Title:	Research Subject to the U.S. Environmental Protection Agency Regulations		
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1 Research Subject to U.S. Environmental Protection Agency Regulations

Environmental Protection Agency (EPA) policy requires that researchers submit 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 requirements for protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA requirements for protecting human research subjects apply.

Researchers must submit IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

All covered human research conducted or supported by Environmental Protection Agency (EPA) must be compliant with 40 CFR 26 and EPA Order 1000.17 Change A1. 40 CFR 26 includes EPA-specific additional protections and prohibitions for children, pregnant women and fetuses, and nursing women in research conducted or supported by the Agency at Subparts B-D. It also contains regulations for third-party human research for pesticides and rules for data use, compliance oversight, and other matters. EPA Order 1000.17 Change A1 requires that all human subjects research conducted by EPA be reviewed and approved by the EPA Human Subjects Research Review Official (HSRRO) as compliant with 40 CFR 26, or be determined to be exempt research, before the research begins. This requirement is in addition to IRB review and approval, and it occurs subsequent to it as the final step before the research commences.

- Subpart B of the regulations prohibits intentional exposure research, under all circumstances, in children and women who are pregnant or nursing. The ban is categorical and is not based on a risk-benefit ratio, including prospect of direct benefit.
- Subpart C establishes rules for studies that involve pregnant women (and thus their fetuses) participating in observational research. Research of this nature can be conducted when there is direct benefit to the woman or the fetus. However, in the absence of direct benefit, if the risk is no greater than minimal to the fetus and the research is important for biomedical knowledge which cannot be obtained in any other manner, the research is permissible.

- Subpart D establishes rules for studies that involve children participating in observational research. Research of this nature can be conducted on children as long as it involves no more than minimal risk. Research that involves greater than minimal risk can only be conducted when there is direct benefit to the subject. There is no provision in the EPA rule for the conduct of research when there is greater than minimal risk and no direct benefit to the child.

Unlike the regulations adopted by the Department of Health & Human Services, EPA's regulations:

- Do not further regulate research involving prisoners, beyond those additional protections found in the Common Rule.
- Define a child as someone less than 18 years of age (whereas HHS regulations defer to state or local law).
- Contain no exceptions to the rule prohibiting intentional exposure research involving children, nursing women, and pregnant women and fetuses
- Do not recognize a category of research on children involving "a minor increase over minimal risk."
- Have no provisions for "research not otherwise approvable" for children, nursing infants, or fetuses.
- The IRB is permitted to approve observational research involving children that does not involve greater than minimal risk only if 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 26..406.
- The IRB is permitted to approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual subjects if the IRB finds and documents that:
  - The intervention or procedure holds out the prospect of direct benefit to the individual subject or is likely to contribute to the subject's well-being.
  - The risk is justified by the anticipated benefit to the subjects.
  - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
  - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 26.406.