

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.

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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