

IRB Reviewer Checklist Federal Funding Environmental Protection Agency

Reviewer: PRO # PI:

This checklist is designed to support the IRB reviewer in evaluation of protocols funded by			
he Environmental Protection Agency (EPA):			
Does the research exclude intentional exposure of pregnant women, nursing women or children to any substance regulated by the EPA?	Yes	No	
Does the research exclude intentional exposure of non-pregnant, non-nursing adults to any substance regulated by the EPA where the research does not comply with the provisions of 40 CFR 26?	Yes	No	
Does the research involve observation of pregnant women and children and does the research meet conditions of HRPP Section 8 "Vulnerable Populations"?	Yes	No	
If the research poses greater than minimal risk to children, does the research present the prospect of direct benefit to individual subjects? If yes,	Yes	No	NA
Does the intervention or procedure hold out the prospect of direct benefit to the individual subject or is it likely to contribute to the subject's well-being?	Yes	No	
 Is the risk justified by the anticipated benefits to the subjects? 	Yes	No	
• Is the relation of the anticipated benefit to risk at least as favorable to the subjects as that presented by available alternative approaches?	Yes	No	
 Are there adequate provisions for soliciting the assent of the children and permission of their parents or guardians? 	Yes	No	