

NIAID Oversight of Clinical Research and Funding Opportunities

The Fundamentals of International
Clinical Research Workshop
Dar es Salaam, Tanzania

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NIH Requirements for Human Subjects Research

- Research involving human subjects requires additional oversight
- In application, must include:
 - Research plan (not protocol) and concept
 - Data and safety monitoring plan, if proposing clinical trial
 - Targeted enrollment – projected demographics information
 - Discussion of risk to participants



NIAID Clinical Terms of Award

- Before beginning enrollment of subjects in study/trial:
 - Clinical protocol and consent forms, *approved by NIAID*
 - *DMID procedures for review of all international clinical protocols*
 - *Assistance with protocol development available from DMID and FHI - ISCCS*
 - Final data and safety monitoring plan, *developed with and approved by NIAID*
 - IRB/EC approval from all relevant groups



NIAID Clinical Terms of Award

- Before beginning enrollment of subjects in study/trial (con't):
 - If study is under IND, decision about who will hold the IND
 - Approval Recombinant DNA Advisory Committee (RAC) approval, if relevant
 - Documentation of training in human subjects protections for all key personnel
 - NIAID restricts funds until all requirements have been met



NIAID Clinical Terms of Award

- During conduct of study:
 - Annual IRB review and approval
 - Any other IRB actions or changes in protocol status
 - Protocol amendments (with IRB approval)
 - Data and Safety Monitoring reports
 - Safety reports – unexpected AEs and SAEs
 - Annual inclusion enrollment demographics reports



NIAID Clinical Terms of Award

- Additional requirements for
 - Clinical trials conducted under IND
 - Clinical trials using recombinant DNA



NIAID Clinical Terms of Award

- Award is NOT approval to start human subject research
- NIAID review and approval
 - Concept
 - Clinical protocol
- Review for scientific content, design, safety, feasibility, statistical, and regulatory compliance



Monitoring

- Monitoring of clinical studies: commensurate with the degree of potential risk to study subjects and complexity of the study.
- <http://grants.nih.gov/grants/guide/notice-files/NOT-AI-02-032.html>



NIAID Clinical Terms of Award

■ Resources:

■ NIAID Clinical Terms of Award

<http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf>

■ Guidance for Terms of Award

<http://www.niaid.nih.gov/ncn/pdf/clintermguidance.pdf>

■ How to write a human subjects application

<http://www.niaid.nih.gov/ncn/clinical/humansubjects/default.htm>

■ Education for protection of human



NIAID Clinical Protocols

Grant Application \neq Clinical Protocol



NIAID Clinical Protocols

DMID Protocol Template – designed to assist investigators and NIAID

- All necessary sections (ICH)
- Standardized format
- Assistance from NIAID Program staff and the International Clinical Studies Support Center

http://www.niaid.nih.gov/dmid/clinresearch/protocol_template.doc



NIAID Clinical Protocols

Need HELP?

-  Contact your NIAID Program Officer
-  Contact the International Clinical Studies Support Center (ICSSC)



ICSSC - FAQs

How can I access the ISCCS resources?

- Call your program officer
- International Clinical Studies Support Center
<http://www.icssc.org/>
- Contact me – psager@niaid.nih.gov



Funding Opportunities

The screenshot shows a web browser window displaying the NIAID website. The browser's address bar is empty, and the menu bar includes 'File', 'Edit', 'View', 'Favorites', 'Tools', and 'Help'. The website header features the NIAID logo and the text 'National Institute of Allergy and Infectious Diseases' and 'National Institutes of Health'. Below the header is a navigation menu with tabs for 'NIAID Home', 'Health & Science', 'Research Funding', 'Research', 'News & Events', 'Labs at NIAID', and 'About NIAID'. The 'Research Funding' tab is selected, and a breadcrumb trail shows 'NIAID > Research Funding'. A left sidebar contains a 'Research Funding' menu with sub-items: 'NIAID Funding News', 'Funding Opportunities', 'Paylines and Budget', 'Grants and Contracts', 'Question and Answers', 'Extramural SOPs', 'Council', 'Calendars and Timelines', 'Glossary', and 'Find It Index'. The main content area is titled 'Research Funding' and features a photograph of two scientists in a lab. Below the photo are several sections: 'NIAID Funding News' (newsletter), 'Funding Opportunities' (concepts, RFAs, RFPs, PAs), 'Paylines and Budget' (stipends, financial management), 'Grants and Contracts' (tutorials, research grants), 'Questions and Answers' (Q&As), 'Extramural Standard Operating Procedures' (policy), 'Council' (advisory), and 'Glossary of Funding Terms'. On the right side, there is a search box, a 'Search in Research Funding' box, and links for 'Print this page', 'E-mail this page', and 'Plug-ins and Viewers'. A 'Highlights' section lists 'NIAID Funding News' (July 29, 2005) and 'Latest Site Updates' (July 29, 2005). A 'Special Announcements' section lists 'Support of Clinical Trials for Ks', 'Medical Countermeasures to Chemical Threats RFI', and 'More...'. A 'Glossary terms for this page' section lists 'Concept', 'Extramural research', 'Initiative', 'Payline', and 'More...'.





