

considered by FDA and the Quality Expert Working Group.

The draft guidance provides guidance on the development, implementation, operation, and lifecycle management of CM.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on "Q13 Continuous Manufacturing of Drug Substances and Drug Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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

Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22451 Filed 10–13–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the COVID–19 Health Equity Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the COVID–19 Health Equity Task Force (Task Force) will hold a virtual meeting on October 28, 2021. The purpose of this meeting is to present and vote on the Task Force Final Report with recommended Implementation Plan and Accountability Plan for mitigating inequities caused or exacerbated by the COVID–19 pandemic and for preventing such inequities in the future. This meeting is open to the public and will be live-streamed at www.hhs.gov/live. Information about the meeting will be posted on the HHS Office of Minority Health website: www.minorityhealth.hhs.gov/healthequitytaskforce/ prior to the meeting.

DATES: The Task Force meeting will be held on Thursday, October 28, 2021, from 1 p.m. to approximately 4 p.m. ET (date and time are tentative and subject to change). The confirmed time and agenda will be posted on the COVID–19 Health Equity Task Force web page: www.minorityhealth.hhs.gov/healthequitytaskforce/ when this information becomes available.

FOR FURTHER INFORMATION CONTACT: Samuel Wu, Designated Federal Officer for the Task Force; Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6173; email: COVID19HETF@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background: The COVID–19 Health Equity Task Force (Task Force) was established by Executive Order 13995, dated January 21, 2021. The Task Force is tasked with providing specific recommendations to the President, through the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), for mitigating the health inequities caused or exacerbated by the COVID–19 pandemic and for preventing such inequities in the future. The Task Force shall submit a final report to the COVID–19 Response Coordinator

addressing any ongoing health inequities faced by COVID–19 survivors that may merit a public health response, describing the factors that contributed to disparities in COVID–19 outcomes, and recommending actions to combat such disparities in future pandemic responses.

The meeting is open to the public and will be live-streamed at www.hhs.gov/live. No registration is required. A public comment session will be held during the meeting. Pre-registration is required to provide public comment during the meeting. To pre-register, please send an email to COVID19HETF@hhs.gov and include your name, title, and organization by close of business on Friday, October 22, 2021. Comments will be limited to no more than three minutes per speaker and should be pertinent to the meeting discussion. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute-taking purposes. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing COVID19HETF@hhs.gov no later than close of business on Thursday, November 4, 2021. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact: COVID19HETF@hhs.gov and reference this meeting. Requests for special accommodations should be made at least 10 business days prior to the meeting.

Dated: October 7, 2021.

Samuel Wu,

Designated Federal Officer, COVID–19 Health Equity Task Force.

[FR Doc. 2021–22330 Filed 10–13–21; 8:45 am]

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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 Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of 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.

DATES: The meeting will be held on Tuesday, October 26, from 11:00 a.m. until 4:30 p.m., and Wednesday, October 27, 2021, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at on the SACHRP website when 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 one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

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>.

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 Tuesday, October 26, followed by opening remarks from Dr. Jerry Menikoff, Director of the Office for Human Research Protections (OHRP), and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with discussion of draft recommendations on ethical and regulatory considerations for the use of

artificial intelligence in human subjects research, followed by a presentation of draft recommendations on the status of third parties in research. The second day, October 27, will include consideration of the current HHS policy of engagement and the interpretation of HHS support in 45 CFR part 46, and continue discussion of topics from the first day's agenda. Other topics may be added; for the full and updated meeting agenda, see <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 4:30 p.m. October 27.

The public will have an opportunity to send comment to the SACHRP during the meeting's public comment session or to submit written public comment in advance. Individuals submitting written statements as public comment should submit their comments to SACHRP at SACHRP@hhs.gov by midnight October 22, 2021, ET. Comments are limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Dated: September 28, 2021.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

[FR Doc. 2021-22351 Filed 10-13-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Small Business: Radiation Therapy and Biology SBIR/STTR.

Date: November 9-10, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-996-6208, hongb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.

Date: November 10, 2021.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, (301) 435-1766, bennettc3@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Biotherapeutics Development (CBD).

Date: November 15-16, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shahana Majid, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, shahana.majid@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.

Date: November 18-19, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Krystyna H. Szymczyk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-4198, szymczykhk@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 7, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-22327 Filed 10-13-21; 8:45 am]

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