

NIH Research Agenda

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Complications & Co-Infections

Research Branch

Division of AIDS

National Institute of Allergy

and Infectious Diseases

National Institutes of Health, DHHS

Bethesda, Maryland

The NIH Program Perspective on the Grants Process

- The role of Program in the grants process
- Types of grant mechanisms
- Institute-specific funding and resources
- Updates on the NIH grant application process

What is “Program”?

- Divisions of Labor at the NIH Institutes
 - Intramural
 - Biomedical scientists performing bench research and clinical research
 - Extramural
 - Biomedical scientists administering research grants given to the outside community, i.e., YOU
 - Scientific Review Officials
 - Grants Management Officials
 - Program Officials

What Program Officials Can Do for You

- Advise you before you write your grant application
 - Research priorities and areas of interest
 - Grant mechanisms and relevant PAs/RFAs
 - Human subjects and other application issues
- Advise you after your grant application is reviewed
 - Revision and resubmission
 - Advisory Council and negotiation of award
 - Progress reports and supplements

How Do You Find A Program Officer?

- Key Contacts listed in Institute web pages
- Scientific contacts listed in PAs/RFAs
- The SRO conducting your review
- NIH eRA Commons
<https://commons.era.nih.gov/commons/>
- NIH and Institute-specific communications
- Your Summary Statement and Notice of Award

Types of Grants

- Unsolicited = investigator initiated (e.g., R01 Research Project)
- Solicited = Program Announcement (PA, PAS, PAR) or Request for Application (RFA) by one or more NIH Institutes requesting applications in a specific area of interest
 - May have specific funds set aside
 - More flexibility in funding
 - May be restricted to certain grant mechanisms
 - Not all Institutes may be participating
 - Institute contacts are listed in the announcement
- Areas of funding
 - Training, Research, Conference, Equipment, Infrastructure

Grant Mechanisms

- Training and Career Awards
 - Advice on Research Training, Career Awards, and Research Supplements
 - <http://www.niaid.nih.gov/ncn/training/advice/index.htm>
 - Important to check Institute-specific guidelines!
 - T = Institutional support to defer training costs
 - F = Fellowship support for independent research
 - K = Career development support
 - <http://grants.nih.gov/training/careerdevelopmentawards.htm>
 - PA-07-297: NIH Pathway to Independence Award (K99/R00)

Grant Mechanisms (cont)

- PA-06-180: NIH Small Research Grant Program (R03)
 - Investigator-initiated, small pilot or seed grants to develop data for a larger grant application or develop new technology
 - 2yrs/50K per year, no preliminary data required
- PA-06-181: NIH Exploratory/Developmental Research Grant Award (R21)
 - Investigator-initiated, novel/high-risk ideas with substantial impact on current understanding of scientific area
 - 2yrs/275K total, no preliminary data required but may be included if available
- Small Business Technology Transfer (STTR) Grants (R41/R42) and Small Business Innovation Research (SBIR) Grants (R43/R44)
<http://grants.nih.gov/grants/funding/sbir.htm>

Grant Mechanisms (*cont*)

- NIH Clinical Trial Planning Grant (R34)
 - Supports initial development of a clinical trial
 - PA-06-363: NIAAA, NIDA, and other ICs
 - PAR-06-358: NIDDK
 - PAR-06-384: NIAID
<http://www.niaid.nih.gov/ncn/clinical/R34.htm>
- PAR-05-113: Clinical Trial Implementation Cooperative Agreements (U01) – NIAID
- PA-08-149: NIH Support for Conferences and Scientific Meetings (R13/U13)
 - Among the costs eligible for support are salaries, equipment rental, travel, consultant services, and supplies. Prospective applicants should inquire in advance about an Institute's interest

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

- Alcohol and HIV/AIDS
 - <http://www.niaaa.nih.gov/ResearchInformation/ExtramuralResearch/NIAAAResearchAreas/AlcoholAIDS.htm>
- Biomedical Aspects of AIDS, Alcohol, and Liver Pathogenesis & Treatment Implications for Antiretroviral Effectiveness
 - Hepatotoxic interactions between chronic alcohol consumption and antiretroviral therapy
 - Pathogenic interactions between alcohol and HCV in HIV/HCV patients
 - Interactions between alcohol and medications for HCV treatment in HIV/HCV co-infected populations

National Institute on Alcohol Abuse and Alcoholism (NIAAA) (cont)

Recent HIV/AIDS liver disease-related PAs and RFAs:

- PA-07-028/PA-07-063: Research on Alcohol and HIV/AIDS (R01/R21)
- PA-07-052: Development of Disease Biomarkers (R01)
- PA-07-006: Structural Interventions, Alcohol Use, and Risk of HIV/AIDS (R03)
- RFA-08-013/RFA-08-014: Alcohol, AIDS, and Liver Disease: Preventable Side-effects of Antiretroviral Therapy (R01/R21) 2007
- RFA-09-002: Comprehensive Alcohol Research Center on HIV/AIDS (P60) 2008

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<http://www.niaaa.nih.gov/ResearchInformation/ExtramuralResearch/NIAAAResearchAreas/contact.htm>

National Institute on Drug Abuse (NIDA)

NIDA AIDS Research Program (ARP) Priorities

<http://www.nida.nih.gov/about/organization/arp/arp-current.htm>

NIDA spends ~\$25M on research on HIV and Liver Disease (see below)

- PA-07-307: Drug Abuse Aspects of HIV/AIDS and Other Infections (R01)
- PAS-07-115: Non-injection Drug Abuse and HIV/AIDS (R01)
- PAS-07-116: Health Disparities in HIV/AIDS: Focus on African Americans (R01)
- PA-07-275: International Research Collaboration on Drug Addiction (R01)
- NOT-DA-08-036: Notice of Availability of Administrative Supplements (\$2.5M) for Drug Abuse Research on GALT and HIV/SIV Pathogenesis
- Jag H. Khalsa, PhD, Chief, Medical Consequences of Drug Abuse and Infections, Division of Pharmacotherapies and Medical Consequences of Drug Abuse;
 - Telephone: (301) 443-2159; e-mail: jk98p@nih.gov
 - <http://www.nida.nih.gov/about/organization/arp/arp-aidsworkgrouplist.htm>

National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)

- Trans-NIH Action Plan for Liver Disease Research
http://www2.niddk.nih.gov/AboutNIDDK/ResearchAndPlanning/Liver_Disease/Action_Plan_For_Liver_Disease_Intro.htm [Ch. 6 – HIV and Liver Disease]
- PA-06-396: New Technologies for Liver Disease STTR (R41/R42)
- PA-06-397: New Technologies for Liver Disease SBIR (R43/R44)
- PA-07-052: Development of Disease Biomarkers (R01)
- RFA-DK-07-011: Hepatitis B Clinical Research Network (U01)
- RFA-DK-07-012: Continuation and Expansion of the Drug Induced Liver Injury Network (DILIN)[U01]
- NIH Consensus Conference October 20-22, 2008 on the Management of HBV
<http://consensus.nih.gov/2008/2008HepatitisBCDC120main.htm>
- Drug Induced Liver Injury: Standardization of Causality and Nomenclature
December 1-2, 2008; <http://www3.niddk.nih.gov/fund/other/diliworkshop2008/>
- Edward Doo, MD; Director; Liver Diseases Research Program
 - Telephone: (301) 451-4524; e-mail: dooe@niddk.nih.gov
 - http://www.niddk.nih.gov/welcome/org/tables/ddn_table.htm#serrano

National Institute of Allergy and Infectious Diseases (NIAID)

- NIAID Funding Opportunities
<http://www.niaid.nih.gov/ncn/budget/opps.htm>
- NIAID Funding News (funding, policy, and other information)
<http://www.niaid.nih.gov/ncn/newsletters/default.htm>
- NIAID Resources for Researchers
<http://www3.niaid.nih.gov/research/resources/>
- NIH AIDS Research and Reference Reagent Program
<http://www.aidsreagent.org/> (includes hepatitis reagents as well)
- Hepatitis Resources (Both DMID and DAIDS)
<http://www3.niaid.nih.gov/topics/hepatitis/research/resources.htm>
 - In Vitro Screening for HBV: Chris Tseng, PhD, ctseng@niaid.nih.gov
 - In Vitro Screening for HCV: Susan Brobst, PhD, sbrobst@niaid.nih.gov
 - In Vivo Screening for HBV: Diana Berard, PhD, dberard@niaid.nih.gov
 - In Vivo Screening for HCV: Rajen Koshy, PhD, rkoshy@niaid.nih.gov

National Institute of Allergy and Infectious Diseases (NIAID) (cont)

