# IRBT001b:
# WORKING WITH MINORS EZ

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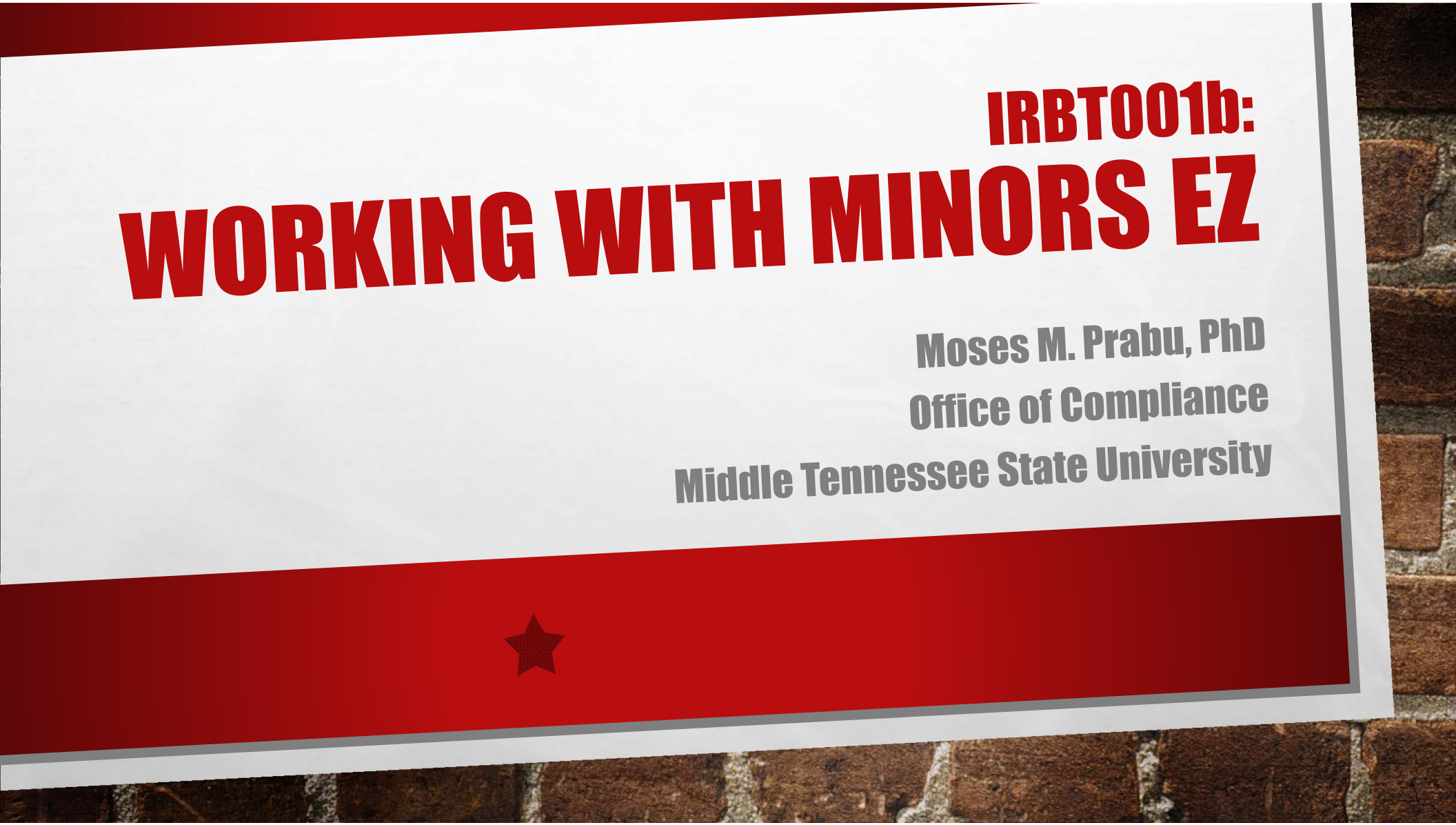

