IRBT001a:
WORKING WITH MINORS EZ
Information for the Researchers

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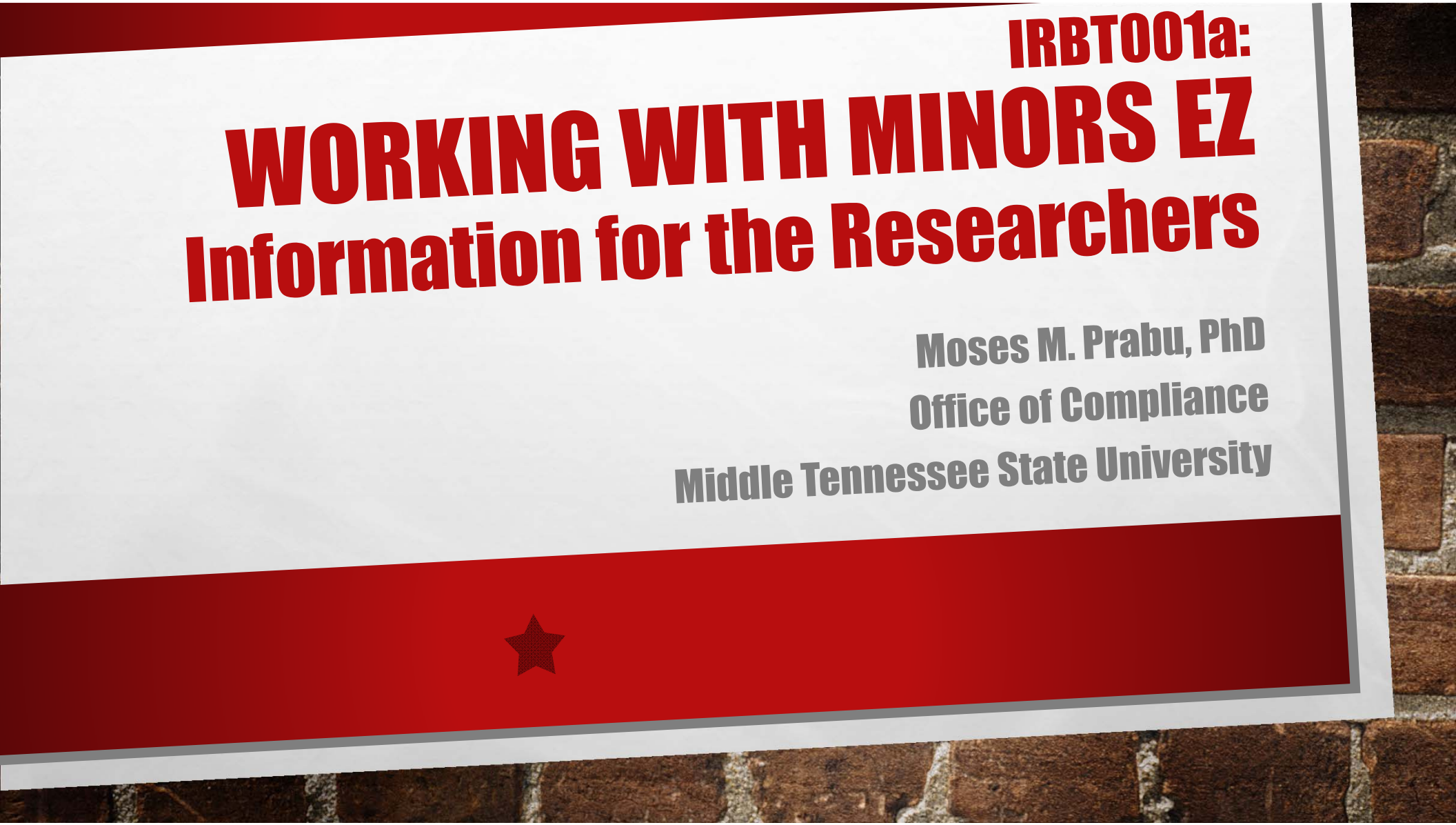

About this Training

- Please note that this information sheet is not the actual training, but this will be circulated among the researchers who are interested in requesting a provision in a study to sub-delegate qualified teachers to conduct some of the portions of their study that involves under-aged participants
- This training will take between 20-30 minutes and the teachers may be asked to take a quiz subsequently to become eligible to serve as a designee
- Once qualified through this training, the teacher can serve as a designee for upto ONE year
- These slides are expected to provide more information on the purpose of this provision and how the Middle Tennessee State University (MTSU) researchers can make a request when they apply for a new protocol or through amendment to a previously approved study
- Additional information on researching with minors is also provided here to help researchers understand their crucial responsibilities when enrolling children in their study

