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OAKWOOD UNIVERSITY

INSTITUTIONAL REVIEW BOARD

**ADDENDUM D**

**RESEARCH INVOLVING CHILDREN**

**SECTION I**

**DATE:**

**IRB#:**

**TITLE OF PROTOCOL:**

**PRINCIPLE INVESTIGATOR:**

**SECTION II**

***Instructions:*** Research involving children must comply with 1) HHS regulations at 45 CFR 46, Subpart D in accordance with HEPP policy, and 2) FDA regulations at 21CFR 50, Subpart D, as applicable. Subpart D provides additional protection for children enrolled in research because they are considered to be vulnerable subject population. This addendum application is designed to assist the investigator in developing the documentation necessary to verify compliance with Subpart D. All questions should, therefore, be completely addressed by consulting this section of the regulations which can be accessed at the IRB website: [www.oakwood.eduacademics/faculty-development/irb](http://www.oakwood.eduacademics/faculty-development/irb)

This addendum should be submitted with the IRB application. Information should be provided by site for all studies involving more than one site for which OU IRB is the only IRB of record. *The addendum must provide sufficient information to facilitate an effective review by all members of this IRB including non-specialists. Applications that do not allow for and effective review may be returned to the investigator, without IRB review, for revision and resubmission*

**ADDITIONAL INFORMATION REQUIRED PER 45 CFR 46 AND 21 CFT 50, SUBPART D**

1. **What is the justification for including children in research?**
2. **What is the age range of the children to be included in the research?**
3. **What is the rationale for the age range of the subjects?**
4. **Will this study enroll wards of the state?**

 **No**

 **Yes. Complete the** Addendum H – for Research Involving Children Who Are Wards.

1. **PROCESS OF PERMISSION (CONSENT) OF THE PARENT(S)/GUARDIAN(S)**
2. **When will the parent(s) or guardian(s) of the prospective subject be approached relative to their child’s actual participation in the study?** *Note: Parent(s) or guardian(s) of prospective subjects should be approached sufficiently far in advance to enable them to have time to make an informed decision to permit their child to participate in the study.*
3. **What is the location where informed consent will be obtained?**

*Note: The environment where informed consent will be obtained should be a private and quiet location, conducive to discussion and thoughtful consideration by the parent/ guardian.*

1. **Who will approach the parent(s) or guardian(s) about their child’s participation in the**

**study?** *Note: This section should describe the involvement and responsibility of study personnel who will be involved in the process of consent.*

1. **How much time will be allotted to the process of consent?** *Note: The amount of time allotted to the process of consent is dependent upon the nature and complexity of the study.*
2. **Will a delayed parental/guardian consent procedure be used?**

 **Yes**

 **No. Provide justification.** *Note: A delayed parental/guardian consent procedure is one where the subject’s parent(s)/guardian(s) is presented with the consent form after discussion with the investigator and is encouraged to discuss participation in the study with family, friends, counselors or other confidants before they sign. Delayed consent is strongly encouraged except where the research is simple and low risk, or where the subject’s medical condition precludes such a delay.*

1. **How will it be determined that the parent(s) or guardian(s) understood the information presented?** *Note: All investigators have a legal and ethical obligation to ensure that the parent(s) or guardian(s) of the child has sufficient knowledge and comprehension of all of the elements of informed consent to enable them to make an informed and enlightened decision whether or not to permit their child to participate in research. The fact that an individual is prepared to sign the informed consent form and has no unanswered questions does not necessarily represent sufficient evidence of an adequate level of comprehension. Some investigators, therefore, choose to determine the level of a person’s comprehension by questioning the individual concerning their understanding of all the elements of informed consent. This section should clearly document that the investigator has an adequate plan in place to assure existence of an acceptable level of comprehension of all the elements of consent.*
2. **Who will sign the consent form granting permission for participation of the child in the research?** Note: permission of only one parent/guardian is sufficient for research conducted under HHS regulation at 45 CFR 46.404 and FDA regulations at 45 CFR 50.51 (no more than minimal risk). Permission of both parents, or guardian is required by the IRB for research conducted under 45 CFR 45.405/21 CFR 50.53 (greater than minimal risk and no prospect of direct benefit), unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available or when only one parent/guardian has legal responsibility for the care and custody of the child.
3. **Will there be a formal process of on-going re-consent (over and above re-consent associated with changes in protocol)?**