# Message for the Teachers

- On behalf of the research team, the MTSU Institutional Review Board (IRB) thanks you for your service to our University and we greatly appreciate your commitment to enhance education practices by participating in this research
- The MTSU IRB allows the school teachers to serve as the research team's representative in certain qualifying protocols to complete specific research tasks
- Although educational training and professional certifications have more than adequately prepared teachers to work with minors, the elements of human subject research are not always included
- Moreover, Federal law requires all individuals who conduct human trials to be adequately trained.
- The training must educate the individuals in ethical intervention practices

# About this Training

- This training is expected to last for 20-30 minutes
- Basics of this delegation process
- Overview of human trials
- Research with minors
- Outline for volunteering teachers
- Subsequent to the training, a short quiz may be administered
- Please follow the instructions at the end of this training on how to return your responses

# PURPOSE

- This training is expected to present more clarity on human trials minors to school teachers who may be undertaking certain research-related tasks requested by an MTSU research team
- MTSU's 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 be adequately trained
- For those studies that involve only educational tests on science or/and arts AND pose less than minimal risk, the researchers may request this provision to "delegate" portions of the intervention to a qualified teacher
- This teacher delegation process MUST be approved by the IRB before this intervention can be carried out
- Be advised that this training is not a replacement for the CITI training required for researchers, but a provision for certain qualified studies as identified by the IRB which oversees the ethics of human subject research

# Criteria

- Who are you?
  - You are a certified teacher or a teaching professional at an accredited school
- Why are you asked to take this training?
  - You had agreed to administer the survey, informed consent and the child assent in a study to be conducted by an MTSU researcher
- What will you gain from this training?
  - An understanding of ethical guidelines for conducting research with human subjects, specifically with minors
  - Upon completing this training, the researcher will be able to sub-delegate you to administer the survey and collect consent/assent
- What are your responsibilities or interventions in this study?
  - This study has to only involve educational instruction and its assessment and not other types of intervention
  - You will collect the parental consent, administer child assent and administer the applicable survey(s)
- Whom do you contact in case you have questions or you wish to speak with someone?
  - Please contact the office of compliance at compliance@mtsu.edu or +1.615.494.8918
  - Any information you provide will be confidential

# Introduction

- Researchers and commercial entities alike have enrolled human subjects to validate clinical practices, pharmaceutical compounds, medical devices and even testing popular gadgets like iPhones for several years dating back to the time of the Romans
- Until last century, the use of humans to answer research questions had questionable practices
- In many instances, the human subjects did not have a say in the practiced intervention
- This unfair treatment was however changed partly by the awareness of the research community and the involvement of the Government in the last fifty years
- In the US, guidelines delineating a review process was enacted by the Congress in the 1970s
- Subsequently, major changes and amendments to this enactment have been made continuously

# Declaration of Helsinki

- Major breakthrough in creating awareness and promoting ethical practices
- The conditions to justify research involving human subjects:
  - Voluntary informed consent of subjects
  - Experimental design based on previous animal studies or equivalent
  - Careful risk-to-benefit analysis in the context of the importance of the study
  - Performance of experiments ONLY by scientifically qualified persons
  - Subject-initiated withdrawal from the study at any stage
  - Investigator-initiated cessation of the activity in the face of possible injury, disability, or death

# The Belmont Report

**The US Congress enacted the "Belmont Report" in response to unethical practices by some researchers.**

- RESPECT for Persons
  - The subject can exercise total autonomy
  - Self-rule or Determination in participation or withdrawal from the study
  - Independence – protection of individuals who have reduced autonomy (like prisoners)
- BENEFICENCE
  - Helpful – the study offers advancement of the society
  - Maximize benefits and minimize risks
  - No maleficence – do not harm
- JUSTICE
  - Prevent retribution
  - Fair treatment
  - Distributive of fair share of risks/benefits and resource available

# The Common Rule – 45 CFR 46

- Mandates institutions to enact policies to protect research subjects
- The Institution's policy must provide guidelines for its regulatory body
  - The IRB is a committee appointed by the Organization - It is not an elected entity
  - A typical IRB would comprise of representatives from various research factions of the organization, in addition to community individuals and non-scientific experts
  - IRB only oversees "research" projects
  - The "research" involving human subjects cannot start until an IRB has granted approval for the proposal
- All Federally-funded research programs that utilize human subjects have to adhere by this policy
- MTSU is accredited for Federal-wide assurance and hence it is obligated to follow the Common Rule
- Non-compliance will lead to funding denial and cessation of the human research program