PURPOSE

- This training is expected to present more clarity on human subject research involving minors to school teachers who have been requested by the researchers to administer portions of their study
- In most instances, the MTSU's Institutional Review Board (IRB) requires that everyone who is part of a research team MUST be adequately trained AND be listed in the research protocol –
  - the school teachers cannot conduct the research on behalf of the investigators unless they are listed in the protocol AND they had completed human subject training
- The above mandatory requirement has posed significant hardships to researchers whose studies involve standard educational evaluations and the associated benefits are high with "no more than minimal risks" for the participants
- For those studies that involve only educational tests on science or/and arts AND pose less than minimal risk, the researchers may now request a provision to "sub-delegate" portions of the approved intervention to a qualified teacher
- The proposal to sub-delegate teachers MUST be approved by the IRB before such an intervention can be carried out
- Be advised that this training is not a replacement for the CITI training completed by the researchers, but this is offered as a provision for certain qualified studies as identified by the IRB

Who may Undergo this Training?

- Qualified teachers who work in the school where the proposed research activity is scheduled to take place
- The researcher can request for this provision by demonstrating that:
  - The study poses less than minimal risk to the participating minors AND
  - The research only involves standard academic testing AND
  - The research DOES NOT involve psychological or physical interventions AND
  - The proposed study has the potential to significantly innovate education practices and result in the advancement of knowledge among school children AND
  - The geographic location of the school(s) prevents researchers from making frequent visit to the research site
- A written agreement must be enacted between the participating teacher and the research team to clearly detail the responsibilities of both parties and the proposed intervention(s) of the former
- A written approval from the host school that they grant permission to involve the teacher as a designee

DISCLAIMERS & ELIGIBILITY

- This presentation is NOT a replacement to the CITI training
- This training has been compiled by MTSU's Office of Research Compliance (ORC) to educate the prospective teachers in human subject research so the researchers may sub-delegate a few IRB-approved study-related interventions to a certified teacher when conducting research with minors at an education setting
- The study MUST confine within the allowed exclusion criteria by the MTSU ORC (next slide)
- Satisfying this eligibility criteria will allow the researchers to sub-delegate qualified teachers to administer the survey instruments (restrictions may apply)
- This training must be successfully completed before the participating teacher can assist with the intervention
- Be aware that the IRB reserves the right to disregard this training if the protocol does not qualify

CRITERIA

- In order for a teacher to intervene on behalf of the research team, the study MUST:
  - Only involve standard educational tests within the school's academic programs (Math, Science, Social Studies, Language, Civics and etc.)
  - Enroll minors in high school or higher
  - Appoint the teacher delegate who is an employee of the school where the research activity is scheduled to take place
  - Have a clear plan in writing for the responsibilities and the intervention of the participating teacher
  - Only use the EXPEDITED mechanism and projects reviewed under the Full Review are disqualified
- The study MUST NOT:
  - Involve behavioral or psychological analysis on the minors
  - Enroll minors to analyze their physical activities
  - Reviewed by the full committee

Requesting this Provision

- Submit an IRB petition including these particulars in your EXPEDITED application
  - Articulate why your study qualifies for the teacher sub-delegation provision (Pg 3 – Description)
  - Also, explain the reasons for adopting the teacher sub-delegation process
  - Provide a clear plan for the intervention of the teacher along with a template for a confidentiality agreement
  - List the names, contact information and affiliation of the teachers whom you plan to sub-delegate (Pg 5)
  - Explain how you plan to safely transfer the research-related documents (Pg 5)
  - Complete Appendix B (Pg 9)
  - Describe how you plan to monitor the teachers' research activities to ensure they follow the IRB-approved procedure(s)
  - All other investigators to be included in the protocol MUST have completed CITI training prior to making the request
  - Permission letter(s) from the school(s)
  - Other mandatory and specific support documents as listed in the MTSU IRB website (www.mtsu.edu/irb)
- The expedited petition will be reviewed and the ORC will contact the teachers directly to train them once the IRB approves your protocol. The research team can also request the ORC to conduct an in-person training for a group of teachers
- Once the teachers listed in the protocol take this training successfully, then they are eligible to help the researcher with the approved intervention(s). Additional teachers can be added later to the protocol through amendments. This training is valid for 1 (ONE) year.

