**Human Research Ethics Board (HREB) Policy for Research Involving Children at SUNY New Paltz**

**1. Purpose**

Children are a “vulnerable population,” because they are considered easily susceptible to coercion and undue influence and incapable of completely understanding the risks and benefits in making the decision to participate in research. The respect for persons elaborated in the Belmont Report requires that the decision to participate in research be wholly informed and voluntary. The purpose of this policy is to provide guidelines for researchers conducting studies involving children at the State University of New York at New Paltz (SUNY New Paltz). This policy ensures that research involving children is ethically sound, legally compliant, and prioritizes the protection and well-being of child participants in accordance with federal, state, and institutional regulations. Federally mandated considerations are in place for reviewing research involving children under the Common Rule (45 CFR 46), and federal regulations (45 CFR 46, Subpart D). These provide protections for children involved in research such as obtaining assent from the child and obtaining the permission of the parents/legal guardians for the child to be enrolled in the research protocol.

**2. Scope**

This policy applies to all research involving children (defined as individuals under the age of 18) conducted or overseen by SUNY New Paltz researchers, including faculty, staff, and students, both on-campus and off-campus. This includes both federally funded and non-federally funded research projects, as well as research conducted through collaboration with other institutions.

**3. Definitions**

* **Child**: Under HHS and federal regulations “children” are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of jurisdiction in which the research will be conducted. This includes not only viable neonates, but also college and university students under the age of 18, unless a waiver is approved by the HREB.
	+ According to New York State law, a minor is any person who is not an adult. Relatedly, an adult is any person who is eighteen years of age or older or has married.
		- Any person who is eighteen years of age or older or is the parent of a child or has married, may give effective consent for research, medical, dental, health and hospital services for himself or herself, and the consent of no other person shall be necessary.
		- Any person who has been married or who has borne a child may consent for research, medical, dental, health and hospital services for his or her child.
		- New York State does not automatically recognize the concept of an “emancipated minor” for the purposes of research, unless an individual between 16 and 18 years of age was emancipated by a probate court.
		- All individuals under 18 years of age can participate in research without parental consent when it is specifically limited to:
			* HIV testing, counseling, and treatment
			* Outpatient mental health services
			* Testing or treatment for sexually transmitted diseases
			* Treatment or rehabilitation for alcohol or drug dependence
			* Abortion counseling and treatment
		- All individuals between 16 and 18 years of age if the research procedures are limited to inpatient mental health services.
	+ NOTE: For research conducted in jurisdictions other than New York, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions.
* **Parental Permission**: The process by which a parent or legal guardian provides informed permission for their child’s participation in research.
* **Child Assent**: The agreement of a child who is capable of understanding the research, obtained in addition to parental permission, in a manner that is developmentally appropriate.
* **Minimal Risk**: The risk of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during routine physical or psychological examinations.
* **Greater Than Minimal Risk**: Research involving risk levels that exceed those encountered in daily life.

**4. Legal and Regulatory Framework**

Research involving children at SUNY New Paltz must comply with the following regulations:

* **45 CFR 46, Subpart D** – Additional Protections for Children Involved in Research
* **21 CFR 50, Subpart D** – Protection of Children in Clinical Investigations
* **New York State Public Health Law, Article 24-A** – Human Research Protection Act
* **The Common Rule (45 CFR 46)** – Protection of Human Subjects
* **SUNY New Paltz HREB Policies and Procedures**

**5. Categories of Research Involving Children**

The HREB classifies research involving children into different categories based on the level of risk involved and the potential benefits of the study. Three Categories of Permissible Research Involving Children: Federal regulations require the HREB to classify research involving children into one of three categories and to document discussions of risks and benefits. The HREB Minutes should document how the research protocol meets its assigned category. These are the three categories of permissible research, based on the degree of risk and benefit to the child:

**Category 1**: Research not involving greater than minimal risk (§46.404). Children can be approved for these studies when the HREB finds that adequate provisions have been made for soliciting the assent of the children and the permission of their parents or legal guardians to participate in the research study. The HREB may exercise the option to approve a waiver of parental permission, as long as the child’s assent is obtained. Permission from one parent/guardian is sufficient for Category 1 research unless this is contradictory to the regulations of the U.S. or foreign jurisdiction in which the research is being conducted.

For research that falls into Exempt categories, children without parental permission or a child's assent can only be involved in:

**1. Educational Research**

* Research that involves observation of children in educational settings, as long as the research does not involve interventions or manipulations that would place the child at risk.
* Research focusing on educational practices, teaching strategies, or classroom environments that pose minimal risk to children.

**2. Use of Existing Data or Specimens**

* Research that involves the use of existing data, documents, records, or biological specimens from children that were collected for purposes other than the current research, as long as the research does not contain any personally identifying information and there is no personal interaction with the children.

**3. Observation in Public Settings**

* Observation of children in public or non-private settings, where the children do not have an expectation of privacy (for example, playgrounds, public parks, or streets), may be exempt as long as the research poses no significant risks to the participants.

Children cannot participate in Exempt Survey/Interview studies or Exempt Benign Behavioral Research studies.

Even if the research is Exempt, parental permission and child assent may still be required, depending on the jurisdiction and type of research.

