Environmental Protection Agency – additional obligations

Modified: July 2017

Background:

This guidance outlines the additional obligations of investigators conducting research supported or conducted by Environmental Protection Agency (EPA).

Q: What are the additional obligations that are required when conducting research funded by the EPA?

1. EPA regulates research that is conducted or supported by EPA.
2. EPA regulates research whose results are intended to be submitted to EPA, regardless of whether the research is conducted or supported by EPA or any federal agency.
3. “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.
4. “Observational research” means any human research that is not research involving intentional exposure of a human subject.
5. Research involving the intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.
6. Observational research involving children must meet the criteria in category (1) or (2) of “IRB Guidance Document: Research Involving Children (HRP-310)”:
   a. To limit Children to category (1) in their respective Regulatory Guidance as this limits the criteria to subjects in observational research. The EPA requires application of 40 CFR 26. Subparts C and D to provide additional protections to children as subjects in observational research, i.e., research that does not involve intentional exposure to any substance.
7. Observational research involving pregnant women must meet the criteria in “IRB Guidance Document: Pregnant Women (HRP-305)”:
   a. To limit Pregnant Women to category (1) in their respective Regulatory Guidance as this limits the criteria to subjects in observational research. The EPA requires application of 40 CFR 26. Subparts C and D to provide additional protections to pregnant women as subjects in observational research, i.e., research that does not involve intentional exposure to any substance.

Q: Once the UF IRB approves the EPA study, are there additional requirements?

Yes, research approved by the UF IRB must be submitted to the EPA human subject’s research review official for final review and approval before the research can begin. To ensure the EPA has approved the research before the local PI initiates the protocol:

1. If written consent will be obtained from subjects or a waiver of documentation of consent will be used, the UF IRB will not stamp the approved documents until the PI has submitted a revision to the UF IRB that includes the approval letter from the EPA.
2. If there is no consent form, the UF IRB will approve the study with no study subjects. Once the PI receives approval from the EPA, the PI must submit a revision to include that approval letter, and to change “0” subjects to the number needed to complete this study.

Q: Do these obligations apply when the research is not conducted or supported by any federal agency that has regulations for protecting human research subjects?

Yes, if the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply, including those provisions in 40 CFR 26 regarding human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

REFERENCES

40 CFR §26

EPA Order 1000.17 Change A1