Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 211.1	TITLE: Research with Minors	Date Effective: 12/01/2021 Last Revision Date: initial

I. Purpose

Minors are considered a vulnerable research population and require additional protections when they are potential subjects of research. (45 CFR 46 Subpart D; 21 CFR 50) The WCU Institutional Review Board reviews all research projects involving minors to ensure that inclusion of minors as participants is justified and that adequate procedures are in place to minimize the research related risks. This document outlines ethical and regulatory requirements when minors are utilized as human subjects in research.

II. Scope

This procedure applies to all research involving minors conducted under the authority of the WCU Institutional Review Board, regardless of funding source.

III. Applicability

Under North Carolina law (NCGS § 48A-2), a minor is a person younger than 18 years old unless such person has been emancipated. A married minor is considered emancipated. (NCGS § 7B-3509)

IV. Definitions

Assent: A minor's affirmative agreement to participate in research.

Consent: Permission of the parent(s) or guardian for the child or ward to participate in research.

Guardian: An individual authorized by a court to consent on behalf of a minor.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

Minor: A person under the age of 18 years old.

Parent: A minor's biological or adoptive parent.

Principal Investigator: WCU full time Faculty or Staff Member responsible for the content of the IRB application and the conduct of the study.

Research Personnel: any individual who is involved in conducting human subjects research studies. Such involvement may include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or data for research purposes.

Ward: For the purposes of this procedure, a minor for whom a guardian has been appointed by a court.

V. Permitted Categories of Research with Minors

1. Research not involving greater than minimal risk
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant
3. Research that involves more than minimal risk and presents the prospect of no direct benefit to individual participants, but societal benefits.
4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

VI. Undue Influence Considerations with Minors

Undue influence occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle because influence is contextual. It is likely to depend on an individual's situation:

- Undue influence may come about due to the participant's environment. Assent may only be sought under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether to participate in the research. This includes considering time and place where participants are recruited, consented, and engaging in research activities.
- Undue influence may come from people with real and perceived authority over the possible participant such as parents and guardians, teachers, principals, administrators, case workers, coaches, religious leaders, medical care providers, and siblings. When considering recruitment, consent, and data collection methods, researchers must design their research to manage any aspects of undue influence as a result of power differences between adults and minors.
- Undue influence may come from peer and familial relationships that result in a feeling of pressure to participate in the research. This may occur in situations when groups of friends are participating in the research, an entire class is participating, or when a family member is participating.
- Undue influence may come about due to compensation. These issues range from type of compensation, amount of compensation, and to whom the compensation is given.
    a. When minors are compensated with money, to whom the monetary compensation is paid must be discussed.
    b. The level of compensation should not be so high as to cause a prospective participant or their parent or guardian to accept risks that they would not accept in the absence of the compensation.
    c. Protocols submitted to the IRB should indicate and justify proposed levels and purposes of remuneration.

VII. Informed Consent

Research personnel must make adequate provisions for soliciting the permission of each child's parent or guardian for participation in research, unless waived by the IRB.

Level of Risk/Benefit to participant	Consent Requirements
Minimal Risk	The consent of one parent/guardian is sufficient
Greater than Minimal Risk with Direct Benefit to Participant	The consent of one parent/guardian may be sufficient, unless the IRB determines otherwise
Greater than Minimal Risk with NO Direct Benefit to Participant, but likely to yield	The consent of both parents/guardians is required unless one parent is deceased, unknown, incompetent, not reasonably available, or does not

generalizable knowledge about the participant's condition*	have legal responsibility for the custody of the child
Greater than Minimal Risk with NO Direct Benefit to Participant, but the results may alleviate serious problems affecting the health or welfare of children*	The consent of both parents/guardians is required unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child

*Wards may be included in research only if such research is (1) related to their status as wards; or (2) conducted in a school, camp, hospital, or institution in which the majority of children involved as subjects are not wards.

Waiver of Parental Consent

If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects, it may waive the consent requirement. Applicants requesting a waiver of parental consent, must meet the following conditions:

a. The study is no more than minimal risk.
b. The research could not practicably be carried out without the requested waiver or modification.
c. If identifiable information will be collected, the research could not be carried out without using the information in an identifiable format.
d. The waiver will not adversely affect the rights and welfare of the minors.

Submissions to the WCU IRB requesting a waiver of parental consent will be reviewed by the full board.

Passive Parental Consent (opt-out consent)

Passive parental consent is utilized at various K-12 primary schools. This type of consent is not recognized by the WCU IRB. Researchers intending to rely on parents' passive consent instead of obtaining informed consent for the research are required to request a waiver of parental consent and must meet the requirements set forth above.

VIII. Minor Assent

Research personnel must make adequate provisions for soliciting the assent of each child involved in research when the child is capable of providing assent. A minor's mere failure to object should not, absent affirmative agreement, be construed as assent. This process is separate from parent/guardian informed consent. Children should be given developmentally appropriate information about the research in a language and manner that is understandable, given the child's age, maturity, and cognitive abilities.

Assent expires when a minor becomes an adult. A minor research participant who reaches the age of majority during their participation must be reconsented through the informed consent process approved by the IRB.

Age of Child	Assent Requirements
≥ 5 years of age	Oral assent is appropriate – no script is required to be submitted to the IRB
6-11 years of age	Oral assent is appropriate – an assent script is required to be submitted to the IRB
12-17 years of age	Written Assent is required – assent form is required to be submitted to the IRB

Assent should include:

- Why the research is being conducted;
- What will happen and for how long or how often;
- That it is the child's decision to participate and that it's okay to say no;
- An explanation on whether the intervention will hurt and if so for how long and how often;
- What the child's other choices are;
- A description of any good things that might happen;
- Whether there is any compensation for participating; and
- Ask for questions

Waiver of Assent

The IRB may waive the requirement to obtain assent in the following circumstances:

- The capability of some or all of the minors is so limited that they cannot reasonably be consulted.
- 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 minor and is available only in the context of the research.
- The researcher satisfies the requirements for a waiver of consent.

X. Responsibilities
Principal Investigators, IRB Members

XI. References
45 CFR 46 Subpart D
45 CFR §§ 46.116
21 CFR 50
NCGS § 48A-2
NCGS § 7B-3509
IRB SOP 210.1 – Deception in Research
University Policy 56 – Ethics in Research
University Policy 131 – Research Involving Human Subjects