DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Global Infectious Disease Research Administration Development Award for Low- and Middle-Income Country Institutions (G11).

Date: October 16, 2019.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, Program Management & Operations Branch, Division of Extramural Activities/Scientific Review Program, 3G53A, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892–9823, 301–761–7322, julio.aliberti@nih.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, October 16, 2019, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS subcommittee will discuss their revised recommendation questions posed to SACHRP regarding Deceased Organ Intervention Research (DDIR), with an emphasis on recipient informed consent. This will be followed by a discussion of Ethical Issues and Regulatory Considerations Regarding Re-consent, and Charging Subjects to Participate in Clinical Trials. The meeting is scheduled to end at approximately 4:30 p.m.

The meeting will begin at 8:30 a.m., Thursday, October 17, 2019. The SOH subcommittee will discuss draft recommendations regarding End User Licensing Agreements & Terms of Service; Considerations for IRB Review, and finally, Site Monitoring under the new sIRB Mandate. 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 the 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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). A notice listing all currently HHS-certified laboratories and IITFs is published in the Federal Register during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines. If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter. This notice is also available on the internet at http://www.samhsa.gov/workplace.

FOR FURTHER INFORMATION CONTACT:
Charles LoDico, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N02C, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the Federal Register on April 11, 1988 (53 FR 11970), and subsequently revised in the Federal Register on June 9, 1994 (59 FR 29098); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 16444); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. The “Mandatory Guidelines for Federal Workplace Drug Testing Programs,” as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA, which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories).

HHS-Certified Laboratories


Alero Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.).

Alero Toxicology Services, 450 South Lake Blvd., Richmond, VA 23236, 804–376–9130 (Formerly: Kroll Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7656, 501–202–2781 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).