throughout the medical product lifecycle. In addition, this document discusses methods on how to operationalize and standardize the collection, analysis, and dissemination of patient experience data. Guidance 1 also includes a glossary of terms that will be used in one or more of the series of four guidance documents.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Patient-Focused Drug Development: Collecting Comprehensive and Representative Input.'' 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. This guidance is not subject to Executive Order 12866.

II. Additional Information

Section 3002 of Title III, Subtitle A of the 21st Century Cures Act (Pub. L. 114–255) directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(1) (methodological approaches), which are relevant and objective and ensure that such data are accurate and representative of the intended population, that a person seeking to collect patient experience data to inform regulatory decision making may use.

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.1. of the commitment letter, ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making,'' (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision making.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for 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 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 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 Tuesday, July 10, 2018, from 8:30 a.m. until 5:00 p.m., and Wednesday, July 11, 2018, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: 6001 Executive Boulevard, Conference Room A, Rockville, Maryland 20852.

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 8:30 a.m., on Tuesday, July 10, 2018, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS and SOH subcommittees will present their recommendations regarding the description of ''key information,'' as required by the revised Common Rule at § 46.116(a)(5)(i). This will be followed by a discussion of the application of the revised Common Rule's exemptions at 46.104(d) to FDA-regulated research, and recommendations on the interpretation of § 46.104(d)(1) and (2) for HHS funded research.

The Wednesday, July 11, meeting will begin at 8:30 a.m. The SAS subcommittee will present and discuss recommendations on the interpretation of ''reasonably available'' at § 46.408(b), as well as discuss issues surrounding payment to subjects for participation in research. Modifications to the previous day's work will be discussed and finalized. The meeting will adjourn at approximately 4:00 p.m., July 11, 2018.

Time for public comment sessions will be allotted 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 provide their comments by email to *SACHRP@hhs.gov* or by fax to (240) 453–6909 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 the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: June 7, 2018.

Julia G. Gorey,

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

[FR Doc. 2018–12662 Filed 6–12–18; 8:45 am]

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