 **No**

 **Yes. Describe.**  *Note: Federal regulations, HRPP, and sound ethical practice require that parent(s) or guardian(s) of children who are subjects have the opportunity to withdraw the child from research at any time. In certain cases, it may be appropriate to seek active re-consent from the parent/guardian. Preferences and interests may change over time, even in the absence of material changes in the research protocol. Therefore, instigators should consider obtaining re-consent, or at least verbal reaffirmation of the parent/guardian willingness to permit their child to continue participation, on a routine basis. In most cases, affirmation is all that will be necessary. However in rare cases, more formal re-consent (for example, a signed consent form or notation in the research record) may be appropriate.*

1. **PROCESS OF ABTAINING ASSENT FROM THE CHILD**
2. **Will the investigator ask children and adolescents to assent to participate in the research?**

 **Yes**

 **No. Provide justification for a waiver of assent.** *Note: “Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Federal regulations and sound ethical practice require that assent be obtained when, in the judgment of the IRB, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB takes into account the ages, maturity, and psychological state of the children involved. In general, the OU IRB believes assent should be obtained from subjects 7 years of age and older. The IRB further believes that the capacity of children younger than 7 years of age as a group is limited and that they cannot reasonably be involved in a formal process of assent [ 45 CFR 46.408(a) and 21 CFR 50.55(c)]. However, depending upon the cognitive ability of an individual child, the investigator should engage that child in an appropriate discussion about the research to the extent possible. Note: If a child is 14 years of age or older, assent should be documented by having the child sign the parental consent form. If a child is between the ages of 7 and 13 written documentation of assent by the child is not required. However, the investigator must document obtainment of assent in the research record on a separate form.*

**B. How will it be determined that the child understood the informative presented?** *Note: All investigators have an ethical obligation to ensure that the child has sufficient knowledge and comprehension of the elements of assent to enable them to make an informed decision to participate in the research. The fact that a child has no unanswered questions does not necessarily represent sufficient evidence of an adequate level of comprehension. Some investigators, therefore, choose to determine the level of a child’s comprehension by simply questioning the child’s understanding of the elements of assent. This section should clearly document that the investigator has an adequate plan in place to assure existence of an acceptable level of comprehension of the elements of assent*.

1. **Will children reach the age of majority (i.e., 19 years old) during the course of the study? NO. YES. Describe the process of re-consent.** *Note: if a child is initially enrolled in the study, but during the course of the research he/she reaches the age of majority, the subject must provide written consent to continue participating in the study. In this case an IRB approved adult consent form must be used. Consent of subject is not required if the research only involves data analysis.*

*If and adult subject refuses to continue participating in the research, this must be respected. No new data may be collected, but existing data collected under parental/guardian consent and assent can continue to be used.*

1. **PARENTAL CONSENT FORM**

The parental consent form should include all relevant elements of informed consent as outlined previously and be written in a proxy consent style that indicates it is the parent, or legally authorized representative, who is consenting to allow the child to participate in the study. The standard statements must be modified for the Parental Consent form (e.g., all references to “you” must be change to “your child.”) In addition, if it is expected children 14 years of age or older will be enrolled, the Parental Consent form must include and additional signature line for child participants

1. **CHILD AND YOUTH INFORMATION SHEETS**

To facilitate the process of assent, the investigator must prepare brief simple narrative summaries of the research (without subheadings) which include only a description of the purpose, methods, potential risks, potential benefits, and the fact that the child/youth does not have to participate. Signature blanks and the names of the investigators should not be included.

The Information sheets must be written at an appropriate educational level for children (7 to 13 years of age) and youth (14 – 18 years of age). These forms must be reviewed by the IRB, and given to child and youth subjects at the time that assent is negotiated.