biological products, medical devices, and combinations thereof.

To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the agencies' regulatory requirements and guidance for human subject research, and the FDA draft guidance document was developed as a part of these efforts. Although the document is issued by FDA and is drafted as guidance that would apply to FDA-regulated clinical investigations, OHRP is considering whether to adopt the positions and recommendations proposed in this guidance for research regulated under the HHS protection of human subjects regulations, 45 CFR part 46, and to issue a joint OHRP and FDA guidance document on this topic when the final guidance document is developed. OHRP asks for public comment about whether a joint guidance document would be useful for the regulated community. In particular, OHRP is interested in public comment regarding whether FDA's draft guidance would be appropriate for all research regulated under 45 CFR part 46, including research studies other than clinical investigations or clinical trials, such as social and behavioral research studies. If different guidance should apply to social and behavioral research, or other non-FDA-regulated studies, OHRP asks that the public comments address how the guidance should differ from the proposed guidance for FDA-regulated clinical investigations.

OHRP specifically welcomes feedback regarding when it might or might not be appropriate, for studies other than clinical trials, for OHRP to recommend that researchers verify that the person signing the informed consent form is the subject participating in the research.

OHRP and FDA will consider these comments in deciding whether to issue a joint OHRP/FDA guidance document on this topic when the final guidance document is developed.

DATES: May 7, 2015.

ADDRESSES: You may submit comments identified by docket ID number HHS–OPHS–2015–0002 by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Enter the above docket ID number in the Enter Keyword or ID field and click on ''Search.'' On the next page, click the ''Submit a Comment'' action and follow the instructions.

Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions] to: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; phone 240–453–6900; email *Irene.Stith-Coleman@hhs.gov.*

Dated: March 3, 2015.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. 2015–05301 Filed 3–6–15; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 Human Genome Research Institute Special Emphasis Panel Loan Repayment Program.

Date: April 30, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635 Fishers Lane, Rockville, MD, (Telephone Conference Call).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–05305 Filed 3–6–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0647]

Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), in co-sponsorship with the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO), is announcing a public workshop entitled ''Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies.'' The objective of the workshop is to facilitate an in-depth discussion of harmonization of companion diagnostic devices across a class of targeted therapies. The workshop aims to foster collaborations in the clinical cancer research community; provide a deeper understanding of anticancer drug and device development related to personalized medicine; provide a unique perspective of personalized medicine; and help incorporate emerging scientific findings to harmonize companion diagnostics across a class of targeted therapies.

Date and Time: The public workshop will be held on March 24, 2015, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Mayflower Hotel, Grand Ballroom, 1127 Connecticut Ave. NW., Washington, DC 20036, 202–347–3000.

Contact Persons: Kaitlyn Antonelli, American Society of Clinical Oncology, 2318 Mill Rd., suite 800, Alexandria, VA 22314, 571–483–1606, *Kaitlyn.Antonelli@asco.org*; Pamela Bradley, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–731–3734, *Pamela.Bradley@fda.hhs.gov*; and Rasika Kalamegham, American Association for Cancer Research, 1425 K