

particular, this meeting seeks to evaluate the cost recovery system of blood centers, their perceived capacity for product and services innovations, and to promote risk based decision making from donor to recipient. The Committee will also hear from the World Health Organization's NOTIFY Library Project and their efforts to improve vigilance and surveillance of adverse transplant events relating to human cells, tissues, and organs. Additionally, the Committee will receive updates on recommendations from the ACBTSA Subcommittees addressing Disaster Preparedness; Tissue and Blood Safety; and Informed Consent in Transfusion and Transplantation.

The public will have the opportunity to present their views to the Committee during a public comment session scheduled for December 4, 2013. Comments will be limited to five minutes per speaker and must be pertinent to blood and tissue safety and availability. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session should to contact the designated Federal official to register prior to close of business on December 2, 2013. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to the close of business on December 2, 2013. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection to submit the necessary material to the Executive Secretary prior to the close of business on December 2, 2013.

Dated: October 28, 2013.

**James J. Berger,**

*Senior Advisor for Blood and Tissue Safety Policy.*

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**BILLING CODE 4150-41-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Solicitation for Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

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

**ACTION:** Notice.

**Authority:** 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

**SUMMARY:** The Office of Human Research Protections (OHRP), a program office in the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS, through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary, HHS, on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill three positions on the Committee membership that will be vacated during the 2014 calendar year.

A notice was published in the **Federal Register** on September 27, 2013, to solicit names of qualified applicants to be considered for appointment to the Committee. The due date for all applications was October 28, 2013. Response to this solicitation notice has been low; a sufficient number of applications has not been received to identify qualified candidates to be considered for appointment. In view of the Government shutdown, it has been determined that more time should be given for individuals to submit applications to be considered for appointment to the Committee. Therefore, this notice is being published in the **Federal Register** again to allow more time for qualified individuals to submit applications to fill the impending vacancies on SACHRP.

**DATES:** Nominations for membership on the Committee must be received no later than December 4, 2013.

**ADDRESSES:** Nominations should be mailed or delivered to Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Nominations will not be accepted by email or by facsimile.

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240-

453-8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP Web site at [www.hhs.gov/ohrp/sachrp](http://www.hhs.gov/ohrp/sachrp), or requesting via email at [sachrp@osophs.dhhs.gov](mailto:sachrp@osophs.dhhs.gov).

**SUPPLEMENTARY INFORMATION:** The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, and the decisionally impaired; pregnant women, embryos and fetuses; individuals and populations in international studies; investigator conflicts of interest; and populations in which there are individually identifiable samples, data or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

**Nominations:** The OHRP is requesting nominations to fill three positions for voting members of SACHRP. One position will become vacant in March, 2014; two others will become vacant in July. If you submitted a nomination in response to the solicitation request posted in the **Federal Register** on September 27, 2013, you do not need to resubmit your nomination. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: Public health and medicine, behavioral and social sciences, health administration, and biomedical ethics. To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four

years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee. Interested applicants may self-nominate. Nominations may be retained and considered for future vacancies.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (i.e., specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address, daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: October 25, 2013.

**Jerry Menikoff,**

*Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-14-14BB]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

*Proposed Project:*

Evaluation of Rapid HIV Home-Testing among MSM Trial—New—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description**

Innovative testing strategies are needed to reduce levels of undiagnosed Human immunodeficiency virus (HIV) infection and increase early access to treatment. Rapid home HIV tests may play an important role in efforts to reduce both HIV morbidity and mortality. Given the unrelenting HIV crisis among men who have sex with men (MSM) and the release into the market of a rapid HIV test for at-home use, it is necessary to evaluate the impact of providing rapid HIV home-test kits on repeat HIV testing, linkage to care, partner testing, serosorting, and HIV sexual risk behaviors among MSM.

This information will assist the Division of HIV/AIDS Prevention (DHAP) in developing recommendations, future research and program needs concerning home-testing for MSM.

**Specific Aims**

This study is a randomized trial which aims to evaluate the use and effectiveness of home-test kits as a public health strategy for increasing testing among MSM. A secondary aim of the randomized trial is to evaluate the extent to which MSM (both HIV-negative and HIV-positive) distribute HIV home-test kits to their social and sexual networks.

The population for the randomized trial will be men over the age of 18 years who self-report that they have had anal sex with at least one man in the past year. We will recruit approximately 3,200 men who report their HIV status to be negative or who are unaware of their HIV status and 300 men who self-report that they are HIV-positive. Men will be recruited from the 12 cities: Atlanta, Georgia; Baltimore, Maryland; Chicago, Illinois; Dallas, Texas; District of Columbia; Houston, Texas; Los Angeles, California; Miami, Florida; New York City, New York; Philadelphia, Pennsylvania; San Francisco, California; and San Juan, Puerto Rico. We will ensure that at least 20% of participants are black and at least 15% are Hispanic. Recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam.

This study also has a qualitative component that aims to examine the experiences of participants in the randomized control trial (RCT). Participants for the qualitative data collection will be drawn from the randomized control trial. Two data collection techniques will be used: focus group discussions (FGD) (both online and in-person) and individual in-depth interviews (IDIs).

CDC is requesting approval for a 3-year clearance for data collection. All participant consenting and data collection for the RCT will be completed using an online reporting system. Data will be collected using an eligibility screener, an online study registration process, a baseline survey, HIV test results reporting system, and follow-up surveys. Men will be asked to use the study Web site or download and access a secure cell phone application prior to enter results of their rapid HIV home-tests that they receive and conduct at home and to take the follow-up surveys which will collect information on HIV