**Form IRBF021- RESEARCH with MINORS: ADDITIONAL INFORMATION**

**Use this form to disclose additional information when researching with minors or adolescents**

1. **GENERAL INFORMATION**
   1. **Protocol Title:**
   2. **Protocol ID:**
   3. **Today’s Date:**
   4. **Primary Investigator (PI) Information:**

Faculty/Staff Graduate Undergraduate Other

|  |  |
| --- | --- |
| Name |  |
| MTSU Email | mtsu.edu |

* 1. **Faculty/Senior Investigator Information** (Skip if same as PI)

|  |  |
| --- | --- |
| Name |  |
| MTSU Email | @mtsu.edu |

\*The application documents MUST be emailed to [irb\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu) by the faculty investigator. Suggested subject line to the email is “Protocol Addendum”

DO NOT CONVERT THIS APPLICATION TO PDF – There are embedded XML features

1. **RESEARCH CLASSIFICATION – RISK TO BENEFIT RATIO**

|  |
| --- |
| * 1. **Lower than minimal risk:**   §46.404 **- No greater than minimal risk** to children is presented.  **⇒**Jump to section 3 |

|  |
| --- |
| * 1. **Risk is foreseen but the minor subjects would receive direct benefits**   **§**46.405 - **More than minimal risk** is presented by an intervention or procedure that **DOES** hold out the prospect of a direct benefit for the individual child or by a monitoring procedure that is likely to contribute to the child’s well-being. The following must be justified:   * + 1. **Describe how the risk is justified by the anticipated benefit to the subjects.**      * + 1. **Describe how the relation of the anticipated benefit to the risk is at least as favorable to the child as that presented by available alternative approaches.** |

|  |
| --- |
| * 1. **Risk is foreseen and NO direct benefits to the minors – CATEGORY 1**   **§46.406** - **More than minimal risk** to the child is presented by an intervention or procedure that **DOES NOT** hold out the prospect of direct benefit for the individual child or by a monitoring procedure which is not likely to contribute to the well-being of the child. All of the following conditions must be met:   * + 1. **Describe how the risk represents only a minor increase over minimal risk.**      * + 1. **Provide the rationale for the intervention or procedure that presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.**      * + 1. **Provide a rationale for the intervention or procedure that is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.** |

|  |
| --- |
| * 1. **Risk is foreseen and NO direct benefits to the minors – CATEGORY 2**   **§46.407** - **Research not otherwise approvable** and it presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The research may not meet the requirements of the three statutes described above (§46.404, §46.405, or §46.406).  Is the study federally funded?  Yes, the study must be submitted to the Secretary of Health and Human Services for approval.  No, the IRB may approve the research only if the following conditions have been met:   * + 1. **Provide justification as to how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a problem affecting children’s health/welfare.**      * + 1. **Support the justification that the research will be conducted in accordance with sound ethical principles.** |
| **The IRB Committee must review the recommendations from both the Expert and Community Review Panels (IRB USE ONLY)** |
|  |

* ***The research studies listed under 2.1 would qualify for expedited review while 2.2 may require a full committee review under certain circumstances***
* ***Studies classified under 2.3 and 2.4 would require a full committee review***

1. **PARENTAL CONSENT**
   1. **Describe the provisions that are present for soliciting permission of the parents or legal guardians.** Provide a clear plan for how the parents will be contacted either in person or other means and how the information about the research will be conveyed to them so they can make an informed decision. Please note that the parental consent form alone would not be sufficient.

Parents/Legal guardians permission will be obtained (§46.408(b)).

Permission by one parent is sufficient.

Permission will be sought from both parents.

The permission will be sought:

In person by one of the investigators

By mail or other means by one of the investigators

In person by persons designated by the investigators as approved

Other:

Documentation of parents/legal guardians permission will be obtained (§46.117).

Language of the parental consent form is appropriate for the expected educational level and ethnical background of the parent.

Requesting waiver of parents/legal guardians permission (§46.408(c)).

**Justification**:

***NOTE:*** *The IRB may waive the requirement to obtain permission from the parents/legal guardians when the research protocol is designed for a condition or for a subject population in which parents or legal guardians’ permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children).*

* 1. **Describe the mechanism for how a parent would us to withdraw his/her child**

* 1. **Describe the mechanism for protecting the children who will participate as subjects in the research.** The waiver may not be granted if in violation of Federal, state and local laws.

1. **CHILD ASSENT**
   1. **Describe the provisions for obtaining assent of the children**.

* 1. **Child Assent Check List**

**Children are NOT capable of providing assent**.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research (§46.408(a).

**Children are capable of providing assent.**

In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child as the IRB deems appropriate (§46.408(a)).

**4.3 Documentation of child assent** is in following format: (§46.409(e)).

Written Form  Short Form  Script

**4.4 Assent Signature**

Signature of child will obtained for assent.

Signature will be obtained on a case-by-case manner depending on the the age, maturity, and psychological state of the child.

Explain:

Language of the assent is age-appropriate to meet the the maturity, and psychological state of the child.

**4.5 Describe the process for obtaining assent/consent and identifying dissent.**

1. **DECLARATION**

I, **,** certify that:

1. this project is carried ot by me or and under my direct supervision
2. I have read this application thoroughly and I am fully aware of the activities to be performed under this protocol involving minors

PI Signature \_\_\_\_

Date \_\_\_\_

(Enter your name and TODAY’s date in the space provided)