

INVESTIGATOR GUIDANCE: Additional EPA Obligations

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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