

Place: National Institutes of Health, Building 35, Conference Room 620/630, 9000 Rockville Pike, Rockville, MD 20852.

Contact Person: Shayla Beckham, Extramural Support Assistant, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892-9606, 301-496-9838, beckhams@mail.nih.gov.

Information is also available on the Institute's/Center's home page: <http://oba.od.nih.gov/rdna/rdna.html>, where an agenda and any additional information for the meeting will be posted when available.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 23, 2016.

Carolyn Baum,

Program Specialist, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on the Development of the FY 2018 Trans-NIH Plan for HIV-Related Research

SUMMARY: Through this Request for Information (RFI), the Office of AIDS Research (OAR) in the Division of

Program Coordination, Planning, and Strategic Initiatives, National Institutes of Health (NIH) invites feedback from investigators in academia, industry, health care professionals, patient advocates and health advocacy organizations, scientific or professional organizations, federal agencies, and other interested constituents and the community on the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. This plan is designed to identify and articulate possible future directions to maximize benefits of investments in HIV/AIDS research.

DATES: The Office of AIDS Research Request for Information is open for public comment for a period of 30 days. Comments must be received by June 27, 2016 to ensure consideration. After the public comment period has closed, the comments received will be considered in a timely manner by the Office of AIDS Research in the Division of Program Coordination, Planning, and Strategic Initiatives.

ADDRESSES: Submissions may be electronically to OAR_RFI18@od.nih.gov.

FOR FURTHER INFORMATION CONTACT:

Questions about this request for information should be directed to Shoshana Kahana, Ph.D., Office of AIDS Research, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, 5601 Fishers Lane, Bethesda, MD 20892, OAR_RFI18@od.nih.gov, 301-496-0357.

SUPPLEMENTARY INFORMATION: OAR oversees and coordinates the conduct and support of all HIV/AIDS research activities at the NIH. The NIH-sponsored HIV/AIDS research program includes both extramural and intramural research, buildings and facilities, research training, and program evaluation and supports a comprehensive portfolio of research representing a broad range of basic, clinical, behavioral, social science, and translational research on HIV/AIDS and its associated coinfections. The NIH HIV/AIDS research program is conducted and supported by nearly all of the NIH Institutes and Centers (ICs).

OAR plans and coordinates research through the development of an annual Trans-NIH Plan for HIV-Related Research (the "Plan") that articulates the overarching HIV/AIDS research priorities and serves as the framework for developing the trans-NIH AIDS research budget. The Plan provides information about the NIH's HIV/AIDS research priorities to the scientific community, Congress, community stakeholders, HIV-affected communities,

and the broad public at large. The fiscal year 2017 Plan was recently distributed on the OAR Web site: (http://www.oar.nih.gov/strategic_plan/fy2017/OARStrategicPlan2017.pdf).

New overarching priorities for HIV/AIDS research for the next three to five years were defined in the NIH Director's Statement of August 12, 2015 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>).

High Priority topics of research for support include:

- (1) Reducing the incidence of HIV/AIDS (including the development of a safe and effective vaccine, microbicides, and pre-exposure prophylaxis candidates);
- (2) Developing the next generation of HIV therapies with less toxicity, better safety, and ease of use;
- (3) Identifying strategies to cure AIDS; and
- (4) Improving the prevention and treatment of HIV-associated comorbidities, coinfections, and complications.

There also are three cross-cutting areas associated with these overarching priorities which include:

- (1) Basic research underlying the basic biology of HIV (*e.g.*, transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and genetic determinants);
- (2) Research to reduce health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS; and
- (3) Research training of the workforce required to conduct high priority HIV/AIDS research.

Information Requested

OAR is seeking input on the inclusion of important new and/or emerging areas of scientific investigation to inform the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. The overarching high-priority areas of research as delineated in NOT-15-137 will remain unchanged. OAR would like feedback on those scientific and research opportunities that refine the NIH HIV/AIDS research agenda and optimize the investment of HIV/AIDS research resources to search for critical strategies to prevent, treat, and cure AIDS.

Please provide your perspective on any of the following topics as they relate to the development of the fiscal year 2018 Trans-NIH Plan for HIV-Related Research. Comments can include but are not limited to the following areas:

1. Emerging strategies and technologies related to the development, testing, and production of promising HIV vaccine candidates (active and

passive), and novel adjuvants, including the coordinated role that mucosal and systemic immunity play in protection from viral acquisition and infection.

2. Emerging topics related to the development, testing, and formulation of microbicides, pre-exposure prophylaxis candidates, long acting/ and/or injectable formulations of antiretroviral treatment candidates (and related methods of delivery for HIV treatments) that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens.

3. Emerging topics that relate to the research toward a cure, including the development of novel approaches and strategies that could lead to sustained HIV remission or viral eradication without the continuing need for combination antiretroviral therapy, including studies of HIV persistence, latency, and reservoir formation.

4. Emerging topics that relate to the HIV cascade of care, including the development, testing, and implementation of integrated biomedical, behavioral, and social science strategies to improve HIV testing and entry into prevention and treatment services, including linkage, engagement, and retention in these services for optimal treatment response.

5. Emerging topics that relate to basic research underlying the basic biology of HIV, (e.g., acquisition, transmission and pathogenesis; viral persistence; immune dysfunction and chronic inflammation; host microbiome and genetic determinants; and pathogenesis of opportunistic infections, coinfections, comorbidities, and HIV-related mortalities.

6. Emerging topics that relate to reducing health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS, with a specific focus on structural, environmental, and community-level determinants of health and the interplay of these determinants in developing strategies to mitigate the disparities in HIV incidence and access to HIV preventive and treatment services.

7. Emerging topics that relate to the challenges and opportunities that should be considered for research training and career development programs targeting researchers conducting high priority HIV/AIDS research.

Please limit responses to <1500 characters. Responses to this RFI Notice are voluntary. The submitted information will be reviewed by NIH staff and may be made available to the public. Submitted information will not be considered confidential. This request is for information and planning purposes and should not be construed as a solicitation or as an obligation of the federal government or the NIH. No awards will be made based on responses to this Request for Information. The information submitted will be analyzed and may be used in reports or presentations. Those who respond are advised that the NIH is under no obligation to acknowledge receipt of your comments, or provide comments on your submission. No proprietary, classified, confidential and/or sensitive information should be included in your response. The NIH and the government reserve the right to use any non-proprietary technical information in any future solicitation(s).

Dated: May 20, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Clinical Trials Reporting Program (CTRP) Database (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 11, 2016 (Vol. 81, P. 12914) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an

information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Jose Galvez, MD, Office of the Director, National Cancer Institute, 9609 Medical Center Drive, Rockville, MD 20852 or call non-toll-free number 240-276-5206 or Email your request, including your address to: *jose.galvez@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Clinical Trials Reporting Program (CTRP) Database (NCI), 0925-0600, Expiration Date 05/31/2016—Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 18,000.