THE OHIO STATE UNIVERSITY

ASSENT AND PARENTAL PERMISSION

LANGUAGE IN GRAY BOXES IS ONLY APPLICABLE TO STUDIES APPROVED ON/AFTER JANUARY 21, 2019

1. Overview

Assent and parental (or guardian) permission must be obtained as required by federal regulations and IRB determinations for research involving children. Assent is generally required for children based on their ages, maturity, condition, and the nature of the research, unless assent can be appropriately waived or some or all of the children are not capable of providing assent.

The purpose of this policy is to describe the requirements for assent and parental (or guardian) permission for research involving children.

2. Definitions

Assent: Agreement to participate in research expressed by an individual (e.g., a child) who cannot provide legally effective informed consent to participate on his/her own behalf. *Note: Failure to object does not constitute assent.*

Child/Children: Person(s) 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. For purposes of HRPP policy, individuals under 18 years of age are considered children in Ohio unless they meet the definition of emancipated minors.

Emancipated Minors: For purposes of HRPP policy, the following persons under the legal age of 18, who because of their unique circumstances have the legal rights of adults, including the right to consent to treatments or procedures involved in research:

- Persons under the age of 18 on active duty in the military
- Married persons under 18 years of age.

Note: Pregnancy or childbirth outside of marriage does not emancipate a minor in Ohio.

Guardian: An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. In Ohio, a guardian may be a grandparent, other family member, or other person, association, or agency other than the biological or adoptive parents who has been formally appointed as a guardian or legal representative by a court to care for a child, including to consent on behalf of a child to general medical care. *Note: Grandparents or other family members who are not formally appointed as guardians or legal representatives by a court generally do not have the authority to provide consent on behalf of a child without consent by the child's parents.*

Parent: A child's biological or adoptive mother or biological or adoptive father.

Permission: The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research.

3. General Information

A. The requirements for obtaining the informed consent of research participants or their legally authorized representatives apply when children are the subjects of research, unless these requirements are waived by the IRB. A parent (one or both) or, in some cases, a guardian must provide permission for his/her child to participate in research based on sufficient information and adequate opportunity to consider the child's voluntary participation. For more information about the requirements for informed consent processes see HRPP policy [Informed Consent Process and the Elements of Informed Consent].

B. The requirement for documenting informed consent by use of a written consent form (electronic or hard copy) approved by the IRB and signed by the subject or the subject's legally authorized representative applies when children are the subjects of research, unless this requirement is waived by the IRB. A parent (one or both) or, in some cases, a guardian must document permission for his/her child to participate in research as described below and in HRPP policy [Documentation of the Informed Consent Process].

C. Although according to federal regulations children cannot provide valid informed consent to participate in research, they may be able to assent to participation. In general, investigators should obtain the assent of children to participate in research whenever children are capable of assenting. The IRB is responsible for determining when the assent of some or all children is required in proposed research and the appropriate method for documenting a child's assent (if any), as described below.

D. Assent may also be appropriate for adults with diminished decision-making capacity and other adults unable to consent for themselves, for whom a legally authorized representative will provide informed consent. For more information about assent in adults see HRPP policy [Vulnerable Populations: Students, Employees, and Adults Unable to Provide Consent].

4. Assent of Children

For research involving children, the requirements for obtaining and documenting a child's assent and waiver of these requirements are described below. Additional requirements for research involving children are described in HRPP policy [Research Involving Children].

4.1 Assent Process

A. In addition to the requirements for parental or guardian permission, adequate provisions for soliciting the assent of a child to participate in research are required when the child is capable of providing assent. In determining whether proposed participants are capable of assenting, investigators and IRBs will take into account the ages, maturity, condition, and psychological/emotional states of the children involved. The IRB's determination of the children's capacity to assent may apply to some or all of the children to be involved in a proposed research activity.

B. Assent processes are to include the key elements of informed consent described in HRPP policy [Informed Consent Process and the Elements of Informed Consent] and

are to be provided in language appropriate for children, based on the nature of the study and the expected capacity of the potential participant(s) to understand the purpose and the procedures involved in the research.

