

SUBJECT: Children in Research		Policy Number: 10.3.6
	Effective Date: October 9, 2015	Renewal Date: October 9, 2017
	Supersedes: 10.3.6 (10/6/11 version) 10.3.7, K-12 Students in Research (10/6/11 version)	Page 1 of 7
	Responsible Authorities: Vice President, Research Institutional Review Board Director, Research Integrity	

I. Background

Research involving minors is governed by Department of Health and Human Services (DHHS) regulations ([45 CFR 46 Subpart D](#)) and Food and Drug Administration (FDA) regulations ([21 CFR 50 Subpart D](#)), where applicable.

In addition, the Department of Education's Family Educational Rights and Privacy Act (FERPA) and 34 CFR Part 97, Subparts A & D provide oversight for research that occurs in educational settings. Title 34 provides the overall regulatory principles for human subjects research activities supported by the Department of Education. FERPA is a federal law that protects the privacy of personally identifiable information contained within a student's educational record. FERPA applies to all schools that receive funds under various programs from the U.S. Department of Education.

The IRB follows the federal regulations when reviewing studies involving minors. State and local laws may also apply when they provide additional protections beyond those provided by federal regulations.

II. Purpose

The purpose of this policy is to provide guidance to the FAU Institutional Review Boards (IRBs) and FAU researchers when reviewing or conducting human research

activities that involve children (from infancy to teenage years, up to the age of 17) as research participants.

III. General Statement

Minors are considered a vulnerable research population because their intellectual and emotional capacities are still under development and thus are limited. Minors are not legally able to give valid consent to participate in research. Special procedures and considerations are, therefore, required by the federal regulations for the review of research involving minors.

For purposes of this policy, “children” and “minors” can be considered synonymous.

IV. Policy
Consent

- Consent must be obtained from a parent or legal guardian if the research involves children under the age of 18 unless the individuals are legally emancipated or the IRB waives the requirement. Consent forms must take into account that parents and children often come from diverse educational backgrounds; therefore they should be written succinctly in simple, understandable language and translated into other languages as appropriate.
- As part of its review, the IRB will determine whether the consent can be signed by one parent if the research is not greater than minimal risk or greater than minimal risk but presents the prospect of direct benefit to individual subjects. For all other risk categories of research, the IRB will require the permission (and signature) of both parents unless one parent is not reasonably available, deceased, unknown, legally incompetent, or when only one parent has legal responsibility for the care and custody of the child.
- The IRB may waive the requirement for parent/guardian permission *only in non-FDA regulated studies* if the following conditions are met: a) The research involves no more than minimal risk to the subjects; b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; c) The research could not practicably be carried out without the waiver or alteration; and d) Whenever appropriate, the subjects will be provided with additional pertinent information (e.g., a general notice or letter) after participation. [45 CFR 46.117(d)].
- The IRB may also waive the requirement for parental permission if it determines that a research protocol is designed for conditions or for a child population for which parental or guardian permission is not a reasonable requirement to protect the child (*for example, neglected or abused children*), provided there is an appropriate mechanism substituted for protecting the children who participate in the research, and that the waiver is consistent with federal, state, or local law. The choice of an appropriate mechanism will depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the children, and their age, maturity, status, and condition [45 CFR 46.408(c)].
- The IRB will only approve “passive consent” if the federal criteria for waiving informed consent have been met. [Refer to Policy 10.3.11- Waiver of Informed Consent

http://www.fau.edu/research/docs/policies/research-integrity/10.3.11_waiver_informed_consent_final.pdf

“Passive Consent” has been used in school based research in response to the challenges of securing prior written permission from parents. The process involves notifying parents that research will take place and giving them the opportunity to state they do not want their children to participate. However, passive consent is not equivalent to “informed consent.” Sending notice does not mean the notice has been received or understood.

Therefore, passive consent is strongly disfavored unless justified.

- Under Florida law, a temporary custodian/guardian may not consent to a child’s participation in research. Permission must be sought from the parent or legal guardian of the child except where a court order authorizes participation of the child in a specific, named research project [Florida Statute §751.01], or that guardian has been named a permanent guardian of the child as defined in Florida Statute 39.01(55).
- The IRB may consider some individuals under the age of 18 to be “emancipated,” “in accordance with state law.” In these cases, parental permission may be waived upon request. For example, married minors do not need parental permission for participation in research [Florida Statute §743.01].
- Pregnant minors do not need parental permission to participate in research related to the pregnancy or the fetus [Florida Statute §743.065]. Similarly, minors who are mothers do not need parental permission to participate in research related to their child.

Assent

- In general, minor participants who are 7 years of age or older should be involved in the decision to participate in a research project unless the requirement for assent is waived by the IRB. (See Waiver of Informed Consent policy 10.3.11 for criteria.)
- Documentation of assent is required for participants between the ages of 7--17 unless justified by the researchers and the requirement is waived by the IRB. The document should be a *simplified* version of the elements of informed consent at a level appropriate to the child’s age, maturity and condition. Children should also be informed that their parent’s consent is also being sought, and the parent can have their research information provided to them or withdrawn from the research records (if identifiable).

School-Based Research

In some research situations, involvement of minor students is integral to a research protocol, particularly research on teaching methods, curricula and other areas related to the scholarship of teaching and learning. Given the unique dynamic of the student-teacher relationship, care should be taken to eliminate or reduce the risk that students may be unduly influenced or coerced to participate in research, and to minimize students’ perception that not participating in research will negatively affect their relationship with the researcher or teacher. As such the following principles apply:

1. Recruitment of minor students must be done in a non-coercive manner, such as a general announcement, central posting or a letter to parents.
2. Consent and assent procedures should clearly distinguish between which activities are specifically for the research, and which are part of normal class instruction.

3. Special care must be taken to minimize the perception of coercion when the researcher has the dual role of also being the teacher of the class in which research is conducted (see procedures below).
4. Generally researchers may not access classroom performance evaluations, grades, or information in a student's records without prior written permission from a parent/guardian or the student's authorized legal representative, and adherence to the institution's FERPA policies.
5. When extra credit is to be given to students who participate in research, students who choose not to participate in the research must be given other options for extra credit that are comparable in terms of time, effort and educational benefit as the research. If extra credit is offered, it is favorable to still give credit if the child minor withdraws, unless the student withdraws immediately or there is evidence of bad faith on the part of the student.
6. Whenever possible, researchers should refrain from data collection during regular class meetings. If study participation consumes a significant portion of a class, loss of instructional time for both participants and non-participants may be considered a risk or a loss of benefits. Also, when research participation is expected during the same class session at which recruitment occurs, students may be unduly influenced to take part due to peer pressure, perceived stigma from not participating, or a sense of having otherwise wasted time by attending that day's class.
7. Since there are risks of breach of confidentiality in the close environment of the school setting, special attention should be given to disclosure of these risks in the consent process, and developing procedures for collecting, handling, and protecting research data in a manner that minimizes the risk of breach of confidentiality. Additionally, if the research project involves collection of data from a group, or the group is audio- or videotaped, each student's assent is necessary for the use of that data in the research. If one student does not assent, data may be used only if the non-assenting student's data can be effectively excluded.
8. If the researcher has the dual role of also being the teacher/instructor of the class in which research is conducted, the researcher/teacher should arrange to have the data collected in a manner that is objective and non-coercive to the subjects involved (e.g., data collected by an independent third party, providing students with the name of a neutral third party to contact should they feel coerced, etc.).

Wards of the State

- For research involving minors who are wards of the state (e.g., foster children) or any other agency, institution, or entity, the IRB may permit them to be included in research that is greater than minimal risk (45 CFR §46.406 or §46.407) *only if* the research is: (1) Related to their status as wards; or (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

In these cases, the IRB must require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis* (in place of the parents). One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and

experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization (45 CFR §46.409).

Clinical Trials

- Under Florida law, a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in experimental research (§381.026, Florida Statutes). In the case of a child minor, the parent or natural guardian can consent to the minor's participation in experimental research. In the absence of a natural parent/guardian, permission must be sought from other means, such as the courts or a relevant legal guardian.
- If the research involves procedures that are greater than minimal risk research with no direct benefit to the participant, the IRB will require the permission of both parents unless one parent is not reasonably available, deceased, unknown, legally incompetent, or when only one parent has legal responsibility for the care and custody of the child.

V. Definitions

Assent: A child's affirmative agreement (e.g., saying 'yes' or non-verbally expressing agreement / yes) to participate in research.

Child:

DHHS regulations define children as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402 (a)].

FDA regulations define children as persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted [21 CFR 50.3(o)].

The State of Florida Statute §39.01(12) defines "child" or "youth" as any unmarried person under the age of 18 years who has not been emancipated by order of the court. In research conducted in other States or territories, the legal definition of children will be determined by reference to the law of that state or territory.

Emancipated Minor:

A child is considered "emancipated" and therefore able to give consent on behalf of him/herself in the State of Florida if the child is or has been married (Section 743.01, Fla. Stat.) or was emancipated under a court action (Section 743.015, Fla. Stat.).