# “Research” and “Human Subjects”

- ***Research*** **refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge**
  - **Activities which meet this definition constitute research for purposes of the OHRP’s policy, whether or not they are conducted or supported under a program which is considered research for other purposes**
  - **For example, some demonstration and service programs may include research activities**
- ***Human subject*** **refers to a living individual about whom an investigator (whether professional or student) conducting research obtains –**
  - **data through intervention or interaction**
  - **udentifiable private information**

# Research with Vulnerable Populations

- ***Definition***:
  - **Individuals whose willingness to volunteer in a study may be unduly influenced by the expectation, whether justified or not, of benefits associated with the participation**
- ***Examples***:
  - **Groups with a hierarchical structure**
  - **Patients with incurable disease or persons in nursing homes**
  - **Ethnic minority groups**
  - **Homeless individuals, nomads and refugees**
  - **Minors and those incapable of giving consent**

# Vulnerable Subjects

- Cognitive and Communicative vulnerability:
  - Children, adolescents, patients suffering from mental retardation or dementia
  - Educational deficits, unfamiliarity with language, stressful emergency conditions, and etc.
- Juridical or Institutional vulnerability:
  - Person who is under official authority who may have their own benefits
- Deferential vulnerability:
  - Influence of other people in the subjects' life (relatives, friends, etc.)
- Medical vulnerability:
  - Prospective patients with severe medical condition
- Social vulnerability:
  - individuals belonging to undervalued social groups (sex workers)
- Economic vulnerability:
  - subjects with low economic background
- Infrastructural vulnerability:
  - patient tempted to enroll in trials offering resources or facilities

# The Researchers' Commitment

- When a study includes vulnerable subjects, additional care must be taken to protect their rights
- It is the responsibility of the investigator and his/her investigative team to ensure that the vulnerable subjects 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 informed consent and a concerted goal to protect the subjects' confidentiality must be part of the research plan and not merely a compliance paperwork

# The Institution's Responsibility

- The overseeing IRB must have the necessary training and expertise to regulate studies involving vulnerability
- Written standard operation procedures must be maintained
- Requirements must be established for all studies regardless of whether they involve vulnerable subjects
- Assign IRB members with appropriate expertise to serve as primary reviewers
- 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 IRB ensures the research activities conducted or sponsored by the University are carried out in ethical manner as described in this training

# Research Involving Children

- 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 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

# Informed Consent and Assent

- **Parental consent:**
  - Children below the age of 18 cannot legally give valid informed consent.
  - Permission from parent(s)/guardian(s) must be obtained before beginning the intervention (s)
  - The researcher must describe all of the 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
  - In most cases, the researchers have to receive written consent from the parent(s) or guardian(s)
- **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

NOTE: Both parental consent and child assent cannot be waived at the same time under any research scenarios

# Requirements for Parental Consent

**The following types of research require consent from ONE parent along with child assent:**

- Research involving no more than minimal risk with no direct benefits to the minor(s)
- Research with more than minimal risk but presents the prospect of direct benefits to the subject(s)
  - The risk must be justified by anticipated benefits – "minimal risk" is defined in the next slide

**The following types of research require consent from TWO parents along with child assent:**

- Research with more than minimal risk but presents NO DIRECT BENEFITS to the subject(s)
  - The risks are a small increase over "minimal risk" (Defined in the next slide)
  - The intervention(s) or procedure(s) are commensurate with those associated with the minors' actual or expected medical, dental, psychological, social or education situation
  - The research will likely yield generalization information about the subjects' disorder, or condition, which is of vital importance in treating other minors but not necessarily beneficial to the participant

# OHRP's Definition of "Minimal Risk"

- Definition - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).
- Determining that a research activity presents "no more than minimal risk" involves comparing the possible harms or discomforts experienced in normal daily life or during routine physical or psychological examinations or tests with the possible harms or discomforts that will be faced by subjects as a consequence of research participation.
- The nature of the harms or discomforts (e.g., physical, psychological, legal) should be considered, as well as the chances that they will occur and the seriousness of their impact if they were to happen. Depending on what kind of experience(s) are involved in participation in a specific research activity, it may be easier to compare the anticipated experience of participation in research to the possible harms or discomforts of daily life, or to the possible harms or discomforts of a routine physical or psychological examination or test. Including measures to prevent or decrease the likelihood of harm or discomfort from the research may affect whether the proposed research activity involves no more than minimal risk.

