

US EPA ARCHIVE DOCUMENT

Research involving intentional exposure

The EPA has special protections related to the “intentional exposure of a human subject.” According to **40 CFR 26.201**: “research involving the 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.

In addition, EPA Policy 1000.17 Change A1 requires the HSRRO to conceptualize intentional exposure research quite broadly:

- (1) Research that includes the gathering of physiological measurements (e.g. monitoring a subject's cardio respiratory performance) or the collection of body fluids, tissue or expired air from subjects; or (2) Research that requires subjects to perform specific tasks other than their normal activities or manipulates their environment (e.g., modifies their exposure); or (3) Research that gathers or records private information (as defined in 40 CFR 26.102 (f)(2)) in a manner that associates such information with an identifiable subject.

What this means is that any modification of exposure – **even if the modification decreases a subject’s exposure** – cannot be funded by EPA when subjects are members of the protected groups outlined in **40 CFR 26 Subpart B**: pregnant women, nursing women, or children. Any research proposal that describes what the EPA defines as “research involving intentional exposure” must clearly describe how these protected groups will (a) be excluded from recruitment, and (b) not be affected by the intervention. For example, a proposal to change the filters in a school and only survey the teachers about the impact would still not be permitted, since the children in the classrooms would also be subject to the modified exposure. Please contact the HSRRO with questions about these types of proposals.

"Observational research" means any human research that does not meet the definition of research involving intentional exposure of a human subject, *even if that research involves an interevention.* Please note that surveys, interviews, and focus groups with individuals may constitute observational human subjects research.