The Researchers' Commitment

- When a study includes vulnerable subjects, additional care must be taken to protect their rights
- It is the responsibility of the investigational team to ensure that the vulnerable subjects, children in this case, are not exploited in the name of research
- The study design team must be aware of the special requirements needed for the vulnerable population and they should develop their study protocol appropriately
- A clear strategy for obtaining parental consent and child assent must be detailed
- A concerted goal to protect the subjects' safety and welfare must be part of the research plan and not merely a compliance paperwork

The Researchers' Duties

- Know the teachers and maintains connection throughout the period this research
- Maintain records on the teacher and their activities
- Answer questions by the parents or children if the teachers are unable to do so
- Teacher making mistakes – promptly notify ORC and proactively mitigates the deviation(s)
- Ensure the teachers are familiar with the educational portion of the study and educate them on their responsibilities for the human subject research part
- Provide the resources needed to address questions or concerns from the minors and parents

The Institution's Responsibility

- Studies involving vulnerability must be reviewed by the IRB for fair treatment and risk to benefit ratio
- Written standard operation procedures must be reviewed and maintained
- Requirements must be established for all studies regardless of whether they involve minors
- Assign IRB members with appropriate expertise to serve as primary reviewers when involving children
- Make the IRB determinations and recommendations in convened full committee meetings when needed
- Require the researchers to justify the reason to use vulnerable populations
- Impose mandatory measures to ensure participant rights and confidentiality are protected
- The MTSU Office of Compliance and the IRB have the shared responsibility to ensure the research activities conducted or sponsored by the University are carried out in ethical manner

Basic Requirements

- Children are considered as “vulnerable” because their intellectual/emotional capacities are limited
- Moreover, they are legally incompetent to give valid informed consent
- The federal law mandates the following minimum requirements in order to obtain an IRB approval:
  - The researcher has to demonstrate that the study entails no more than minimal risk
  - Consent from parent(s) or legal guardian(s)
  - Assent from the participating child
- The IRBs can impose further constraints and requirements depending on the participants’ age and the proposed activities within the protocol

Parental Consent and Assent - Basics

- **Parental Consent:**
  - Children below the age of 18 cannot legally give valid informed consent.
  - Written permission from parent(s)/guardian(s) must be obtained before beginning the intervention(s) –
    - there are no specific requirements for how many times the parents can be reminded to exercise their rights after they consent. But, the research team must periodically remind them that they can withdraw at any time.
  - The researcher must describe all procedures and interventions to be performed on their child
  - The parental consent can be waived only if there is proof that parental abuse of the minor(s) is evident
    - Parental consent CANNOT be waived for teacher sub-delegation provision
- **Child Assent:**
  - Although the child cannot enroll in a study directly, every minor subject has the right to withdraw from the study. The researcher cannot assume the child has approved only based on the parental consent
  - However, in case of life threatening events, only parental consent would suffice – Nonetheless, the child must be given full explanation of the intervention if the IRB approves a waiver for child assent
    - Child assent CANNOT be waived for teacher sub-delegation provision

Who can give Parental Consent?

- Who may provide consent for a child to participate in a research study?
  - Natural or adoptive parents
  - Legal custodians or legal guardians
  - Individuals who posses power of attorney or authorized by a court to consent
  - Minors emancipated by marriage or court order

- Who may not give parental consent?
  - Stepparents
  - Grandparents
  - Adult siblings
  - Adult aunts or uncles
  - Foster parents
  - Minors emancipated by pregnancy outside of marriage or by adjudication as an adult

Scenarios for Parental Consent

Regulatory Category of Permitted Research with Children	One versus Both Parents' Permission
Minimal Risk (45 CFR 46.404, 21 CFR 50.51)	One parent/legal guardian may be sufficient
Greater than Minimal Risk, Direct Benefit to Subject (45 CFR 46.405, 21 CFR 50.52)	One parent/legal guardian may be sufficient but IRB must determine whether one or two is required
Greater than Minimal Risk, No Direct Benefit to Subject, but Likely to Yield Generalizable Knowledge about Subject's Condition (45 CFR 46.406 21, CFR 50.53)	**Both parents**/legal guardians, unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child.
Greater than Minimal Risk, No Direct Benefit to Subject, but Results May Alleviate Serious Problems of Children's Health or Welfare (45 CFR 46.407 21 CFR 50.54)	

What happens when the Parents Disagree?

- If there are two parents available to give permission but they disagree about allowing their child to participate in the study:
  - Then, the child may not be enrolled unless that disagreement can be resolved
  - AND this applies to all permissible categories
    - even if only one parent's signature is required, when both parents are involved in the decision, they must agree for the child to be enrolled.
- If a parent who was not involved or available for the original consent later becomes involved or available, the two parents must then agree.