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Search in Research Funding Go

Funding Opportunities List

Last updated on February 7, 2007. All NIAID-relevant FOA, RFA, PA, and RFP announcements, newer items first. Stay informed by signing up for [Email Alerts](#). Learn [How to Filter](#) and [How to Use This Page](#).

Filter the opportunity list

Opportunity type Application method

NIAID division See all or parent only

Mechanism code (R01)

Reference Number, Title, and Link	Division	Mech.	Apply	Due Date*
RFP-NIH-NIAID-DAIT-08-13, NIH Tetramer Facility	DAIT	Contract	See RFP	2007-04-30
RFA-AI-07-009, HIV Interdisciplinary Network for Pathogenesis Research in Women	DAIDS	U19	Paper	2007-06-25

IRIDA

International Research on Infectious Diseases including AIDS

- International investigators in resource-constrained countries (low, middle income); US, other high economy countries not eligible
- PI on other NIH funded grants not eligible
- All infectious diseases, including HIV/AIDS
- R01; 4 yrs; \$100,000 direct costs (+8% indirect)
- ELECTRONIC SUBMISSION via Grant.gov
- <http://grants.nih.gov/grants/guide/pa-files/PAR-08-130.html>

BEI Research Resources Repository

Provide reagents and resources for biodefense and emerging infections agents to the scientific community for use in basic and applied research

American Type Culture Collection (ATCC)

The screenshot shows the homepage of the BEI Resources website. At the top, the logo for 'beiresources' is displayed, with the full name 'BIODEFENSE & EMERGING INFECTIONS RESEARCH RESOURCES REPOSITORY' below it. A search bar is located in the top right corner, with a dropdown menu for 'Select a Reagent' and a 'Go' button. To the right of the search bar, there is a link to 'Advanced Search' and a 'Login' button. Below the logo, there is a navigation menu with buttons for 'Home', 'Catalog', 'Deposits', 'Register', and 'About'. The main content area is divided into several sections: 'Quick Links' with a list of links including 'Quick Order', 'Terms', 'Suggest a Reagent', 'New Reagents', 'Coming Soon', 'Compliance', 'NIAD', 'Resource Links', 'Contact Us', and 'FAQs'; 'BET Highlights' with a news item about the launch of the new BEI Resources portal; 'Catalog' with a green background and a list of pathogens; 'Deposits' with a red background and a list of pathogens; and 'Register' with a blue background and a list of pathogens. At the bottom, there is a footer with the ATCC logo, contact information (toll-free number and email), and a copyright notice for 2009 ATCC.

Call Us Toll-Free: (800) 359-7370 | E-mail: custserv@beiresources.org
Home | [Suggest a Reagent](#) | [FAQs](#) | [Privacy Policy](#) | [Contact Us](#) | [Sitemap](#) | [Terms of Use](#)
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www.beiresources.org

NIAID Research Resources for Influenza : Reagents

■ BEI/ATCC Repository (currently)

- Influenza viruses
- Recombinant proteins - HA and/or NA
 - H5, H6, H7, H9, H15, N2, N4, N9,
- Polyclonal antibodies
 - Goats, sheep, rabbit
- Monoclonal antibodies
 - H5, H9 & and epidemic strains (various proteins)
- Influenza peptide arrays
 - NS1, NS2, NP, M1, M2, PB1, PA
- Human vaccinee sera (H5N1 trials)
- Inactivated H5N1 vaccine (sanofi)
- Seasonal influenza vaccine

**NEW: Antisera Panel
H1-H11 & N1-N8**

■ 350-400 reagents shipped/year (\$ shipping)

Genomics and Sequencing Resources

Microbial Genome Sequencing Centers (MSCs) : provide high-quality genome sequences of NIAID Category A-C priority pathogens, related organisms, clinical isolates, closely related species, and invertebrate vectors of infectious diseases and microorganisms

Data and Analytic Tools

[Bioinformatics Resource Centers \(BRCs\)](#)

[Clinical Proteomics Centers for Infectious Disease and Biodefense](#)

[Pathogen Functional Genomics Resource Center \(PFGRC\)](#)

[Proteomics Research Centers \(PRCs\)](#)

[Structural Genomics Centers for Infectious Diseases](#)

[Systems Biology for Infectious Diseases Research](#)

