

CHILDREN/ADOLESCENTS IN RESEARCH

- **Restriction on using minors in research.** If you conduct research using minors as subjects, there are special regulatory and ethical issues. The study cannot be approved unless the following criteria are met:
 - Research using children needs to have a firm theoretical background; where applicable, studies on animals and/or in adults must have already been completed. The study cannot use children just because they are a convenient population.
 - The research must minimize the risk to minors.
 - The research staff needs to have experience working with minors, and the study must be designed to be sensitive to the special needs of this population.
- **Investigation that is not considered research and not subject to IRB oversight.**
 - Internal data collection for the purpose of determining the quality of an internal process, which is not used outside of the school/agency, is not research. Examples would include assessment of the progress of children in therapy, and educational achievement of children. If the data are to be presented to others outside the agency (other than to demonstrate accountability to a funding or oversight agency), then it is considered research (e.g. reporting results as an outcomes measurement study) and IRB oversight is required.
 - Class projects that involve data collection as an academic exercise, and do not result in dissemination of the results outside of the class, are not considered research. The instructor has discretion on how the class project is conducted, and is responsible for the legal and ethical behavior of the students completing the class project. However, interviews or surveys of children, or observations that involve the investigator interacting with children require IRB review, even if conducted only as a class project.
- **Risk classifications.**
 - **Minimal risk.** Studies are considered as having minimal risk if they meet the following federal definition: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
 - **Greater than minimal risk.** If the study involves more than minimal risk, then the risk to benefit ratio of the study will be assessed. The researchers will be required to describe how the study risks have been minimized, and the study benefits maximized. Risk classification influences the level of review that NSU’s IRB conducts.
- **Types of research that can be approved by the IRB.** Federal rules only permit approval of the following types of research involving children.
 - **Research not involving greater than minimal risk.**
 - **Research involving greater than minimal risk but presenting the prospect of direct benefit to the subjects.**
 - **Research involving greater than minimal risk, with no prospect of direct benefit to the subjects, but likely to yield generalizable knowledge about the disorder/condition.**
 - **Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. If federally funded, this study requires review by Health and Human Services. If not federally funded, the review must be at a higher level than convened full IRB.**
- **Informed consent and assent.** Informed consent is generally a two-part process. The parents must provide informed consent, and then the child must assent to participate. Assent and consent must be obtained before a child can participate in research.
 - Informed consent from both parents or both guardians is generally required. If the IRB determines that a study has only minimal risk, or has more than minimal risk but has the prospect for direct benefit to that child, then consent of only one parent or guardian is acceptable. If the research involves more than minimal risk, and while benefiting the scientific community, the research project will not directly benefit the child, then both

parents/guardians must consent. The other exceptions to the requirement for both parents/guardians to consent are as follow:

- one parent/guardian is deceased
 - parent/guardian is unknown
 - parent/guardian is incompetent
 - parent/guardian is not reasonably available
 - one parent/guardian has legal responsibility of minor/child
- There are a few circumstances where the IRB may grant a waiver of parental consent for the participation of a child, when applicable law (state and local) has demonstrated that such a waiver would be acceptable.
- If the child is a victim of abuse or neglect and the study protects the child. If a guardian had been named, then the guardian's consent is required.
 - Research on mature adolescents that involves minimal risk. The decision on who is a mature minor is made on a case-by-case basis. The IRB would in no circumstances consider a child younger than 16 to be a mature minor. The State of Florida does not permit research on children below the age of 18 without parental consent.
 - In emergency situations, where life or health is threatened, when there is no acceptable treatment for a disease/disorder, and the study holds the prospect for benefit to the subject, and parents are not available to provide consent in a timely manner, then parental consent may be waived.
- Children 6 and over must assent to participate in the study before the child can participate. In most cases, children age 7 or older are asked to provide written documentation of their willingness to be part of the study.
- **Under 7.** Assent from children under 7 should be obtained orally. A witness needs to document that the child has provided assent.
 - **Ages 7 to 13.** In addition to verbal assent, the child's signature on the written assent form must be obtained before the child can participate. The language of the assent form must be tailored to the developmental level of the child. (The child cannot give informed assent if the child cannot understand the language used.) The child assent form must be witnessed.
 - **Above age 13** – Adolescents also must assent. The assent form must be age appropriate, and the form should contain all the essential elements of an adult consent form. The adolescent assent form should be witnessed.
 - There are circumstances in which research can be conducted even if the child does not provide assent. (e.g., the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that 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 children and is available only in the context of the research).

- **Levels of Review.** NSU has three levels of review of research: center-level, expedited, and full review. NSU's center-level review is what is termed by some other IRBs as exempt from review. NSU does not use this term, as all research must be reviewed by an IRB member to determine its status; the researcher is not authorized to make the determination that the research is exempt from IRB review.
 - **Full review.** Research involving children is presumed to require full review by the IRB, because children are a vulnerable population. In certain circumstances, the IRB representative / chair may determine that a lesser level of review is permitted.
 - **Expedited review.** In some circumstances, if there is no more than minimal risk, expedited review can be conducted on studies involving minors. In the following circumstances, the center-level representative and the IRB chair (or another IRB member that the chair designates) may review the study. The categories for expedited review are the same as in adult studies, but the blood collection limits differ. Research involving collection of PHI that is approved by both the parents and child with appropriate consent/assent forms can use expedited review. The categories for expedited review are:
 - Surveys/interviewing of children, or observation of public behavior involving children when the researcher participates in the activity being observed.
 - Surveys that request information that potentially expose the informant to criminal or civil liability or are extremely personal in nature in which the likelihood of associating the individual with the responses is very small.
 - Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, not to exceed 50 ml or 3 ml per kg (whichever is less) in an 8 week period, and collection may not occur more frequently than 2 times per week.
 - Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
 - Collection of excreta and external secretions including sweat or uncannulated saliva.
 - Collection of both supra-and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
 - Recording of data from subjects using noninvasive procedures routinely employed in clinical practice, excluding X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples include-the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, diagnostic infrared imaging, doppler blood flow, and electroretinography. Subjects can participate in moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
 - Voice, video, digital or image recordings made for research purposes, such as investigations of speech defects. For example: An audio tape on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for Expedited Review. A tape of a therapy session with a patient would not qualify for Expedited Review. Although the research involved an audio tape, the sensitive nature of the contents would require a Full Review.
 - Research on individual or group behavior characteristics of individuals, (such as studies of perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies when the research does not qualify for center-level review.

- Research on drugs or devices for which an investigational device exemption is not required.
- **Center-level review.** In certain circumstances, the center representative can approve a study, without further review, if the study poses only minimal risk to the child. The categories for center level review are:
 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 - Research involving watching public behavior of children, where the investigator does not take part in the activities, can be reviewed at the center level. (Note: surveys or interviews cannot be center-level reviewed.)
 - Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
 - Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Reminder to researchers on reporting child abuse and neglect. The IRB assumes that if a researcher has reason to believe that a minor is abused or neglected, the researcher is required to report this suspicion to Child Protective Services. Accordingly, this constitutes a risk to the parents, who may be perpetrators of abuse. This must be disclosed on the informed consent.