	UNIVERSITY RESEARCH POLICY: Children as Research Subjects			
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving the use of children as subjects in research. Research involving children as subjects requires compliance with the Common Rule at 45 CFR 46, Subpart A as well as compliance with 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research. For research that is FDA regulated, investigators must comply with the regulations at 21 CFR 50, Subpart D.

Reason for Policy

This policy helps ensure that human subjects research involving children as research subjects protects the rights and welfare of this vulnerable population, as well as meets all regulatory requirements.

Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research involving children as research subjects; the IRB committee members and chairs; Research Integrity office staff.

Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff


Responsibilities

Responsible Party	List of Responsibilities
Designated reviewers	Apply this policy when conducting reviews of IRB applications.
Lehigh University faculty, staff, and students submitting human subjects research for IRB review	Read, understand, and follow this policy when preparing applications for submission to the IRB. Read, understand, and follow this policy when conducting human subjects research.
Research Integrity office staff	Process IRB reviews and apply this policy when research involves children as research subjects.

Principles

The IRB reviews all research involving children as participants and approves only research that satisfies all of the conditions of applicable federal regulatory subpart sections. The IRB assesses the potential risks and benefits for each research proposal, and the provisions for permission and assent, to determine if the activity satisfies the conditions for a category of research permitted for children.

Investigators who are considering using child subjects should ask themselves if the proposed research is directly important to the health and well-being of the children, if it will answer a question affecting the health or welfare of children, or whether the study objectives can be met by using adult subjects. When children will be enrolled, the IRB

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will consider if the study methods are appropriate and assure that parental consent and child assent are being obtained in a manner that is appropriate.

Procedures

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study. The IRB Worksheet: [Research Involving Children](#) is provided to IRB reviewers when this policy applies.

Recruitment of Child Participants

The age, maturity and psychological state of the children as well as the research topic should be considered when determining whether recruitment efforts should be targeted towards the parent/legal guardian or the child.

For instance, for research involving adolescents it may be appropriate to approach the child subjects first to ascertain their interest prior to approaching the parent/legal guardian. This ensures that adolescents have time to consider whether they would like to participate in the study without undue influence from the parent/legal guardian. If the adolescent agrees that they would like to move forward, the discussion can then open up to include the parent/legal guardian and obtain parental/legal guardian permission.

For research involving younger children or children with developmental delays, recruitment efforts should be targeted towards the parent/legal guardian. For example, recruitment materials should use language such as “your child” (e.g. “Has your child been diagnosed with ADHD? S/he may be eligible to participate in a research study being conducted at Lehigh University”).

Parental Permission


In order to approve research involving children, the IRB must determine that adequate provisions are made for soliciting assent of the children and permission of their parents or legal guardian. Written permission is generally required of both parents or the child’s guardian for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; or (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child.

Depending on the nature of the research design, both parents may not be with the child when the research consent process takes place. It is up to the investigator to determine if the absent parent is reasonably available. Generally speaking, a parent that is unknown, incarcerated, uninvolved in the child’s life, deceased, or deployed may be considered “not reasonably available.” However, context and circumstances need to be very carefully considered. When attempts are made to contact a parent, the attempts need to be documented in detail, as should the entire consent process. Additionally, a parent may have sole legal responsibility for the child. In such cases, permission from that parent is sufficient for participation.

Waiver/Alteration of Parental Permission

The IRB may waive the requirements for obtaining parental or legal guardian permission under the following provisions:

1. The IRB may approve a consent procedure which does not include, or which alters or waives the requirements to obtain informed consent provided the IRB finds and documents that:
 - a. The research involves no more than minimal risk to the subjects;

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- 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 after participation.
2. The IRB may determine that a research protocol is designed to study conditions in children or a participant population for which parental/legal guardian permission is not a reasonable requirement to protect the participants and the following 2 additional criteria are also met:
 - a. an appropriate mechanism is in place to protect the children, and
 - b. the waiver is not inconsistent with federal, state, or local law

Waiver of Requirement to Document Parental / Legal Guardian Permission

A waiver to document parental/legal guardian permission can be useful in situations where the research will take place over the phone or in situations where parental permission is required but the parent/legal guardian is not in the physical company of the child who is being enrolled. Under a waiver to document, the full consent process still takes place but no signature is obtained. Investigators should document in the research record when and how the consent process took place and that affirmative agreement was given.

The IRB may waive the requirements for documentation of parental or legal guardian permission provided that the research is determined to be no greater than minimal risk and one of the following is true:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or;
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Assent


In addition to the written permission required of parents, it is necessary to acquire the assent of children when they are capable of providing assent. While children are unable to provide legally effective informed consent to participate in research, some children are able to give their assent to participate. Assent is a child's affirmative agreement to participate in research. Mere failure to object may not be construed as assent.