Child Assent - Basics

- Federal regulation and most State statutes require that minors assent to participate in research
  - Assent is defined as a minor's affirmative agreement to participate
  - Unless approved by the IRB, this process must be documented in writing when the subjects are 7 years or older
  - The IRB can require assent from children younger than seven
  - The assent process requires allowing voluntary participation of the child

Child Assent Form - Elements

- What is the study about?
- Why the child is eligible to participate?
- What are the procedures the child will perform or will be performed on the child?
- What are the potential risks and discomforts the child will be experiencing?
- What are the potential benefits to the child or the society?
- A statement clearly notifying the child that he/she can choose whether to participate and can withdraw at any time without any negative consequences
- An invitation to ask questions at any time
- Names and phone numbers of whom to contact should the child have any questions

Child Assent Procedure

- The assent process is different with age of the participants – typically, the documentation for children under 7, between 7-12 and adolescents (13-17) may be different and so are the procedures
- The children constantly change age groups during the span of a study. Therefore, it is vital that the assent process is refreshed at a periodic basis
- The consent/assent are not a one-time process; It is important that the research team ensures that the designee reminds the minors and the parents that the participation is voluntary and they can withdraw at any time.
- The teacher designee can explain the elements of the IRB-approved assent document to the participants as a group
- The teacher must give "enough" time for the minors to make a decision to whether to participate or not
- There should be time allotted for the minors to ask questions about the study

Suggestions for Documentation

- The researchers can use the forms and templates posted in the MTSU IRB website for records keeping
- Or, the forms can be customized as long as all of the previously listed elements are incorporated
- In addition to the federal requirements, they must also follow other state and other local requirements
- The following suggestions are for educational research to improve paperwork efficiency:

Minor's Age	Separate Assent Form	Separate Parental Consent
Infant – 6 years	NO – verbal if applicable	YES
7-12 years	YES	YES
13-18 years	YES	NO – create a single document with signature lines for the child and parents
13-18 years	Yes	Yes – when a single document is not feasible or not appropriate

- The teacher designee must administer the assent process as described in the previous slide regardless of what type of documentation is used to receive verbal assent from the participating minor

The Permissible Duties of the Designee

The researchers must clarify the list of activities that a designee will perform on behalf of them. The following duties can be sub-delegated to a teacher who is not a co-investigator

- Send or receive parental consent forms in accordance with the IRB-approved procedure –
  - It is important that the final decision on enrolling minors is made by the researchers
- Provide assistance to the parents in filling their parental consent forms without purposefully influencing their decision
- Administer child assent as instructed
- Reemphasize that the participation is voluntary and they can withdraw at any time – the teacher can remind the participants multiple times that they can withdraw at any time during the course of the study
- Distribute and collect the survey questions upon completing the study's educational procedure
- Mail or send all of the research-related documents and records immediately upon completion of the approved intervention
- Other "common sense" intervention(s), if needed, to protect the subjects from unexpected harm – The teacher MUST report any unexpected intervention to the PI immediately so the investigator can file an "adverse event report"

What NOT "to do"

The designee MUST NOT unduly intervene in the following:

- Actively recruit participants
- Convince the parents to enroll in the research
- Coerce student minors or the parents or the guardians to complete the study
- Influence the decision of the minor from withdrawing if he or she intended to do so
- Intervene in any other way in the study other than the intended purpose of the sub-delegation
- Retain records of the study materials, names or other types of accounts on the students or the parents
  - The research team will be held liable for any unlawful access of research-related documents by the teacher(s) or by other school authorities
- Speak about any confidential conversations to colleagues or other members of your school - UNLESS a participant is in potential danger or may experience unforeseen harm or there is evidence to believe that the participant may cause potential danger to others
  - This MUST be reported to the Office of Compliance if any such incident must take place when the research portion is administered

Failure to Comply

- The IRB may not take direct action against the designee(s)
- However, the investigative team will be notified to withdraw any data collected by the designee(s) in question
- The IRB reserves its authority to revoke this provision or parts of it, or even cancel the protocol should non-compliance to the Committee's directives become a repeating phenomenon

Handling Genuine Mistakes

The IRB recognizes that mistakes can happen despite caution and due diligence. In case a designee made an inadvertent mistake while serving on behalf of the investigator, the following remedial steps must be taken:

- Immediately file an "Adverse Event Report" to the Office of Compliance clearly outlining the deviation from the procedure described in the protocol
- The Compliance Officer will work the research team to mitigate the error
- Parts of the data may be asked to be omitted if necessary
- The actual course of action will be determined on a case-by-case basis depending on the type of error(s) and the potential consequences to the participant

ADDITIONAL RESOURCES

Click the following items to access resources on human subject research:

- **MTSU Pages**
  - **IRB Webpage**
  - **Compliance Webpage**
  - **Human Subject FAQ page**
- **External Pages**
  - **Research with Children FAQ**
  - **Code of Federal Regulations**
  - **Informative YouTube videos sponsored by the Office of Human Research Protections (OHRP):**
    - **Module 1 (22.13 min)**
    - **Module 2 (27.37 min)**
    - **Module 3 (36.19 min)**