<http://www3.niaid.nih.gov/LabsAndResources/resources/dmid/>



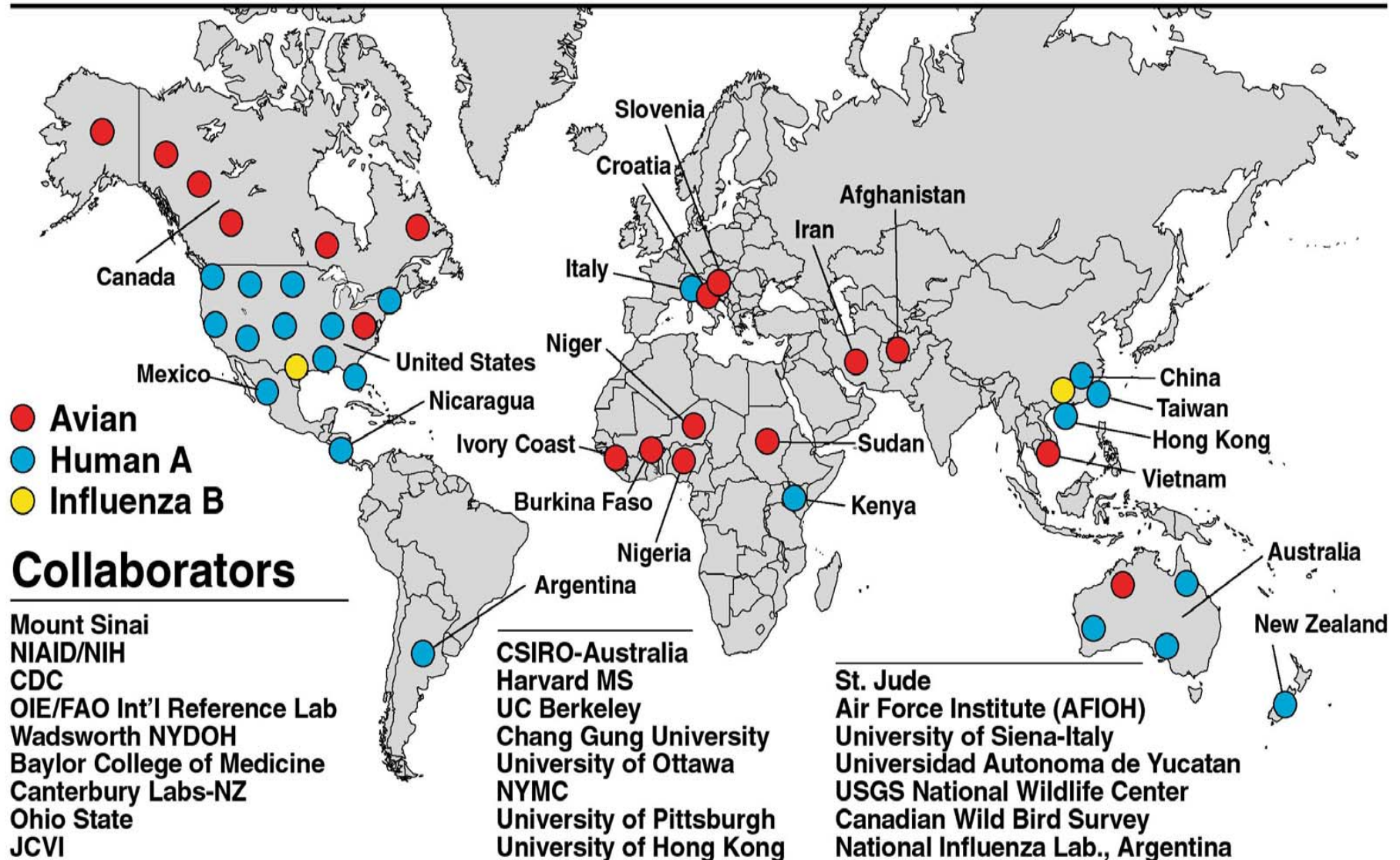
NIAID Influenza Genome Sequencing Project

Goals

- To sequence, assemble and annotate the complete genomes of influenza viruses; make them rapidly available without restriction to the scientific community through [GenBank®](#) and a [NIAID Influenza Research Database at BiohealthBase](#)
- To increase the genome knowledge base of influenza and help researchers understand how flu viruses evolve, spread, and cause disease and provide researchers
- Conducted by the NIAID Microbial Sequencing Center at the [J. Craig Venter Institute \(JCVI\)](#)



Influenza Genome Sequencing: NIAID's International Collaborators



NIAID BioHealthBase

- provides a comprehensive genomic and proteomic data repository for five pathogenic organism groups that pose a threat to public health.
- also provides an analysis platform and appropriate tools to facilitate genomic and proteomic study of these pathogens.
- goal is to provide a resource to the scientific research community
- Organisms:
 - Influenza
 - M tuberculosis
 - Francisella tularensis
 - Microsporidia
 - Ricin



Thank You!