- NIAID-Funded Clinical Research
 - <http://www3.niaid.nih.gov/research/topics/HIV/therapeutics/clinical/default.htm>
 - AIDS Clinical Trials Group (ACTG)
 - <http://www.aactg.org/>
 - Hepatitis Committee Scientific Agenda
 - http://www.aactg.org/science_sciagendas.asp
 - HIV/Hepatitis Co-Infection grant information:
 - Hepatitis, HIV, Metabolic Complications: Contact Susan Brobst, PhD, sbrobst@niaid.nih.gov
 - Epidemiology: Contact Gerald B. Sharp, PhD, gsharp@niaid.nih.gov

HIV-related Cohorts Funded by NIH

- Womens Interagency HIV Study (WIHS)
 - HIV-positive or at risk women enrolled in 1993 and 2001
 - 1/3 used injection drugs and are HCV+
 - 57% Black; 26% Hispanic/Latina; 17% white/other
 - 2,809 HIV-positive, 959 HIV-negative
 - Total of 2,200 women still in follow-up
 - Samples in repository: 2.1 million
 - WIHS Web page
<http://statepiaps.jhsph.edu/wihs/index.htm>
 - Contact Gerald B. Sharp, PhD, gsharp@niaid.nih.gov

HIV-related Cohorts Funded by NIH (*cont*)

- Multicenter AIDS Cohort Study (MACS)
 - Homosexual and bisexual men enrolled in 1984-85, 1987-1991 and 2001-2003
 - 24% Black; 11% Hispanic/Latino; 65% white/other
 - 1,627 HIV-negative, 2,884 HIV-positive, 653 seroconverted on study
 - Samples in repository: 1,189,087
 - MACS Web pages
<http://statepi.jhsph.edu/macs/macs.html>
 - Contact Robin Huebner, PhD huebner@niaid.nih.gov

MACS/ WIHS

- Hepatitis/Liver Disease a focus area in both cohorts
- Data and samples for both cohorts open to outside investigators
 - Concept sheets requested and usually approved

Electronic Submission Requirements

- Transition Dates – 424 (R&R) AIDS applications
 - December 2008 From Pure Edge to Adobe Forms
 - February 12, 2009 Ks except K12
 - April 8, 2009 F
 - September 25, 2009 T&D, D42, D71/U2R, K12
 - Deadline: 5 PM Local Time (Applicant Institution)
- http://era.nih.gov/ElectronicReceipt/files/electronic_submission_timeline_08.pdf
- Electronic Application Resources
<http://www.niaid.nih.gov/ncn/grants/eapp/portal.htm> and
<http://era.nih.gov/ElectronicReceipt/>

Policy Changes

- NIH Policy Notices – Chronological
<http://grants.nih.gov/grants/policy/notices.htm>
- NIH Policy on Submission of Additional Grant Application Materials
<http://grants1.nih.gov/grants/guide/notice-files/not-od-08-082.html>
- Modified Application Submission, Referral and Review for Appointed NIH Study Section Members
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-026.html>
- NIH Public Access Policy <http://publicaccess.nih.gov/index.htm>
Compliance is now mandatory – Get informed!
- Use NIH's new Suggested Cover Letter Format to request assignment to an Institute, a study section, or both
<http://www.niaid.nih.gov/ncn/newsletters/2008/0521.htm#r03>

AIDS-Related Research Review Groups

- AIDS Molecular and Cellular Biology [AMCB]
- AIDS Immunology and Pathogenesis [AIP]
- AIDS Discovery and Development of Therapeutics [ADDT]
- AIDS-associated Opportunistic Infections and Cancer [AOIC]
- NeuroAIDS and other End-organ Diseases [NAED]
- AIDS Clinical Studies and Epidemiology [ACE]
- Behavioral and Social Science Approaches to Preventing HIV/AIDS [BSPH]
- Behavioral and Social Consequences of HIV/AIDS [BSCH]
- HIV/AIDS Vaccines [VACC]
- AIDS and AIDS-related Research Small Business Activities
Special Emphasis Panels
- Center for Scientific Review AIDS-related Review Group Web site
<http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/AARRIRG/>

“All About Grants” and Grant Writing Tips

- NIH Office of Extramural Research (OER): Gateway to a wealth of information on NIH research support <http://grants.nih.gov/grants/oer.htm>
- NIH OER’s Grant Writing Tips sheets http://grants.nih.gov/grants/grant_tips.htm
- “All About Grants” tutorials help you plan, write, and apply for NIH grants <http://www.niaid.nih.gov/ncn/grants/default.htm>
- How to Manage Your Grant Award <http://www.niaid.nih.gov/ncn/grants/cycle/part11a.htm>
- “Find It! A-Z Index” <http://www.niaid.nih.gov/ncn/find/default.htm>