Title: Inclusion of Minors in Post-Secondary Educational Research
Latest Approval Date: 7/30/2025
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Standard Operating Practice: 8

8.1. Executive Summary

This document addresses the policy and standard operating procedures for research occurring in post-secondary education institutions with the intent to include students as research participants and incidentally including minors in the study.

8.2. Standard Operating Practice

When performing minimal-risk research at post-secondary institutions, researchers targeting students as participants may include minors in the project if minors are incidentally involved and not actively targeted as participants due to their status as a minor. In these cases, the IRB has determined that parental permission is not a reasonable requirement to protect students and, in this circumstance, a standard adult consent form should be used and parental permission may be waived.

8.3. Operational Procedures

Chapter 48A-2 (PDF file) of North Carolina state law defines a *minor* as "any person who has not reached the age of 18 years" and the federal regulations governing research with human subjects (45 CFR 46 – opens in a new window) require additional protection for minors participating in research, including provisions for parental permission and restrictions on exemption determinations.

8.3.a. Exemption Determination

1. Federal law 45 CFR 46.104 (opens in a new window) prohibits the application of exemption category 46.101(d)(2) to research involving surveys, interviews, focus groups, or observation of public behavior that involves interaction between researchers and minors.

2. Federal law 45 CFR 46.104 (opens in a new window) prohibits the application of exemption category 46.101(d)(3) to research involving benign behavioral interventions with minors.

3. These prohibitions also apply to research that involves minors attending post-secondary educational institutions. If researchers working with first-year post-secondary students wish to apply for exemption, they must take measures through recruitment, screening, selection, and the consent process to exclude minors from their research or qualify for the NC State University FLEX special exemption category (Word document).

8.3.b. Requirements for Waivers of Parental Permission

8.3.b.i. Federal law 45 CFR 46.408(c) (opens in a new window) allows for waiver of parental permission if it finds that:

1. the research "is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects" and

2. that the researchers provide “an appropriate mechanism for protecting the children who will participate as subjects in the research” and
3. that the waiver of parental permission “is not inconsistent with federal, state, or local law.”

8.3.b.ii. Federal law 45 CFR 46.408 (c) states that an appropriate mechanism for gaining consent would depend upon:

1. “The nature and purpose of the activities described in the protocol”;

2. “The risk and anticipated benefit to the research subjects”; and

3. The participants’ “age, maturity, status, and condition.”

8.3.b.iii. Minors attending post-secondary institutions and the ability to consent

1. Minors in attendance at post-secondary institutions of higher education are usually advanced for their age, attending courses intended for adults, and are likely living away from parents or guardians.

2. Parent/guardian permission is not a necessary or reasonable requirement to protect minors as participants in research.

3. In research targeting students at post-secondary institutions where the nature and purpose of the activities described in the protocol are minimal risk and minors are incidentally involved in the research, parent/guardian permission may be waived, and gaining student assent using a standard adult consent form is sufficient.

8.4. Programs that Involve the Participation of Minors

NC State University has a regulation (REG 01.25.18 – opens in a new window) that will apply to human subjects research reviewed by the IRB if the research activities are occurring in “Programs and Activities in which the University is knowingly supervising the minor participants, providing online programs for minors through a registration process or knowingly allowing a third-party to use University Property for the purpose of operating a Program or Activity primarily serving or including minors.”

Program and activities that are subject to the regulation include those “in-person programs and activities [where] an NC State individual is responsible for the care of the minors” and “online programs and activities [where] an NC State Individuals collects [minors] personally identifiable information such as name, address, phone number, email through a registration process in which minor participants are registered in advance.” It also includes “any […] minor working or volunteering with [an NC State individual in] lab research, office, or field work, it falls within the scope [of the regulation]”. Programs and activities run by outside entities (e.g., 4-H camps, research and extension sites, etc.) on University property or with University resources may be subject to the University regulation if “using an NC State device or computer to contact minors” and “if and who is collecting [minors] personally identifiable information”.

If research falls within the scope of NC State University REG 01.25.18 (opens in a new window), researchers must register with the Office of Youth Programs and Compliance and meet the requirements of the regulation such as having a background check within the last 3 years and completing the required training as well as obtaining a liability waiver and collecting emergency contact information for parents/guardians.

Please contact protectionofminors@ncsu.edu if you have questions for how to comply with the regulation if it applies to your proposed study.