Informed Consent Checklist

	COMMENTS
Introduction ☐ Statement that the study involves research ☐ Description of study goals and purposes ☐ Name of principal researcher(s) ☐ Name of sponsor(s)	
Procedures and Subject Involvement ☐ Expected duration of subject's participation ☐ Approximate number of subjects involved ☐ Description of procedures (where applicable: description of research vs. clinical procedures)	
Possible Risks and Benefits ☐ List of reasonably foreseeable risks and discomforts ☐ Statement that some risks may be unforeseeable ☐ List of reasonably foreseeable benefits ☐ Alternative procedures or treatments	
Costs and Compensation ☐ Description of all costs to the subject that may result from participation in the study ☐ Description of any recruitment incentives, medical treatments, or compensation available to subjects	
Confidentiality ☐ Statement that confidentiality will be maintained to the extent possible by law ☐ Description of procedures for maintaining confidentiality and protecting subject privacy	
Contact Information ☐ Name and telephone number of contact person for questions about the research study ☐ Name and telephone number of contact person for questions about subject rights as a research subject ☐ Where applicable: name and phone number of contact person in case of medical complications	
Subject Rights as a Research Participant ☐ Statement of voluntary participation ☐ Statement of right to withdraw at any right without penalty or loss of benefit ☐ Where applicable: policy on termination of subject participation without subject approval ☐ Where applicable: policy on disclosure of research findings and clinically relevant information	
General Issues ☐ Is the language used in the informed-consent materials understandable to subjects? ☐ Will subjects have the opportunity to ask questions about the study and their participation in the study? ☐ Are the informed-consent materials culturally appropriate for the study population? ☐ Where applicable: Are there plans to obtain the assent of participating children? ☐ Where applicable: Are there plans to recruit individuals with questionable capacity for consent?	

Source: National Institute of Environmental Health Sciences, Research Triangle Park, NC.