

Esther.Yoo@bioethics.gov in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov*, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: April 23, 2012.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2012-10513 Filed 5-1-12; 8:45 am]

BILLING CODE 4154-06-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information on Guidance for the Specification of a Secure, Online Reporting System for Streamlining Programmatic, Fiscal, and Other Data From DHHS-Funded HIV Prevention, Treatment, and Care Services Grantees

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) is seeking to identify interest and obtain information relevant to the design, deployment, operations, maintenance, and future enhancement of a centralized, secure, flexible data reporting system to streamline the collection, processing, and sharing of programmatic, funding, and other data reported to DHHS Operating Divisions (OpDivs) by grantees funded to provide HIV prevention, treatment, and care services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on May 17, 2012.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to [*HIVOpenData@hhs.gov*]. Written responses should be addressed to: U.S. Department of Health and Human Services, Room 443-H, 200 Independence Ave. SW., Washington, DC 20201. Attention: HIV Open Data Project.

FOR FURTHER INFORMATION CONTACT:

Andrew D. Forsyth Ph.D. or Vera Yakovchenko, MPH, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), (202) 205-6606.

SUPPLEMENTARY INFORMATION:

In July 2010, the White House released the National HIV/AIDS Strategy (NHAS) for the United States that outlined four key goals: (1) Reduce the number of people who become infected with HIV; (2) increase access to care and optimize health outcomes for people living with HIV; (3) reduce HIV-related health disparities; and (4) achieve a more coordinated national response to the HIV epidemic in the United States.¹ Central to the latter goal were two related directives. The first was to develop improved mechanisms to monitor, evaluate, and report on progress toward achieving national goals. And the second was to simplify grant administration activities by standardizing data collection and reducing undue grantee reporting requirements for federal HIV programs.

In December 2009, the White House also released its Open Government Directive,² which seeks to improve access to government data in a manner that enhances transparency, fosters participation through the public's contribution of ideas and expertise to decision-making, and enhances collaboration through new partnerships within the federal government and between public and private institutions. Notwithstanding existing clearance requirements or legitimate reasons to protect information, the Directive highlighted the need for the following: (1) Timely and accessible online publication of government information; (2) improved quality of government information; (3) creation of a culture of open government; and (4) establishment of a policy framework for Open Government. The release of the Directive was followed shortly thereafter by the DHHS Open Government Plan,³ which seeks to build upon the White House's emphasis on transparency, collaboration, and collaboration to ensure that the government works better for all Americans.

An important contribution of the DHHS Open Government Plan is its reference to new technological developments that make it possible to streamline the collection, sharing, and

processing of programmatic and fiscal data in a manner that facilitates greater transparency, participation, and collaboration, even in such critical and sensitive areas as the DHHS investment in HIV prevention, treatment, and care services. At present, DHHS OpDivs that fund these services use a mixture of non-interoperable information processing systems to collect programmatic, fiscal, and other data from grantees. Moreover, these systems often utilize different indicators to monitor the progress of HIV/AIDS programs that vary in their specifications (*e.g.*, numerators, denominators, time frames) and other key parameters. As a result, many required HIV/AIDS data elements are inconsistent, impede evaluation and monitoring of all relevant DHHS-funded services, and add undue burden to HIV services grantees charged with reporting obligations often from multiple DHHS OpDivs.

Under consideration at DHHS is the design, deployment, operations, maintenance, and future enhancement of a centralized, secure, flexible data reporting information system to compile programmatic, funding, and other data reported to DHHS OpDivs by grantees funded to provide HIV prevention, treatment, and care services. In effect, DHHS is exploring the possibility of establishing a single data reporting tool for funders, grantees, and sub-grantees that builds upon or shares many of the features of the Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Services Report (RSR), which is a secure, online, data collection system for programmatic and fiscal data. Similarly, such a system might share features central to the National Institutes of Health's Electronic Research Administration (ERA), which offers a one-stop solution "to manage the receipt, processing, review, award and monitoring of over \$30 billion in research and non-research grants" (see <http://era.nih.gov>). Moreover, such a system would offer a secure data solution that permits internal and external access to data, eliminates paper-based reporting, and streamlines the process of data collection and sharing in a manner that advances the DHHS Open Government Plan.

The HIV Open Data Project envisioned might offer several benefits, such as: (1) Improve mechanisms to monitor, evaluate, and report on progress toward achieving NHAS goals; (2) ensure more coordinated program administration; (3) utilize a common protocol for establishing patient identifiers to protect confidentiality and de-identify client data; (4) reduce

¹ <http://www.whitehouse.gov/administration/eop/onap/nhas>.