C. For research activities involving older children or adolescents whose capacity to understand is similar to that of adults, the assent process will include information similar to what would be provided for informed consent by adults or for parental/guardian permission. For children whose age and/or maturity level limits their ability to fully understand the research but who are still capable of being consulted about participating, it may be appropriate to focus only on providing an accurate description of the experience itself (e.g., what will happen, how long it will take, whether it might involve any pain or discomfort, etc.).

D. The assent of children to participate in research is to be obtained except in the following circumstances:

- The children are not capable of providing assent based on age, maturity, or psychological state
- The capability of some or all of the children is so limited that they cannot reasonably be consulted
- The intervention or procedure involved in the research holds out a prospect of direct benefit to the health or well-being of the children and is available only in the context of the research
- Assent can be waived using the criteria for waiver (or alteration) of informed consent or parental/guardian permission, as described below (see “Waiver or Alteration of Parental Permission”).

E. The IRBs may determine that the assent of **some** or **all** children is not required. If assent is not a requirement of **some** children, the IRB will indicate which children (e.g., children less than 2 years old) are not required to assent.

4.2 Documentation of Assent

A. When a child’s assent is required, investigators and IRBs must determine the appropriate method, if any, of documenting assent. This decision should be based on considerations such as the length and complexity of the research and the child’s age, maturity, and degree of literacy.

B. If older children or adolescents will be involved in research for which a consent form would have been used if the participants were adults, a similar form to document the child’s assent is generally appropriate. For younger children who are as yet unable to read or other children unlikely to be familiar with signing documents (e.g., through prior experience with testing or other procedures normally encountered in their lives), documentation of assent may be limited to verifying that assent took place using a witness or other method. Alternatively, the IRB may decide that documentation of assent for children of any age is not warranted.

C. Assent form templates containing the basic elements of informed consent are available on the ORRP website. When documentation of assent is required, use of the applicable assent template language is generally required. Alternatively, based

on the age and literacy level of the children and nature of the research, for some studies investigators may add an assent signature line to the consent document that parents will sign. The IRBs can also approve assent forms on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting assent.

D. When documentation of assent is required for studies involving children of various ages, more than one assent form may be necessary depending on the intellectual and emotional ability of the children to comprehend the concepts involved – e.g., a form with a fully detailed explanation for older children and a shorter, simpler document for younger children.

E. If verbal assent will be obtained, the IRB must review a written description of the information (i.e., a "script") that will be provided to children during the assent process.

5. Parental Permission

A. For research involving children, the permission of a parent(s) or guardian must be obtained and documented for his/her child to participate in research, unless these requirements are waived by the IRB. The requirements for informed consent processes apply when children are the subjects of research, including disclosure (to parents or guardians) of the basic and additional elements of consent. For more information about the requirements for informed consent see HRPP policies [Informed Consent Process and the Elements of Informed Consent] and [Documentation of the Informed Consent Process].

B. Parental permission form templates containing the basic elements of informed consent are available on the ORRP website. To streamline IRB review and assure that regulatory requirements are met, use of the applicable template language is generally required. The IRBs can also approve parental permission forms on a case-by-case basis in other formats that may more appropriately satisfy requirements for obtaining and documenting parental permission.

C. Based on regulatory requirements, when children are involved in research investigators and IRBs must determine whether the permission of both parents is required or if the permission of one parent is sufficient as described below.

D. For research that involves minimal risk or more than minimal risk with the prospect of direct benefit to the individual child, the IRB may determine either of the following:

- Permission of **both** parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or
- Permission of **one** parent is sufficient.

E. For research that involves more than minimal risk without the prospect of direct benefit to the individual child, the permission of **both** parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

F. For children who are wards of the state (or any other agency, institution, or entity), a guardian must provide permission for the ward to participate in research, in lieu of a child's biological or adoptive parents. When research involves more than minimal risk without the prospect of direct benefit to the child, an advocate who agrees to act in the best interests of the child throughout the duration of the child's participation, including ensuring that to the extent possible the child understands what will be required of him/her during the research, must also be appointed.

G. Additional requirements for research involving children, including children who are wards of the state, are described in HRPP policy [Research Involving Children].

6. Waiver or Alteration of Parental Permission

In the limited circumstances described below, the IRB can waive or alter the requirements for obtaining parental or guardian permission.

