

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 25, 2019.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## 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, RM 3E71, National Institutes of Health, NIAID, 5601 Fishers Lane, Rockville, MD 20852, 301-761-3100, [cruza@niaid.nih.gov](mailto:cruza@niaid.nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Centers for Medical Countermeasures Against Radiation Consortium.

*Date:* October 23-25, 2019.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Palomar, 2121 P Street NW, Washington, DC 20037.

*Contact Person:* Julio C. Aliberti, Ph.D., Scientific Review Officer, Immunology

Review 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](mailto:julio.aliberti@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 25, 2019.

**Tyeshia M. Roberson,**

*Program Analyst, Office of Federal Advisory Committee 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, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, 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, October 16, 2019, from 8:30 a.m. until 4:30 p.m., and Thursday, October 17, 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](mailto: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, 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](mailto: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: September 25, 2019.

**Julia G. Gorey,**

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

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**BILLING CODE 4150-36-P**

## 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 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644);

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 (formerly: HHS/NIDA), 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

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844-486-9226.

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

Alere Toxicology Services, 450 South lake Blvd., Richmond, VA 23236, 804-378-9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.).

Baptist Medical Center-Toxicology Laboratory, 11401 I-30, Little Rock, AR 72209-7056, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).

Clinical Reference Laboratory, Inc., 8433 Quiver Road, Leone, KS 66215-2802, 800-445-6917.

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800-442-0438 (Formerly: STERLING Reference Laboratories).

Desert Ox, LLC, 10221 North 32nd Street Suite J, Phoenix, AZ 85028, 602-457-5411.

Drug, Scan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800-235-4890.

Dynacare, \*245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630 (Formerly: Gamma-Dynacare Medical Laboratories).

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609.

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387.

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986 (Formerly: Roche Biomedical Laboratories, Inc.).

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group).

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center).

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.).

\* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.