1. PURPOSE

1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by EPA or whose results are intended to be submitted to EPA.

2. GUIDANCE

2.1. EPA regulates research that is conducted or supported by EPA.
2.2. 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.
2.3. “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.
2.4. “Observational research” means any human research that is not research involving intentional exposure of a human subject.
2.5. Research involving the intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.
2.6. Observational research involving children must meet the criteria in category (1) or (2) of "CHECKLIST: Research Involving Children (HRP-310)"
2.7. Observational research involving pregnant women must meet the criteria in “CHECKLIST: Pregnant Women (HRP-305).”
2.8. Research approved by the IRB must be submitted to the EPA human subjects research review official for final review and approval before the research can begin.

3. REFERENCES

3.1. 40 CFR §26
3.2. EPA Order 1000.17 Change A1