Guardian:

DHHS regulations define guardian as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. [45 CFR 46.402(e)]. FDA regulations define guardian as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care, when general medical care includes participation in research [21 CFR 50.3(s)].

Florida law defines guardian as follows:

Guardian: a person who has been appointed by the court to act on behalf of a ward's person or property or both.

Permanent guardian: The relative or other adult in a permanent guardianship of a dependent child under FS§39.6221 [Florida Statute §39.01(54)]. "Permanent guardianship of a dependent child" means a legal relationship that a court creates between a child and a relative or other adult approved by the court which is intended to be permanent and selfsustaining through the transfer of parental rights with respect to the child relating to protection, education, care and control of the person, custody of the person, and decision making on behalf of the child. *This is distinct from temporary legal custody defined below.*

Temporary legal custody: The relationship that a court creates between a child and an adult relative of the child, legal custodian, agency, or other person approved by the court until a more permanent arrangement is ordered. Temporary legal custody gives the custodian of the child the right to have temporary physical custody of the child and the right and duty to protect, nurture, guide, and discipline the child and to provide the child with food, shelter, and education, and ordinary medical, dental, psychiatric, and psychological care, unless these rights and duties are otherwise enlarged or limited by the court order establishing the temporary legal custody relationship. Florida law allows a state agency or institution to serve as guardian of a child and in this circumstance the child will be considered a "ward of the state."

In research conducted in other states or territories, the legal definition of guardian will be determined by reference to the law of that state or territory.

Legal Age of Consent: The State of Florida recognizes the legal age of consent as 18 years of age [Florida Statute §743.07]. In other States or territories, the legal age of consent will be determined by reference to the law of that state or territory.

Minor: Under Florida law, any person who has not attained the age of 18 years.

Parent: a child's biological or adoptive parent [45 CFR 46.402 (d); 21 CFR 50.3 (p)]. Biological or adoptive parents are the child's natural guardians, which means they can exercise all the legal rights and powers for the minor.

PI: Principal Investigator

Ward: a child, who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law [21 CFR 50.3 (q)]. In the State of Florida, a ward is defined as person for whom a guardian has been appointed [Florida Statute 744.102(22)].

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Identifying and documenting procedures to determine how and when parental permission and child assent will be obtained, or requesting a waiver of parental permission, or child assent, with appropriate justification;
- Ensuring that appropriate steps are taken to identify and document when a potential research participant is either a) a ward of the state or b) has a temporary guardian; consulting with the appropriate agency or entity to determine if legally authorized informed consent can be obtained;

- In the case of greater than minimal risk research, developing procedures to identify whether one, or both parents, can consent to their child's participation in research.

The Institutional Review Board (IRB) will be responsible for:

- Upholding this policy when reviewing protocols involving children as research participants.
- Determining the appropriate risk category for research protocols involving children in accordance with applicable federal regulations.

The Research Integrity (RI) office will be responsible for:

- Assuring there is representation of those with appropriate specialties involving children when reviewing human research activities involving children.
- Assigning protocols involving children to those Board members with appropriate expertise when administering IRB application submissions involving children.

VII. Procedures

- When preparing an IRB submission that involves minors as research participants, describe in the research protocol what special considerations will be utilized to recruit this population, balance risks and benefits, and ensure proper consent/assent procedures and documentation have been met. *If applicable*, the PI should also take into account the added risks and administrative procedures that accompany research with wards, children with developmental disabilities, and juveniles in the criminal justice system.
- Prepare and submit the appropriate parental consent and assent forms, ensuring that both are written in language that is simple and non-technical. For parents, the consent should be written at an eighth grade level. For children, the assent should be written at an age appropriate level.
- **If requesting a waiver of child assent, waiver of documented child assent, or waiver of parental permission, a request for waiver should be included in the IRB submission** that meets the guidelines of the federal regulations (see Waiver of Informed Consent policy) and describes the alternate communication mechanisms that will be used (e.g., assent script, debriefing document, or other measures).
- If the research will involve minors in their educational setting, coordinate as appropriate with the school principal and/or School District Offices about their specific processes for approving research protocols involving their students. *Note:* some local school districts require FAU's IRB approval before issuing approval to enter their schools. In these circumstances, the FAU IRB can grant approval without the school district approval letter, but the PI must provide a written assurance to the IRB that a school district approval letter will be submitted once it is obtained.
- Consult Research Integrity or the Division of Research's General Counsel if assistance is required in implementing these policies and procedures.

VIII. Policy Renewal Date October 9, 2017

IX. References
45 CFR 46 Subparts A and D

POLICY APPROVAL

Initiating Authority

Signature:

Date:

Name: Daniel C. Flynn, Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)