In addition to the requirements outlined in VUMC HRPP Policies, additional requirements apply in some cases depending on the funding mechanisms. These additional requirements are outlined below. Researchers are responsible for reviewing these documents to understand the applicable requirements and ensure compliance.

**Environmental Protection Agency (EPA)**

The EPA has adopted the Common Rule at 40 CFR 26 and has published additional requirements for research it supports or conducts and for research intended for submission to the EPA as described in EPA Order 1000.17A.

EPA requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance. Such research will not be approved by the IRB.

EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.

* IRBs may approve observational research involving children only if it finds that no greater than minimal risk to children is presented and only if the IRBs find that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
* IRB may review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that: (i) The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being. (ii) The risk is justified by the anticipated benefit to the participants. (iii) The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches. AND (iv) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 26.406.

Similar to the requirements for EPA-supported research, research to be submitted to the EPA (but not conducted or supported by any federal agency that has regulations for protecting human research subjects) is subject to the same requirements as above.

**Department of Energy**

* The HRP Program Manager at DOE or NNSA must be notified:
	+ Immediately:
		- Upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
		- Any suspected or confirmed compromise of personally identifiable information, with a description of any corrective actions taken or to be taken. The incident must also be immediately reported to the DOE-Cyber Incident Response Capability.
	+ Within 48 hours, with a description of corrective actions taken, of:
		- Unanticipated problems
		- Significant adverse events, and
		- Complaints about the research
		- Suspensions of IRB/EC approval
		- Terminations of IRB/EC approval
		- Any significant noncompliance with HRPP procedures or other requirements
		- Known or potential incidents of noncompliance