

US EPA ARCHIVE DOCUMENT

Federal Regulations/Policies

Human subjects research that is conducted, sponsored, or regulated by the EPA is subject to the following regulations and policies:

EPA Regulation 40 CFR 26 (Protection of Human Subjects): The EPA regulations designed to protect human subjects can be broken down into three parts:

- **Subpart A (Common Rule):** In 1991, the EPA joined 16 other Federal Agencies in adopting a standard set of regulations designed to protect human participants in research. While the EPA codified this at 40 CFR 26, many other agencies refer to the parent regulation at 45 CFR 46.
- **Subparts B-D:** In 2006, the EPA added special protections for pregnant and nursing women and children. Those protections include:
 - **Subpart B:** This subpart prohibits intentional exposure research with pregnant women, nursing women, or children as participants
 - **Subpart C:** This subpart describes the regulatory protections for including pregnant women in observational research (defined as anything that is not intentional exposure research)
 - **Subpart D:** This subpart describes the regulatory protections for including children in observational research (defined as anything that is not intentional exposure research)
- **Subparts K-Q:** In 2006, the EPA also added special regulations related to the review of pesticide research involving human participants. These regulations were updated in 2013. The regulations include:
 - **Subparts K-L:** Regulations about third party pesticide research
 - **Subparts M-Q:** Regulations regarding reviews of completed research that is submitted to the EPA for regulatory purposes

EPA Policy Order 1000.17 Change A1: This policy (most recent version 2011) requires that all human subjects research that is conducted, sponsored, or regulated by EPA must be reviewed by the **Human Subjects Research Review Official (HSRRO)**. The policy also describes the procedures for review, including those that the HSRRO must use in making his or her determination of approvability.

Note: Because this is an EPA Policy Order, it is only binding on EPA employees. However, since the HSRRO must assess all human subjects research – including research proposed by grantees – under this policy order, it is important that extramural researchers also understand these guidelines. For more information, see the [Review Process section](#).

Federal-Wide Assurance (FWA) #00012755: The EPA holds an FWA, which is an assurance of compliance that covers the engagement of the Agency in any HSR conducted or supported by any Common Rule agency, including EPA. This assurance covers all Agency components and therefore provides a basis for the participation of EPA personnel anywhere in the Agency in HSR under conditions that are compliant with applicable regulations.

Additional Information

When deciding what to submit for review, and when the HSRRO considers your documents for approval, the following definitions and interpretations of 40 CFR 26 apply:

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.
 - **"Intervention"** includes both physical procedures by which data (think: blood draws, urine samples, questionnaires) are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Examples of "manipulations of the subject's environment" include, but are not limited to:
 - Changing the air or water flow (through filters, etc.) in a home, school, or other facility
 - Altering a subject's normal commute specifically for the purposes of the research study
 - Replacing an apparatus (like a cook stove, windows, etc) as part of a research study
 - **"Interaction"** includes communication or interpersonal contact between investigator and subject. Importantly, **it does not matter if the data gathered and recorded are identifiable or not**; interaction constitutes human subjects research according to the regulatory definition. Examples of interactions include, but are not limited to:
 - Taking blood or other kinds of physical samples from a subject
 - Asking a subject questions through an interview or focus group
 - Administering a survey that subjects fill out for the purposes of research
 - **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
 - **"Individually identifiable"** means the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Some projects (especially surveys, questionnaires, and record reviews) may count as **exempt** from the regulations according to 40 CFR 26.101. The project still must be submitted to your local IRB, as it is the IRB that makes the determination of what constitutes exempt research. *However, exempt research still must be submitted to the EPA HSRRO for approval (see "**Where to Submit Documents for Review**").