

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2014-032.0
Policy Title: Additional Requirements – Environmental Protection Agency

Purpose

The purpose of this policy is to set forth additional requirements that are applicable to research supported by the Environmental Protection Agency.

Definitions

Policy

For non-exempt research conducted or supported by the EPA, the EPA:

- prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance;
 - the IRB will not approve such research
 - research intended for submission to the EPA will comply with this prohibition
- requires application of 40 CFR 26 Subparts C* (Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research) and D* (Additional Protections for Children Involved as Subjects in Observational Research) to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance;
 - research involving intentional exposure of a human subject means 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.
 - observational research means any human research that does not meet the definition of research involving intentional exposure of a human subject
- requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

For research not conducted or supported by any federal agency that has regulations for protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply, including:

- EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

*equivalent to protections at 45 CFR 46 Subpart B and D

Procedure

If pregnant women or children are to be included in observational research conducted or supported by the EPA, the additional protections described in Policy 2011-006.1 and 2011-006.3 are applicable and the procedures described in Policy 2011 – 006.0 – Vulnerable Populations - General Policy, are to be followed.

Related Policies

2011-006.0 - Additional Protections: General Policy
2011-006.1 – Additional Protections: Pregnant Women, Fetuses or Neonates
2011-006.3 - Additional Protections: Children
2011-008.0 – Informed Consent Forms
2011-008.5 – Providing and Obtaining Informed Consent
2011-009.3 - Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

40 CFR 26

Document Attributes

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Reviewed and Approved By:

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Date