IRB GUIDANCE: Research Involving Minors

This guidance addresses the special requirements when including humans subjects under the age of 18 as research subjects.

Minors are considered a protected class or vulnerable population in research and are afforded additional protections in the Common Rule under 45 CFR 46 Subpart D – “Additional Protections for Children Involved as Subjects in Research.”

The following considerations should be addressed if a research project will be involving minors:

**Minimal Risk**

Research must present minimal risk to participants.

**Exemptions**

The IRB is often asked why all education-based research is not considered Exempt – citing the exemption for 45 CFR 46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices. What many researchers are not aware of is that, as noted above, research involving minors is also reviewed under Subpart D of the regulations, “Additional Protections for Children Involved as Subjects in Research.” Per 46.401(b): The exemption for research involving survey or interview procedures, or observations of public behavior does not apply to any research covered by Subpart D. Because most proposals that are submitted with minors as participants also include survey and/or interview procedures – so in those situations the exemption does not apply.

In addition, research that is exempt under 45 CFR 46 is still subject to other federal regulations, such as FERPA. Educational records pertaining to minors are never “exempt” from FERPA and consent or a data use agreement is always required.

**Reporting Requirements**

Reported, suspected, or observed abuse or neglect of a minor must be reported. Per Colorado Revised Statutes, Title 19, Children’s Code, it is by law that if an individual (mandatory reporter) has reasonable cause to know or suspect that a child has been subjected to abuse or neglect, or observed the child being subjected to circumstances or conditions that would reasonably result in abuse or neglect, the mandatory reporter shall immediately upon receiving such information report or cause a report to be make of such fact to the county department, the local law enforcement agency, or through the child abuse reporting hotline system (this would include students when working in the role of a researcher).
“Abuse” includes physical, emotional, or sexual abuse; treatment without consent; confinement or restraint; “Neglect” means failure to provide adequate food, shelter, clothing or medical care.

Consent/Assent

Minors, under the age of majority, may not legally consent to participate in research. For participants under the age of 18 years of age, parental consent must be obtained. Waivers of parental consent may only be applied 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 (for example, neglected or abused children).

In addition, as all human subjects research must be voluntary, child assent must be obtained in addition to parental consent. Assent can only be obtained after parental consent is obtained. Both parental consent and minor assent are required; a minor may decide not to participate even if their parent(s) have provided consent.

Participants between the ages of 11–17 must sign an assent form (unless an appropriate justification is provided for a waiver of the signature through a request of a Waiver of Documentation of Informed Consent). The assent form contains the same information as the parental consent form, written at an age-appropriate level. For participants under age 11, an oral assent process is often most appropriate.

As noted above, if the IRB feels that participants may disclose information that requires reporting, consent forms may have to include text that informs participants that confidentiality may be broken in those situations. An example of that wording might be: “While it is the intention of the Principal Investigator and/or research staff to keep all of the information you provide confidential, if we become aware of abuse or neglect of a minor, that confidentiality may be broken”.

For additional guidance and information, contact University of Denver Office of Research Compliance at (303)871-4050 or at: IRBAdmin@du.edu