The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB will decide what form of documentation, if any, is most appropriate. Written assent is ordinarily required for children 14 years and older. Verbal assent may be obtained for children under 14. The Principal Investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented. The information given to the children should be in language that is understandable by children. Written materials and a script for verbal descriptions and assent must be submitted for review.

Waiver/Alteration of Assent

The assent of children is required to be obtained and documented from all child participants; however, the IRB may approve a waiver of assent from some or all of the child participants, provided that one or more of the following are true:

- The capability of the children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted.
- 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.

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- The proposed research involves no more than minimal risk to participants; the waiver of assent will not adversely affect the rights and welfare of the participants; the research could not practicably be carried out without the waiver or alteration; and participants will be provided with additional information after participation.

Assessing Risk Level of Research Involving Children as Subjects

The IRB assesses the potential risks and benefits for each research proposal, and the provisions for permission and assent, to determine if an activity satisfies the conditions for a category of research permitted with children. The determination of risk is made using the [“Assessing Risk Level Using Magnitude of Harm”](#) guidance.

Federal regulations classify four permissible categories for research involving children, based on degree of risk and type of prospective benefit. These categories are described in relation to “minimal risk.” For research involving children, “minimal risk” is defined as the level of risk that a normal, average, healthy child may be exposed to in the course of that child’s everyday life, or those risks encountered by normal, average, healthy children living in safe environments in daily life or during the performance of routine physical or psychological examinations or tests. For research involving children as subjects, the IRB must also consider the “minor increase over minimal risk” category; such research may be approvable under 45 CFR §46.406.

Categories of Research Involving Children as Subjects

Research not involving greater than minimal risk (21 CFR §50.51/45 CFR §46.404)


- Research that does not involve greater than minimal risk may be approved if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. The IRB will determine if the permission of one parent/legal guardian is sufficient for participation in the research approved under this category.

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (21 CFR §50.52/45 CFR §46.405)

- Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant, or a monitoring procedure that is likely to contribute to the participant’s well-being may be approved if the IRB finds that:
 - The risk is justified by the anticipated benefit to the subjects;
 - The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and
 - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians. The IRB will determine if the permission of one parent/legal guardian is sufficient for participation in the research approved under this category or if both parents’ permission is necessary.

Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition (21 CFR §50.53/45 CFR §46.406)

- Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition may be approved if the IRB finds that:
 - The risk represents a minor increase over minimal risk;
 - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

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- The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- Adequate provisions are made for soliciting assent of the children or permission of their parents or guardians. Both parents must provide permission for the child to participate in research approved under this category.

Not otherwise approvable research involving children (21 CFR §50.54/45 CFR §46.407)

- Research that is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children may be approved if the IRB and the Secretary of Health and Human Services (DHHS), after consultation with a panel of experts in pertinent disciplines and following an opportunity for public review and comment, find that the research in fact satisfies one of previous three categories; or satisfies all of the following requirements:
 - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children;
 - The research will be conducted in accordance with sound ethical principles; and
 - Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians. Both parents must provide permission for the child to participate in research approved under this category.

Research involving wards of the state or any other agency, institution, or entity (45 CFR §46.409)

Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background and experience to act in the best interests of the children for the duration of their participation in the research. The principal investigator should identify a suitable advocate and secure his/her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or for research presenting the prospect of direct benefits to the individual children.

Collection of Data in School / Institutional Settings

If the research involves the collection of data in a school (or other institutional) setting, a letter of approval from the principal or superintendent of the school must be submitted to the IRB before final approval can be granted for the study.

Research Involving Student Records


Research of this type may be subject to the Family Educational Rights and Privacy Act (FERPA). Investigators should refer to the [FERPA guidance](#) when using children's education records.

Web Address For This Policy

[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

Related Resources

University Policies and Documents

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<p>Lehigh University IRB Glossary</p> <p>Worksheet: Research Involving Children</p> <p>Guidance: Assessing Risk Level Using Magnitude of Harm</p> <p>Guidance: Family Educational Rights and Privacy Act (FERPA)</p> <p>External Resources</p> <p>Code of Federal Regulations 45 Part 46, Protection of Human Subjects, Subpart D</p> <p>Code of Federal Regulations 21 Part 50, Protection of Human Subjects, Subpart D (FDA)</p>

Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Senior Research Integrity Specialist	610-758-2871	https://research.cc.lehigh.edu/contact-us-0