# Parental Consent and Scenarios

- Who may provide parental 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
- Situations when only ONE parent can provide consent:
  - When one parent is deceased, unknown, incompetent, or not reasonable available, or when only one parent has legal responsibility for the care and custody of the child
  - The researcher must document this in the subject's research record
- Situations when a guardian can provide consent:
  - When both parents are deceased, unknown, or incompetent
  - Research with more than minimal risk but presents NO DIRECT BENEFITS to the subject(s)

# 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.

# Who MAY NOT consent a child?

- Stepparents
- Grandparents
- Adult siblings
- Adult aunts or uncles
- Foster parents
- Minors emancipated by pregnancy outside of marriage or by adjudication as an adult

# 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) are different and so are the procedures
- As we all know, 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 designee reminds the participants and the parents that the participation is voluntary and they can withdraw at any time.
- For the purpose of educational studies, the teacher designee can explain the elements of the IRB-approved assent document to the participants as a group
- The designee must give "enough" time for the minors to make a decision to whether to participate or not
- There should be "enough" time allocated for the minors to ask questions about the study

# Acceptable Child Assent Procedure

The process for obtaining oral and/or written consent for children is similar to that of obtaining consent for adults. OHRP requires that an effective informed consent process involves at minimum these elements:

- Conducting the process in a manner and location that ensures participant privacy
- Giving adequate information about the study in a language understandable to the participant
- Providing adequate opportunity for the participant to consider all options
- Responding to the participant's questions
- Ensuring the participant has understood the information provided
- Obtaining the participant's voluntary agreement to participate
- Continuing to provide information as the participant or research requires.

# Teachers -- What “to do” as a Designee

As a teacher who has been sub-delegated to intervene in this research, you are specifically required to complete the following duties on behalf of the research team:

- Send or receive parental consent forms in accordance with the IRB-approved procedure
- Provide assistance to the parents in filling their 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 the survey questions upon completing the study’s educational procedure
- Collect the surveys
- Mail or send all of the research-related documents and records immediately upon completion of the intervention
- Other “common sense” intervention(s), if needed, to protect the subjects from unexpected harm – This must be reported to the PI of this research project immediately so they can file an “adverse event report”

# What NOT "to do"

As the research team's designee, you are not allowed to do or 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
- Keep records of the study materials, names or other types of records on the students or the parents
- Speak about any confidential conversations to colleagues or other members of your school UNLESS a participant is about experience unforeseen harm or there is evidence to believe that the participant may cause potential danger to others

# Failure to Comply

- There may be no direct consequence to you for failure to comply – the MTSU IRB may not take direct action
- The investigative team will be notified to withdraw any data you may have helped them collect
- The researcher may not use you as a designee in their future studies

# What to do if you made a mistake?

To err is human and the IRB recognizes that mistakes can happen despite caution and due diligence.

In case you think you may have made an inadvertent mistake while serving as the investigators' designee, please ….

- Contact the researchers and notify them immediately
- There will be no consequences to you for genuine inadvertent mistakes
- The research team will work with the ORC to mitigate the error

# ADDITIONAL RESOURCES

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

- **MTSU Pages**
  - IRB Webpage – www.mtsu.edu/irb
  - Compliance Webpage – www.mtsu.edu/compliance
  - Human Subject FAQ page - http://www.mtsu.edu/irb/faq.php
  - Researching with Minors page - http://www.mtsu.edu/irb/FAQ/WorkinWithMinors.php
- **External Pages**
  - Research with Children FAQ - http://www.hhs.gov/ohrp/policy/faq/children-research/index.html
  - Informative YouTube videos sponsored by the Office of Human Research Protections (OHRP)
    - Module 1 (22.13 min) - https://www.youtube.com/watch?v=174SkSszRVg
    - Module 2 (27.37 min) - https://www.youtube.com/watch?v=Up09dioFdEU
    - Module 3 (36.19 min) - https://www.youtube.com/watch?v=Cr-xd7hQhHo

# THANK YOU FOR YOUR SERVICE