Note: "Passive consent" is sometimes used in research with children to describe a situation where the investigator assumes that the parent permits a child to participate (e.g., information about a study is mailed to the parent and if the parent does not want their child to participate, they must return a form "opting out"). This procedure is not consistent with the regulatory requirement to obtain parental permission. In these instances, the investigator can request the IRB to consider if the conditions for a waiver of parental permission can be met under 45 CFR 46.408(c) or 45 CFR 46.116(f)(3).

A. Research on Public Benefit or Service Programs

The IRB can waive or alter the requirements for parental permission for non-exempt research examining state or local public benefit or service programs or certain features of those programs if all of the following criteria are met:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs
- The research could not practicably be carried out without the waiver or alteration
- The research is not FDA-regulated.

Note: Similar research conducted under federal authority or research conducted by (or subject to the approval of) a private entity would not qualify.

B. Minimal Risk Research

The IRB can waive or alter the requirements for parental permission for non-exempt research that meets all of the following criteria:

- The research involves no more than minimal risk to subjects
- The waiver or alteration will not adversely affect the rights and welfare of subjects
- The research could not practicably be carried out without the waiver or alteration

- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
- Whenever appropriate, subjects or their parent/guardian will be provided with additional pertinent information after participation.

C. Research Designed to Study Conditions in Children

1. The IRB can waive or alter the requirements for parental permission for non-exempt research designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children) when the following additional criteria are also met:

- An appropriate mechanism is in place to protect the children
- The waiver is not inconsistent with federal, state, or local law.

Note: IRBs may waive the requirement for obtaining parental or guardian permission as described above even if the research involves greater than minimal risk to the participants.

2. When determining an appropriate mechanism for protecting child participants (e.g., appointment of an advocate or assent monitor), investigators and IRBs will consider the nature of the research (including any potential risks and anticipated benefits) and the children's ages, maturity, condition, and psychological/emotional states.

D. Planned Emergency Research

The IRB can approve a waiver of the requirements for informed consent for non-exempt research in life-threatening situations in which it is not possible to obtain informed consent from subjects or their legally authorized representatives, including studies in which children are the subjects of the research. For more information, see HRPP policy [Planned Emergency Research].

7. Special Circumstances

A. A mother under 18 years of age (i.e., a parent that is legally still a child) can provide permission for her child to participate in research. However, for her own research participation, the permission of one or both of the mother's parents is required, unless the requirement for parental permission has been waived by the IRB.

B. Under the Family Educational and Rights Privacy Act (FERPA), a child under 18 years of age who attends a school beyond the high school level (e.g., The Ohio State University) can consent to release information from his/her education records for use in research. However, to participate in research the child must also have the permission of one or both parents, unless the requirement for parental permission has been waived by the IRB.

8. Children Who Reach the Legal Age of Consent While Enrolled in a Study

Informed consent is an ongoing process throughout the duration of a research study. When a child who was enrolled in research with parental (or guardian) permission reaches the legal age of consent, the subject's participation is no longer regulated by the requirements regarding parental permission. Legally effective informed consent must be obtained (unless waived) from the now-adult participant for any continued interactions, interventions, or other activities that meet the definition of "research involving human subjects," including analysis of individually identifiable data or specimens. (For more information on the definition of human subjects research, see HRPP policy [Research Involving Human Subjects]).

9. Applicable Regulations/Guidance

21 CFR 50.3, 21 CFR 50.20, 21 CFR 50.25, 21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54, 21 CFR 50.55, 21 CFR 56.109, 21 CFR 56.111, pre-2018 and Final Rule (45 CFR 46.111, 45 CFR 46.116, 45 CFR 46.402, 45 CFR 46.403, 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407, 45 CFR 46.408), FDA Information Sheets: "A Guide to Informed Consent," FDA Information Sheets: Frequently Asked Questions "Informed Consent Process" and "Informed Consent Document Content," OHRP "Informed Consent FAQs" , The Ohio State University Policy and Procedure Manuals for University Hospitals and James Cancer Hospital and Solove Research Institute (# 03-27), FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects" (07/17)

10. History

Issued: 09/15/2008
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