² <http://www.whitehouse.gov/open/documents/open-government-directive>.

³ <http://www.hhs.gov/open/plan/opengovernmentplan/transparency/dashboard.html>.

administrative and infrastructural costs associated with reporting to or maintaining independent data systems; (5) streamline and standardize data collection; (6) facilitate data sharing among federal and non-federal partners; (7) reduce bottlenecks and redundant data entry to different data systems; (8) integrate with electronic health record systems; (9) improve accountability and tracking of grantees with multiple funding streams; (10) facilitate data standardization and deployment of common core indicators that could form the basis of performance dashboards; (11) identify services gaps and unmet need; and (12) enhance transparency, participation, and collaboration around key public policy decisions relevant to the DHHS investment in HIV prevention, treatment, and care services.

Accordingly, this request for information seeks public comment on several key dimensions of such a project, including but not limited to the following:

1. In evaluating the feasibility of such a centralized data system, what specific steps would be critical to the design, deployment, operations, maintenance, and enhancement of such a system, particularly in light of addressing interoperability issues of existing data systems operated by DHHS OpDivs that support HIV prevention, treatment, or care services (e.g., Centers for Medicare and Medicaid Services, HRSA, Substance Abuse and Mental Health Services Administration, Indian Health Service, Centers for Disease Control and Prevention)?

2. What existing systems currently in use to monitor health grants offer the features desired and what are the strengths and challenges of (a) designing an entirely new online resource or (b) adopting an existing resource (e.g., HRSA's RSR or others)?

3. What are the greatest challenges encountered in reporting data (describe your reporting obligations, if applicable) and what specific solutions have DHHS grantees implemented to streamline divergent, non-interoperable reporting systems?

4. And what data would prove most useful for different stakeholders to receive from such a centralized system?

5. What costs, benefits, and risks need to be given careful consideration in development of such a resource? What are the estimated costs and return on investment of each component?

6. What technological resources and expertise would be needed to design, deploy, operate, maintain, and enhance such a system and what extant models exist for achieving the goal of a secure

electronic resource capable of achieving the benefits noted above?

7. What system architecture do you recommend for the project, particularly considering the government's desire to keep the project simple and streamlined (i.e. using as few different software packages and tools as possible)? What architecture, expertise, and other components are indispensable to the success of the design, deployment, operations, maintenance, and enhancement of such a system?

8. What would a phased implementation plan consist of? If a modular or phased approach is recommended, what is a realistic timeframe for the completion of the project?

9. What additional information not specifically addressed elsewhere in this RFI that would be important for the government to bear in mind in developing such a system?

Dated: April 25, 2012.

Ronald O. Valdiserri,

Deputy Assistant Secretary for Health (Infectious Diseases), Office of HIV/AIDS and Infectious Disease Policy.

[FR Doc. 2012-10591 Filed 5-1-12; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: P4 Peptide From *Streptococcus Pneumoniae*

AGENCY: Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, exclusive license (excluding the nonexclusively licensed field of use entitled "Use of P4 as either a carrier and/or immunoenhancer in a polysaccharide vaccine conjugate for prevention of *Streptococcus pneumoniae* infection in humans") to practice the inventions embodied in the patent application referred to below to Viper Therapeutics, having a place of business in Atlanta, Georgia. The patent rights in these inventions have been assigned to the government of the United States of

America. The patent(s) to be licensed are:

"U.S. Patent 7,919,104 entitled "Functional Epitopes of *Streptococcus Pneumoniae* PsaA Antigen and Uses Thereof," filed 7/18/2008, claiming priority to U.S. Provisional Patent Application No. 60/682,495, filed 5/19/2005, and all related continuing and foreign patents/patent applications for the technology family. CDC Technology ID No. I-030-04.

Status: Issued.

Priority Date: 5/19/2005.

Issue Date: 4/5/2011.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology

This technology consists of a P4 peptide which contains functional epitopes of the PsaA protein of *Streptococcus pneumoniae*. This technology also includes an antibody that can bind to the epitopes of the defined peptides. The technology is a complete kit that includes two vaccines comprised of two separate peptides, a pharmaceutical carrier for each vaccine, methods of using the peptides and antibodies, and diagnostic kits comprising a P4 peptide.

ADDRESSES: Requests for a copy of this patent, inquiries, comments, and other materials relating to the contemplated license should be directed to Donald Prather, J.D., Ph.D., Technology Licensing and Marketing Specialist, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, Telephone: (770) 488-8612; Facsimile: (770) 488-8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within thirty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 23, 2012.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2012-10547 Filed 5-1-12; 8:45 am]

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