**Instructions**: These EPA requirements *differ from* or are *additional to* our current HRPP policies and must be met prior to initiating human research activities, when applicable.

***IRB Manager:***

* *Attach this checklist in eProtocol when completed.*
* *Send comment(s) as appropriate*
* *Refer to Guidance GUI-42 for more information as needed.*

|  |  |
| --- | --- |
| **PD:** | **Protocol ID:** |
| **Checklist completed by** (IRB Staff name)**:** | **Date:** |

1. **Review for the Following Conditions:**
2. **Yes  No  Does research involve exposure to substances?**

**If “*yes*”, note that:**

***Prohibited:*** EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.

***Additional protections:*** 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.

**Before the research can begin**

IRB determinations and approval must be submitted to the EPA Human Subjects Research Review official for final review and approval.

NOTE: For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:

* + The provisions of 40 CFR 26 are extended to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance,
  + The intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.

1. **Yes  No  Does the study involve children in observational research greater than minimal risk but with prospect of direct benefit?**

**If “*yes*”,** **such research is allowable if:**

* 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.
* The risk is justified by the anticipated benefit to the participants.
* The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
* Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §26.406. 40 CFR 26.304, 40 CFR 26.404-405