



**BILLING CODE: 4150-36-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Town Hall Meeting on the Federal Policy for the Protection of Human  
Subjects Notice of Proposed Rulemaking; Notice**

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

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health, Office for Human Research Protections (OHRP), is announcing a public Town Hall Meeting to respond to questions related to the Federal Policy for the Protection of Human Subjects Notice of Proposed Rulemaking (NPRM) that HHS and fifteen other federal departments and agencies published in the **Federal Register** on September 8, 2015, (80 FR No. 173, pp. 53933-54061). The goal of the NPRM is to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was promulgated as a Common Rule in 1991. The NPRM seeks comments on proposals to better protect human subjects involved in

research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. To be assured consideration, comments on the NPRM must be received no later than December 7, 2015.

The purpose of the public Town Hall meeting is for OHRP, HHS agencies, and other Common Rule departments and agencies to provide responses to questions from the public about the NPRM during the open public comment period in order to clarify the NPRM proposals and better inform public comment on the NPRM. The public will be able to ask questions during the Town Hall Meeting, and to submit questions before the meeting. Details about how to submit questions before the Town Hall Meeting are provided below.

**DATES:** The public Town Hall Meeting will be held on October 20, 2015, from 9 a.m. to 5 p.m.

*Deadline for Registration to Attend the Town Hall Meeting:* The deadline to register to attend the town hall meeting and requests for special accommodations must be received no later than 5:00 p.m. on October 13, 2015.

*Deadline for Submission of Written Questions Prior to the Town Hall Meeting:* Written questions on the NPRM must be received no later than 5 p.m. on October 13, 2015, in order to be responded to at the October 20, 2015, Town Hall Meeting.

**ADDRESSES:** Meeting Location: The Town Hall Meeting will be held at the Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Ave., SW, Great Hall, Washington, DC 20201; Metro: Federal Center SW station. In addition, we are providing an alternative to attending the meeting in person—the public may view the meeting via webcast. Information on that option is provided in section D of this notice. An archived version of the webcast will be posted on OHRP’s website after the meeting.

*Registration and Special Accommodations:* While there is no registration fee, individuals planning to attend the public Town Hall Meeting in person must register to attend.

Registration may be completed by sending an email to [OHRP@hhs.gov](mailto:OHRP@hhs.gov), with the subject line “Registration for OHRP Town Hall Meeting;” or a request to register may be sent to: Registration for OHRP Town Hall Meeting, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852. Please include your name, address, telephone number, email address, and fax number.

Registration to attend the Town Hall Meeting will be accepted on a first-come, first-served basis. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

Individuals who need special accommodations should contact staff listed in the FOR FURTHER INFORMATION CONTACT section of this notice.

## **Submission of Questions for the Public Town Hall Meeting**

Submit electronic questions about the NPRM, identified with docket number HHS-OPHS-2015-0009 to: <http://www.regulations.gov>. Submit written questions about the NPRM to: Questions for OHRP Public Town Hall Meeting, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Dr. Irene Stith-Coleman, Director, Division of Policy and Assurances, 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.

### **SUPPLEMENTARY INFORMATION:**

#### **I. Public Town Hall Meeting**

##### **A. Purpose of the Meeting**

The public Town Hall Meeting is intended to provide an opportunity for the public to obtain responses from federal government representatives on a range of questions related to the Federal Policy for the Protection of Human Subjects NPRM that HHS and fifteen other federal departments and agencies published in

the **Federal Register** on September 8, 2015, (80 FR No. 173, pp. 53933-54061), in order to clarify the NPRM proposals and better inform public comment on the NPRM.

#### B. Format of the Town Hall Meeting

The meeting will be conducted by a panel of HHS officials. In addition, other federal government officials will be available to respond to relevant questions. The majority of the meeting will be reserved for responding to questions from the public, including questions submitted in advance of the meeting and during the meeting. Depending on the nature and number of questions received in advance of the meeting, it may not be possible to respond to all of the questions that were submitted, or to respond individually to each of the submitted questions.

#### C. Security and Building Guidelines

Because the public Town Hall Meeting will be located on federal property, for security reasons, any persons wishing to attend this meeting must register by the date specified in the DATES section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at the Hubert H. Humphrey Building no later than 8:30 a.m. if you are attending the public meeting.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Guard Service personnel.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to HHS are subject to inspection.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting in person. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted while in the building.

#### D. Webcast Information

Information on the option to view the meeting by webcast will be posted at a later time on the OHRP website at <http://www.hhs.gov/ohrp>. Please continue to check the OHRP website for updates. An archived version of the webcast will be posted on OHRP's website after the meeting.

## **II. Transcripts**

As soon as a transcript of the public meeting is available, it will be accessible on the OHRP website, <http://www.hhs.gov/ohrp>. A transcript also will be available in either

hardcopy or on CD-ROM, after submission of a Freedom of Information request.

Written requests are to be sent to the PHS FOIA Office, 7700 Wisconsin Avenue, Suite #920, Bethesda, MD 20857; telephone (301) 492-4800; fax (301) 492-4848; email [FOIARequest@psc.hhs.gov](mailto:FOIARequest@psc.hhs.gov).

Dated: October 2, 2015.

Karen B. DeSalvo,  
Acting Assistant Secretary for Health.

[FR Doc. 2015-25564 Filed: 10/6/2015 08:45 am; Publication Date: 10/7/2015]