

Title:	Post-Secondary Ed Research – Inclusion of Minors
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Policy and SOP:	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, incidentally including minors.

8.2. Policy

When performing minimal risk research at post-secondary institutions, researchers targeting students as participants may include minors in the project as long as 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. Standard Operating Procedure (SOP)

Chapter [48A-2](#) 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](#)) require additional protection for minors participating in research, including provisions for parental permission and restrictions on exemption determinations.

1. Exemption determination
 - a. [45 CFR 46.104](#) 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.
 - b. [45 CFR 46.104](#) prohibits the application of exemption category 46.101(d)(3) to research involving benign behavioral interventions with minors.
 - c. These prohibitions also apply to research that involve minors attending post-secondary educational institutions. If researchers, who are working with first year post-secondary students, wish to apply for exemption – they must take measures to exclude minors from their research.
2. [45 CFR 46.408](#) details the requirements for parental permission for when minors are included in research and it outlines conditions under which parental permission may be waived.
 - a. 45 CFR 46.408(c) allows for waiver of parental permission if it finds that:
 - i. 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
 - ii. that the researchers provide “an appropriate mechanism for protecting the children who will participate as subjects in the research” and
 - iii. that the waiver of parental permission “is not inconsistent with federal, state, or local law.”
 - b. 45 CFR 46.408 (c) states that an appropriate mechanism for gaining consent would depend upon
 - i. “The nature and purpose of the activities described in the protocol”
 - ii. “The risk and anticipated benefit to the research subjects” and
 - iii. Their “age, maturity, status, and condition”

- c. Minors who are attending post-secondary educational institutions are usually advanced for their age, attending courses intended for adults, and are likely living away from parents or guardians. In this case, the IRB may determine that
 - i. Parental permission is not a necessary or reasonable requirement to protect minors as participants in research.
 - ii. 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, parental permission may be waived and gaining student assent using a standard adult consent form is sufficient.