Guidance: Additional Requirements for Environmental Protection Agency (EPA) Sponsored Research

1. Introduction

The EPA has adopted the Common Rule at 40 CFR 26 and has published additional requirements for research it supports or conducts and for research intended for submission to the EPA as described in EPA Order 1000.17A. Researchers are responsible for reviewing these documents to understand the applicable principles and the University policy.

2. EPA Human Subjects Research Review

For research conducted or sponsored by the EPA, IRB determinations and approval must be submitted to the EPA Human Subjects Research Review Official (HSRRO) for final review and approval before research may begin.

3. Special Considerations for EPA-supported Research

3.1 Prohibited Research

Research involving the intentional exposure of pregnant women, nursing women, or children to any substance regulated by the EPA is prohibited. (40 CFR 26.203). Such research will not be approved by the IRB.

3.2 Intentional Exposure

Research involving the intentional exposure of adults (except pregnant or nursing women) must comply with 40 CFR 26.

3.3. Observational Research

Observational research (i.e., that does not involve intentional exposure) of **pregnant women and fetuses** is subject to the requirements of 40 CFR 26 subpart C and 45 CFR 46 subpart B (the requirements for research of pregnant women or fetuses prescribed by HHS).

Observational research (i.e., that does not involve intentional exposure) of **children** is subject to the requirements of 40 CFR 26 subpart D and 45 CFR 46 subpart D.

a. IRBs may approve observational research involving children only if it finds that no greater than minimal risk to children is presented and only if the IRBs find that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

b. IRBs may approve research involving an intervention or procedure that presents more than minimal risk to children, only if it 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; **and**
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

4. Research Intended for Submission to the EPA (40 CFR 26 subpart K and subpart L)

Similar to the requirements for EPA-supported research, research to be submitted to the EPA (but not conducted or supported by any federal agency that has regulations for protecting human research subjects) is subject to the same requirements as above:

4.1 Prohibited Research

Research involving the intentional exposure of pregnant women, nursing women, or children to any substance regulated by the EPA is prohibited. (40 CFR 26.203) Such research will not be approved by the IRB.

4.2 Intentional Exposure

Research involving the intentional exposure of adults (except pregnant or nursing women) must comply with 40 CFR 26.

References

40 CFR 26, Protection of Human Subjects

EPA Order 1000.17A, Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research