IRB Policy 41: EPA Policy
Date: June 15, 2016

I. Definitions:

Terms used in this policy and not otherwise defined shall have the same meaning of those terms in the EPA requirements in 40 CFR 26 and EPA Order 1000.17.

A. Research involving intentional exposure of a human subject: a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study. This includes any research in which the subject's exposure is artificially manipulated or controlled.

B. Observational research: Any human research that does not meet the definition of research involving intentional exposure of a human subject. Studies that involve naturally occurring environmental exposures may meet the regulatory definition of observational research (if the subject's exposure is not artificially manipulated or controlled).

C. Child: A person who has not attained the age of 18 years (40 CFR 26.202). There is no provision in EPA regulations for deferral to state or local law in defining "child" and "adult".

D. Substance**:** A substance in the Substance Registry System is any chemical, biological organism, or physical property that is tracked or regulated by an EPA program or identified in an environmental statute.

II. Applicability of EPA Rules

The ETSU or ETSU/VA Institutional Review Board (IRB) ensures that EPA requirements are met before it grants IRB approval to research involving the EPA. This includes research that is conducted or supported by the EPA, conducted in EPA facilities by any person, or research conducted in any facility by EPA employees. The EPA regulations for protecting human research participants also apply to research in which the intent is submission of data to the EPA.

III. Prohibitions

EPA Subpart B **prohibits intentional exposure research, under all circumstances, in children and women who are pregnant or nursing**. Such research will NOT be approved by the IRB.

The risk level of the research (including zero or minimal risk) is irrelevant to the determination of whether the research involves intentional exposure or is observational.

EPA does not permit observational research with children that is greater than minimal risk when there is no direct benefit to the child. EPA does not recognize the "minor increase over minimal risk."

Research may not be approved which involves intentional exposure to a pesticide by subjects who cannot consent for themselves.

IV. Intentional Research

Research involving the intentional exposure of non-pregnant, non-nursing adults must comply with the provisions of 40 CFR 26.

Subpart K applies to other adults (non-pregnant and non-nursing) in studies involving intentional exposure to pesticides.
If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function. In consideration of risks currently unforeseen, the investigator must include in the consent any potential risk to embryo or fetus, should the participant become pregnant. In addition, Subpart K does not include a provision for consent by a subject's legally authorized representative. No researcher may involve a human being as a subject in pesticide research unless the investigator has obtained the legally effective informed consent of the participant.

V. Observational Research

Observational Research, i.e., research that does not involve intentional exposure to any substance, may be approved only if the additional requirements of 40 CFR 26 subparts C (Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA) and D (Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA) are met as outlined below.

Observational research may involve pregnant women or fetuses if, in addition to meeting the requirements described in 45 CFR 46 Subpart B:

a) there is a direct benefit to the woman or fetus or
b) if the risk to the fetus is no greater than minimal and the research is important for biomedical knowledge which cannot be obtained in any other manner.

Observational research may involve children if, in addition to meeting the requirements of 45 CFR 46 Subpart D:

a) the research poses only minimal risk and the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in 40 CFR 26.406.

b) the research is greater than minimal risk but presents the prospect of direct benefit to the participant and the following conditions are documented:

1. The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well being
2. The risk is justified by the anticipated benefit to the participants
3. The relation of anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternatives; and
4. Adequate provisions are made for obtaining the child's assent and the permission of the child's parents or guardians as set forth in 40 CFR 26.406.

VI. EPA Human Subjects Research Review

Researchers must submit the ETSU or ETSU/VA IRB determinations and approval to the EPA Human Subjects Research Review Official for final review and approval prior to the initiation of the research.

VII. Responsibilities

A. The ETSU or ETSU/VA IRB is responsible for:

1. ensuring that the EPA requirements are met prior to granting IRB approval and documenting that review on the EPA review section of the reviewer xform.

B. Researchers are responsible for:

1. Complying with the additional requirements of the EPA
2. Communicating the information required at CFR 20 Part 26. 1125 with the EPA Program Officer (through ORSPA?) to ensure that all EPA requirements are met prior to starting an IRB-approved study, including obtaining approval from the EPA Human Subjects Research Review Official.
3. Identifying on the IRB submission whether the study is conducted or supported by the EPA, conducted in EPA facilities by any person, conducted in any facility by EPA employees, or whether the intent is submission of data to the EPA.

4. After completing research subject to EPA regulations, complying with regulations at CFR 20 Part 26.1303 by providing the information required to the EPA

Sources:

EPA Order 1000.17 A1
https://www.epa.gov/osa/epa-order-policy-and-procedures-protection-human-research-subjects-epa-conducted-or-supported
Substance Registry Services
https://ofmpub.epa.gov/sor_internet/registry/substreg/home/overview/home.do#a1
CFR 40 Part 26
https://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml