R24

- PAR-13-305
- R24 proposals are focused upon a single critical research question that has the potential to be paradigm-shifting
- Investigator team should be interdisciplinary in nature
- Proposals may be discovery, development of unique resources or technologies in nature
- Supports basic, translational or clinical sciences

NIDDK Collaborative Interdisciplinary Team Science R24

- Points to consider for R24 proposals:
 - Strongly encouraged to initiate a dialogue with NIDDK program staff at least 3 (preferably 6) months prior to anticipated application submission
 - Only one receipt date per fiscal year
 - Not intended for:
 - Highly focused, investigator initiated studies
 - Individual projects or cores

Small Business Funding Opportunities

- **Small Business Technology Transfer Grant (STTR) (PA-15-270)**
- **Small Business Innovation Research Grants (SBIR) (PA-15-077)**

SBIR and STTR: Critical Differences

Award is Always Made to a Small Business Concern

Research Partner

- **SBIR:** **Permits** partnering: up to 33% Phase I and 50% Phase II
- **STTR:** **Requires** partnering with Research Institution: *Small business (40%) and U.S. research institution (30%)*

Principal Investigator

- **SBIR:** Primary (>50%) employment **must** be with small business concern
- **STTR:** PI may be employed by either research institution or small business concern

NIDDK Funding Mechanisms for Clinical Trials

- **R01:**
 - Up to two clinical centers
 - Budgetary considerations:
 - Requires NIDDK program staff approval for direct costs exceeding \$500K
 - Requires NIDDK Director approval for direct costs exceeding \$1 million
- **R21 Pilot and Feasibility Clinical and Translational Research Studies**
- **U34: NIDDK Multi-Center Clinical Study Implementation Planning**
- **U01: NIDDK Multi-Center Clinical Study Cooperative Agreement**

Pilot and Feasibility Clinical and Translational Research Studies in Digestive Diseases and Nutrition (R21)

- **Purpose:**
 - Provide up to 2 years of support for preliminary clinical studies
- **Approach:**
 - Investigator initiated
 - Though not required, it is best for the investigator to contact NIDDK program staff in advance

NIDDK Multi-Center Clinical Study Implementation Planning U34

- **Purpose:**
 - To provide support to establish administrative, regulatory, logistical aspects of a clinical study or trial prior to protocol initiation
- **Approach:**
 - Up to 2 years of support
 - Milestone driven
 - Transition to U01 after completion of milestones within the timeframe of the U34 and with NIDDK approval

NIDDK Multi-Center Clinical Study Implementation Planning U34

- **Points to consider for U34 proposals:**
 - Proposal must involve 3 or more clinical sites
 - A complete, **fully developed protocol** must accompany the U34 application
 - Note: U34 is not intended to support protocol development
 - Strongly encouraged to initiate a dialogue with NIDDK program staff at least 6 weeks (**preferably 6 months**) prior to anticipated application submission
 - Receipt dates:
 - 2016: April
 - 2017: January, June

NIDDK Multi-Center Clinical Study Cooperative Agreement U01

- **Purpose:**
 - To provide support for the initiation and conduct of a clinical study or trial after successfully completing the U34 phase
 - On rare occasions and only with NIDDK approval, a U01 proposal may bypass the U34 phase

Requests for Applications (RFA)

- Research initiatives developed by the NIDDK
- Funding Opportunity Announcements that typically have set aside funds
- Information regarding RFAs is made public by the NIH Guide
- Subscribe to the NIH Guide at:
<http://grants.nih.gov/GRANTS/guide/listserv.htm>

Summary of NIDDK Funding Mechanisms for Clinical Trials and Investigative Research

- **Clinical Trials:**
 - U01 (for conduct of clinical study or trial)
 - U34 (for 3 or more clinical sites)
 - R01 (for 2 or less clinical sites)
 - R21 for clinical pilot and feasibility proposals
- **Basic, translational and clinical science:**
 - R01 Standard Research Project
 - R21 for clinical pilot and feasibility proposals
 - P01 Program Project
 - R24 Interdisciplinary Team Science
 - R41/42 or R43/44 Small Business Research and Technology Projects

General Advice

Always feel free to contact us!!

– We're here to help guide you through the bureaucracy, policies, regulations, etc.

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