pertaining to current good manufacturing practice requirements have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04375 Filed 2–29–24; 8:45 am]

BILLING CODE 4164–01–P

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 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, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Wednesday, March 20, 2024 from 11:00 a.m. until 4:30 p.m., and Thursday, March 21, 2024, from 11:00 a.m. until 4:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

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 11:00 a.m., on Wednesday, March 20, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of the draft recommendation, Ethical and Regulatory Considerations for the Inclusion of LGBTQI+ Populations in HHS Human Subjects Research. This topic is a continuation of the discussion and speaker panel presented at the October 2023 SACHRP. This will be followed by discussion of Considerations for Uninformative Research. The first day will adjourn at approximately 4:30 p.m. The second day of the meeting, March 21st, will begin at 11:00 with a discussion of Interpretation of the Best-interests Standard for the Retention of Subjects in Human Subjects Research that Has Been Halted or Suspended. Other topics may be added; for the full and updated meeting agenda, see *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.* The meeting will adjourn by 4:00 p.m., March 21, 2024.

Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to *SACHRP@hhs.gov* no later than midnight March 14th, 2023, ET. Written comments will be shared with SACHRP members and may read aloud during the meeting. Comments which are read aloud are limited to three minutes each. Public comment must be relevant to topics being addressed by the SACHRP.

Dated: February 23, 2024.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

[FR Doc. 2024–04343 Filed 2–29–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this licensing opportunity should be directed to: Andrew Burke Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, email: *burkear@mail.nih.gov* or phone: (240) 276–5484.

SUPPLEMENTARY INFORMATION:

NIH Reference Number: E–251–2023–0.

Title: T Cell Receptors Targeting EGFR L858R mutation on HLA–A*11:01 + Tumors.

Tumor-specific mutated proteins can create neoepitopes, mutation-derived antigens that distinguish tumor cells from healthy cells, which are attractive targets for adoptive cell therapies. However, the process of precisely identifying the neoepitopes to target is complex and challenging. One method to identify such neoepitopes is Mass Spectrometry (MS) when used in conjunction with elution of peptides bound to a specific Human Leukocyte Antigen (HLA) allele. Using MS in this

context can demonstrate which oncogene derived neoepitopes are presented by common HLA alleles, and can provide the data necessary to rapidly develop TCRs against the desired antigens.

Using the MS approach, inventors at the National Cancer Institute (NCI) have identified neoepitopes derived from a mutated isoform of Epithelial Growth Factor Receptor (EGFR) presented by HLA A*11:01 across multiple biological replicates. From this MS data, the inventors were able to successfully isolate murine TCRs that specifically recognize HLA A*11:01 restricted neoepitopes targeting EGFR L858R. According to various cancer genome databases, EGFR L858R is highly prevalent in lung adenocarcinoma, non-small cell lung carcinoma, and non-squamous non-small cell lung carcinoma, making this driver mutation an excellent target to develop off-the-shelf cellular therapies. The clinical potential of these TCRs has not been explored.

Therapeutic Area(s): Cancer.

Research uses include: TCRs may be used as positive controls to identify HLA–A*11:01 EGFR L858R reactive T cells from different sources such as patients or animal models; TCRs recognize the common EGFR L858R driver mutation in the context of HLA–A*11:01; EGFR; the prevalence of EGFR L858R substitutions, relative to the overall EGFR mutation population, ranges from 27.7% to 41.1% in non-small cell lung cancer patients; HLA–A*11:01 allele frequency is particularly high (up to 60%) in Asian and Oceanian populations. This research has validated the effectiveness of using mass spectrometry to detect amino acid sequences on specific HLA complexes.

Achieving expeditious commercialization of federally funded research and development is consistent with the goals of the Bayh-Dole Act, codified as 35 U.S.C. 200–212 and 37 CFR 404.4.

Development Stage: Research Tool.

Dated: February 26, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–04251 Filed 2–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Population Sciences and Epidemiology Integrated Review Group, Aging, Injury, Musculoskeletal, and Rheumatologic Disorders Study Section, March 14, 2024, 09:00 a.m. to March 15, 2024, 08:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 26, 2024, 89 FR 14081, Doc 2024–03762.

This meeting is being amended to change the location to Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314. The meeting time will remain the same. The meeting is closed to the public.

Dated: February 26, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–04306 Filed 2–29–24; 8:45 am]

BILLING CODE 4140–01–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 and Oral Fluid 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 (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) publishes a notice listing all HHS-certified laboratories and Instrumented Initial Testing Facilities (IITFs) in the **Federal Register** during the first week of each month, in accordance with Section 9.19 of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and Section 9.17 of the Mandatory Guidelines using Oral Fluid. 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 *https://www.samhsa.gov/workplace/drug-testing-resources/certified-lab-list.*

HHS separately notifies Federal agencies of the laboratories and IITFs currently certified to meet the standards of the Mandatory Guidelines using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine 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); January 23, 2017 (82 FR 7920); and on October 12, 2023 (88 FR 70768).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020, and subsequently revised in the **Federal Register** on October 12, 2023 (88 FR 70814).

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal