

In 2013, updates were made to the original 1994 *Public Health Service Guidelines on Reducing HIV, HBV, and HCV through Organ Transplantation* (“PHS Guidelines”). Public and private-sector stakeholders in organ transplantation are now seeking to explore potential important updates to the *PHS Guidelines* in order to maintain accordance with current health sector circumstances.

The Committee will meet on April 15–16, 2019 to receive presentations from various public and private sector stakeholders and to listen to public comments regarding the *PHS Guidelines*. The Committee will explore important questions to consider as the *PHS Guidelines* are examined for any such necessary updates. Finally, the Committee will discuss and develop appropriate recommendations for HHS consideration. Additional topics that are pertinent to the mission of the Committee may be added to the agenda.

The public will have an opportunity to present their views to the Committee during public comment sessions scheduled for the second day of the meeting. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is required to submit their name, email, and comment summary prior to close of business on April 8, 2019. If it is not possible to provide 30 copies of the material to be distributed at the meeting, 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 April 8, 2019. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on April 8, 2019.

Dated: February 26, 2019.

James J. Berger,

Senior Advisor for Blood and Tissue Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary’s Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Department of

Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Wednesday, March 27, 2019, from 8:30 a.m. until 4:00 p.m., and Thursday, March 28, 2019, from 8:30 a.m. until 3:00 p.m.

ADDRESSES: 6700B Rockledge Drive, Bethesda, MD 20817.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Wednesday, March 27, 2019, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS subcommittee will present their revised recommendation on Subject Payment: Ethical and Regulatory

Considerations. This will be followed by a discussion of implementation issues experienced to date regarding the newly effective revised Common Rule. The afternoon will conclude with a discussion of questions newly posed to SACHRP regarding Deceased Donor Intervention Research (DDIR), with a particular focus on recipient informed consent. There will be a panel presentations from leading experts in the field of DDIR, followed by SACHRP discussion. The meeting is scheduled to end at approximately 4:00 p.m.

The meeting will begin at 8:30 a.m. on Thursday, March 28th. The SAS subcommittee will present and discuss draft recommendations regarding charging subjects to participate in clinical trials. Additional time is reserved for emerging topics and continuing the previous day’s discussions. The meeting will adjourn at approximately 3:00 p.m.

Time will be allotted for public comment on both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to topics currently being addressed by SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: February 26, 2019.

Julia G. Gorey, J.D.,

Executive Director, Secretary’s Advisory Committee on Human Research Protections.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the