DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Aaron J. Morrow, B.S., Saint Louis University: Based on Mr. Morrow’s admission, the report of an investigation conducted by Saint Louis University (SLU), and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Aaron J. Morrow, graduate student, SLU Graduate School, engaged in scientific misconduct by falsifying and fabricating data in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant 5 R01 GM54428-04, “Elucidation of the mechanisms of in vitro Golgi transport.”

Specifically PHS found that Mr. Morrow falsified data relating to the study of the mechanisms of protein transport using in vitro preparations. From October 1999 through January 2001, he falsified and fabricated data in his research notebook and produced false films and graphs of purported experiments to produce data for his thesis and misrepresent his progress.

Mr. Morrow reported the falsified and fabricated data in: (1) Laboratory group meetings; (2) a poster presentation at the American Society for Cell Biology meeting held in December 2000, and (3) a draft manuscript that he was preparing. Mr. Morrow also provided falsified data to his mentor, who unknowingly included it in a draft of NIGMS, NIH, application 2 R01 GM54428–05A2, “Elucidation of the mechanisms of in vitro Golgi transport.” Given the extensive nature of Mr. Morrow’s data falsification and fabrication, none of his research after July 2000 can be considered reliable. His actions adversely and materially affected the laboratory’s ongoing research in protein transport mechanisms by creating uncertainty about all his experimental results, necessitating verification and repetition of experiments, preventing the reporting of results for publication, and preventing the principal investigator from submitting a competitive renewal application for a NIH grant.

Mr. Morrow has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 CFR part 76 (Debarment Regulations); and

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT:
Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852. (301) 443–5330.

Chris B. Pascal, Director, Office of Research Integrity.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Topical Microbicides To Reduce Sexual Transmission of Human Immunodeficiency Virus (HIV)

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS).

ACTION: Opportunities for collaboration for evaluation of topical microbicides.

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE), Epidemiology Branch (EpiBr), announces an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides designed for vaginal and/or rectal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in women and men.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE) of the National Center of HIV, STD, and TB Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Resources, is seeking collaborators to develop topical microbicides designed for vaginal and/or rectal application that meet the criteria for partial or full approval in the United States market, or have the potential for such approval. The Division of HIV/AIDS Prevention-Surveillance and Epidemiology is interested in evaluating topical microbicides with promising safety and efficacy profiles in an exploratory study to determine the potential for these compounds to reduce HIV transmission and disease progression.

The agreement will be for a fixed term of five years, with the possibility of renewal for an additional five years. Interested persons are encouraged to contact the Special Projects Office at the Centers for Disease Control and Prevention to request additional information.

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Services (DHHS) seeks one or more pharmaceutical, biotechnical, or other companies that hold a proprietary position on agents which may be useful as microbicides to prevent sexual transmission of HIV infection. The selected company and CDC will execute an Agreement under which the company will provide a product for CDC to study the product’s safety and preliminary efficacy as a topical microbicide. Initial studies will include in-vitro assays and may include macaque studies. Agents will be selected for phase I and phase II trials in women and men based upon data obtained in the CDC studies as well as other available published and unpublished safety and efficacy data. Each collaboration would have an expected duration of one (1) to five (5) years. The goals of the collaboration include the timely development of data to further the identification and commercialization of effective topical microbicides and the rapid publication of research findings to increase the number of HIV prevention technologies proven effective and available for use.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient preclinical testing to be prepared to submit an Investigational New Drug (IND) application to the FDA within six months of submitting the proposal.

DATES: This Notice will be open indefinitely.

ADDRESSES: Formal proposals should be submitted to Jeff Efird, MPA, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6136, (office) 404–639–6130; Fax: 404–639–6127; e-mail: JLE1@cdc.gov. Scientific questions should be addressed to Lisa A. Grohskopf, MD, MPH, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6116, (office) 404–639–6146; Fax: 404–639–6127; e-mail: lkg@cdc.gov.

Inquiries directed to “Agreement” documents related to participation in this opportunity should be addressed to Thomas E. O’Toole, MPH, Deputy Director, Technology Transfer Office, CDC, 1600 Clifton Road, Mailstop E–67, Atlanta, GA 30333; Phone: (direct) 404–639–6270, (office) 404–639–6270; Fax: 404–639–6266; e-mail: TEO1@cdc.gov

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch (EpiBr) of DHAP–SE/NCHSTP is to develop and evaluate biomedical interventions to reduce HIV transmission. To this end, the EpiBr is establishing contracts to conduct phase I and phase II trials of topical microbicides. EpiBr also funds research in the Division of AIDS, STD, and TB Laboratory Research (DASTLR) of the National Center for Infectious Diseases (NCID) at CDC and with external laboratories to conduct macaque studies and in-vitro studies in support of human microbicide trials. The goal of these efforts is to provide scientific and technical expertise and key resources for the evaluation of topical microbicides through late preclinical, phase I and phase II safety and phase II efficacy clinical trials.

Technology Sought

EpiBr now seeks potential collaborators having licensed or patented agents for use as vaginal and/or rectal microbicides which:

(1) Have laboratory or animal model evidence of anti-HIV activity;
(2) Have been formulated for vaginal or rectal application;
(3) Are not entering phase III clinical trial in the next 12 months;
(4) Have sufficient preclinical data to submit an IND application within approximately six months following submission of proposal; and
(5) Have manufacturing arrangements for production of clinical trial-grade product (and applicant if necessary) under Good Manufacturing Process (c-GMP) standards.

NCHSTP and Collaborator Responsibilities

The NCHSTP anticipates that its role may include, but not be limited to, the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;
(2) Planning and conducting preclinical (in-vitro and in-vivo) research studies of the agent and interpreting results;
(3) Publishing research results;
(4) Depending on the results of these preclinical investigations, NCHSTP may elect to conduct additional research with macaques to evaluate safety and/or efficacy proof-of-concept; and
(5) Depending on the results of preclinical and/or macaque studies and FDA approval, NCHSTP may elect to conduct phase I/II clinical trials of the agent.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;
(2) Participating in the planning of research studies, interpretation of research results, and as appropriate, joint publication of conclusions;
(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and
(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

Selection Criteria

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;
(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;
(3) Data on the effects of the agent on vaginal and/or rectal commensal microbial organisms; and
(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Joseph R. Carter,
Associate Director for Management and Operations, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send