Environmental Protection Agency – additional obligations

Modified: January 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 conduction 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)”
7. Observational research involving pregnant women must meet the criteria in “IRB Guidance Document: Pregnant Women (HRP-305).”

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 insure 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.

REFERENCES

40 CFR §26
EPA Order 1000.17 Change A1