**Category 2**: Research involving greater than minimal risk but presenting the prospect of

direct benefit to the individual participants (§46.405). Children can be approved for these studies only when the HREB finds that: (1) the risk is justified by the anticipated benefit to the participants; (2) the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and (3) adequate provisions are made for soliciting the assent of the children and permission of their parents or legal guardians to participate in the research study. Permission from one parent/guardian is sufficient for Category 2, unless this is contradictory to the regulations of the U.S. or foreign jurisdiction in which the research is being conducted.

**Category 3**: Research involving greater than minimal risk and no prospect of direct benefit

to individual participants, but likely to yield generalizable knowledge about the participants’ disorder or condition (§46.406) Children can be approved for these studies only when the HREB finds that: (1) the risk represents a minor increase over minimal risk; (2) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (3) the intervention or procedure is likely to yield generalizable knowledge about the participants’ disorder or condition which is of vital importance for the understanding or amelioration of the participants’ disorder or condition; and (4) adequate provisions are made for soliciting assent of the children and permission of their parents or legal guardians to participate in the research study.

For Category 3, both parents must give parental permission. When there is disagreement

between both parents, the child may not be enrolled in the research study. However,

only one signature of a parent is required when the second parent is deceased, unknown,

incompetent, or not reasonably available (e.g., no contact with child, serving in war, in

solitary confinement or otherwise hard to reach in prison), or if one parent has the legal

responsibility for the care and custody of the child, if this comports with the

regulations of the U.S. or foreign jurisdiction in which the research is being conducted.

The rationale for the allowance of only one parental signature should be documented in the research records.

**6. Parental Permission and Child Assent**

* **Parental Permission**: For research involving children, written parental permission must be obtained. The HREB will review the parental permission form for clarity and ensure it includes sufficient information about the study, including its purpose, procedures, risks, benefits, and the voluntary nature of participation.
	+ **Waiver of Parental Permission**: In some cases, the HREB may waive or alter the parental permission requirement if certain criteria are met, such as in emergency situations or when obtaining permission is not feasible.
* **Child Assent**: In addition to parental permission, either verbal or written assent must be obtained from children who are capable of understanding the research. The HREB will review the assent form to ensure it is appropriate for the child's age, developmental stage, and understanding.
	+ **Age-Appropriate Assent**: The HREB will determine if the child is capable of providing assent based on the child's age and cognitive development. Children who are 7 years of age or older are typically expected to provide assent. Children under 7 years old may be able to give assent provided the materials are presented in a way that they can understand.
	+ If a child is capable of giving assent and does not give assent for research, then they should not be included as a participant in the study.

**7. Risk Assessment and Minimization**

The HREB is responsible for assessing the risks involved in research involving children and ensuring that the risks are minimized to the greatest extent possible. The HREB will carefully evaluate the nature, magnitude, and likelihood of any risks involved in the research.

* **Minimal Risk**: Research will be approved if it poses minimal risk to the child participants. Minimal risk is defined as the likelihood and magnitude of harm or discomfort not exceeding what is typically encountered in daily life.
* **Greater Than Minimal Risk**: If the research involves greater-than-minimal risk, the HREB will ensure that the study has the potential for direct benefits to the children involved or that the risks are justified by the scientific or social value of the research.

**8. Special Protections for Vulnerable Children**

Research involving vulnerable children (e.g., children with disabilities, children in foster care, or children from economically disadvantaged backgrounds) will receive additional scrutiny by the HREB. This includes ensuring that appropriate protections are in place to prevent coercion, undue influence, or exploitation.

* **Enhanced Safeguards**: The HREB may require additional safeguards for studies involving vulnerable populations of children to ensure their protection.
* **Monitoring and Reporting**: Researchers may be required to submit periodic reports to the HREB regarding the progress of studies involving vulnerable children and report any adverse events or concerns.

**9. Data Privacy and Confidentiality**

Researchers must ensure that the confidentiality and privacy of child participants are maintained throughout the study. The HREB will review data security plans to ensure compliance with applicable laws and institutional policies, including:

* **HIPAA Compliance**: If the study involves medical information, compliance with the Health Insurance Portability and Accountability Act (HIPAA) is required.
* **Data Storage and Access**: Researchers must outline how data will be securely stored, who will have access to it, and how it will be disposed of after the study is completed.

**10. HREB Review Process**

* **Initial Review**: All research involving children must be submitted to the SUNY New Paltz HREB for review prior to the commencement of the study. This includes a detailed protocol outlining the study’s purpose, methods, risks, benefits, and plans for obtaining parental permission and child assent.
* **Ongoing Review**: The HREB may monitor ongoing studies involving children to ensure that the study continues to meet ethical standards and regulatory requirements.
* **Continuing Review**: Research involving children that is greater than minimal risk may require continuing review at least annually by the HREB to ensure that the study remains in compliance with the approved protocol.
* **Adverse Event Reporting**: Researchers are required to report any adverse events or unanticipated problems to the HREB in a timely manner. Any unanticipated risks or changes to the study must be promptly reviewed by the HREB.

**11. Compliance and Enforcement**

Failure to comply with this policy may result in the suspension or termination of the research project. The HREB will take appropriate action to protect the rights and welfare of child participants, including intervening if there are concerns regarding non-compliance with ethical standards or legal requirements.

**12. Conclusion**

This policy provides a framework for conducting research with children at SUNY New Paltz that protects their rights, safety, and well-being. All researchers must adhere to these guidelines and ensure that their research complies with all applicable ethical, legal, and institutional standards.