|  |  |
| --- | --- |
|  | **GUIDANCE Involvement of**  **Children in Research** |

# Purpose

## To assist University of Washington (UW) Institutional Review Board (IRB) members and UW Human Subjects Division (HSD) staff in applying the federal and state regulations, and institutional policies pertaining to the involvement of children in research, regardless of funding source.

# Special requirements for the inclusion of children in research

## **Determination by the IRB of the level of risk for children.**Refer to the [WORKSHEET Children](https://www.washington.edu/research/forms-and-templates/worksheet-children/) which is used as guidance to facilitate the review of research involving children. Regulatory decisions are documented in the **CHECKLIST Regulatory**.

### The IRB must determine the level of risk, the potential for direct benefits to the children, and other specified features of the research in order to specify the category of research under which the IRB can approve the involvement of children.

* + - **Category 404:** Research not involving greater than minimal risk (§46.404/§50.51)
    - **Category 405:** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (§46.405/§50.52)
    - **Category 406:** 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 (§46.406/§50.53)

## **Review by the HHS Secretary** **or the Commissioner of Food and Drugs (if FDA regulated) for research that an IRB finds not approvable under any of the three levels of risk categories.**

## If the IRB does not believe that a proposed research activity fits into any of the three categories (404, 405, 406), but that it does present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, the IRB may forward that proposed activity to the HHS Secretary or the Commissioner of Food and Drugs (if FDA regulated) for review under conditions identified in section §46.407/§50.54 of the regulations.

## **Review by the IRB of some research activities involving children that would be exempt if the research subjects were adults.**

## Subpart D widens the range of research activities requiring IRB review by reducing the scope of the exemption categories 45 CFR 46.104(d)(2)(i)(ii) regarding research activities involving education tests, survey or interview procedures, or observation of public behavior, if the subjects are children. The exemption of research activities involving survey and interview procedures is not allowed with children, nor is the observation of public behavior if the investigator will participate in the activities being observed. The exemption categories at 45 CFR 46.104(d)(2)(iii) and (d)(3) may not be applied to research subject to this subpart.

## 

## **Review in terms of parental permission and child assent rather than the informed consent process used for research involving adults.**

## Subpart D replaces the concept of “informed consent” with the concepts and procedures of parental permission and child assent. Review the [WORKSHEET Children](https://www.washington.edu/research/forms-and-templates/worksheet-children/) and [GUIDANCE Consent Protected and Vulnerable Populations](https://www.washington.edu/research/hsd/guidance/consent/#6)for details about parental permission and child assent. In general, one or both parents or a guardian must be provided with the information ordinarily required for informed consent, so that they may decide whether to allow the child to participate, and children capable of assent must also express their willingness to participate. Subpart D allows for various conditions and waivers of parental permission and child assent, depending on the nature of the research activity and the maturity of the child.

## **Review in terms of additional requirements if certain research activities involve children who are wards of the State or any other agency, institution, or entity.**

### Subpart D provides additional protections for children who are also wards of the State or any other agency, institution, or entity. These special protections for wards apply to two categories of research: **1)** research approved by an IRB under §46.406/§50.53; **or 2)** research approved in accordance with the requirements of §46.407/§50.54 that requires a special level of review beyond that provided by the Institutional Review Board (IRB).

### Before children who are wards of the State or any other agency, institution, or entity can be included in either of the two categories of research referenced above, the research must meet the following conditions: 1) the research must be either related to the children’s status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards; and 2) 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.

### One individual may serve as advocate for more than one child. An advocate must 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. The advocate should represent the individual child subject’s interests throughout the child’s participation in the research. The regulations further require that the advocate not be 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.

# Determining which subjects are “children” per the legal and regulatory definitions

## By regulatory definition, 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 the jurisdiction in which the research will be conducted”.

### In the United States the **legal age of adulthood** is a matter of state and local law. State law also may address specific circumstances in which a person younger than the age of adulthood is legally authorized to consent to medical procedures; for example, some states allow children younger than the legal age of adulthood to consent to the provision of contraceptive services. Refer to [GUIDANCE Human Subjects Regulations](https://www.washington.edu/research/policies/guidance-human-subjects-regulations-2/) for exceptions or considerations per Washington State law.

### Certain states provide a mechanism for the **emancipation of minors**, through which a child younger than the legal age of adulthood may gain certain civil rights, which might include the legal ability to consent to research participation. Refer to [GUIDANCE Human Subjects Regulations](https://www.washington.edu/research/policies/guidance-human-subjects-regulations-2/) for exceptions or considerations per Washington State law.

## The definition of children also takes into account the **particular interventions or interactions involved in the proposed research** (e.g., surveys, blood tests). For example, in some places individuals who are 16 years of age may legally consent to certain clinical interventions or interactions. If the involvement of human subjects in a proposed research activity consists of these interventions or interactions, then those individuals may be considered as adults for that purpose. If a proposed activity includes an intervention or interaction for which the subject has not yet reached the legal age of consent, however, that person must be considered a child.

# HIPAA Authorization

## If under applicable law a parent, guardian, or other person is acting as in loco parentis *(i.e., “in the place of a parent”)* for a child who is not emancipated, they havethe authority to act on behalf of the child in making decisions related to health care, including the signing of a HIPAA Authorization form.

## Specifically, under the federal privacy rule research participants or in the case of children, a parent, guardian, or other person acting in the place of a parent have the:

### Right to privacy of the child’s protected health information;

### Right to authorize use of identifiable PHI for research purposes;

### Right to an accounting from the covered entity of how the child’s identifiable PHI was disclosed without their authorization for the past six years;

### Right to revoke authorization in writing. No further PHI may be collected for the research after the authorization is revoked. (Researchers may continue to use and disclose PHI that was collected under the authorization. Such uses might include adverse event reporting, submissions of marketing applications to FDA, accounting for participant’s withdrawal from the research, investigation of scientific misconduct.)

## A child may provide their own HIPAA authorization if it is determined that: (A) The child is legally allowed to consent to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative; or (B) The child may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the child, a court, or another person authorized by law consents to such health care service.

# FERPA

## The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records.

## FERPA regulates the disclosure of Personally Identifiable Information from youth education records in all public elementary and secondary schools, school districts, intermediate education agencies, state education agencies, and any public or private agency or institution that uses funds from the U.S. Education Department.

## FERPA and IRB requirements are usually met if a parent (or “Eligible Student” as defined in § 99.3) signs a consent form to participate in a research study and authorizes the release of his/her child’s Education Records for research purposes.

## FERPA regulations specify that a parent or Eligible Student must provide a signed and dated written consent in accordance with the requirements of §99.30 before Personally Identifiable Information from Education Records is disclosed, unless the disclosure falls within one of the exceptions set forth in §99.30

## FERPA’s consent provisions require a specification of 1) the records that may be disclosed;2) the purpose of the disclosure; and 3) the identity of the party or class of parties to whom the records may be disclosed.

## FERPA allows an educational agency or institution to disclose personally identifiable information from an Educational Record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

### Develop, validate, or administer predictive tests

### Administer student aid programs

### Improve instruction (34 CFR §99.31)

## A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the organization or researcher conducting the research that specifies:

## The determination of the exception

## The purpose, scope, and duration of the study

## The information to be disclosed

## That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR §99.31 (a)(6) on re-disclosure and destruction of information.

## That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than the representatives of the organization with legitimate interests

## That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.

## The time period during which the organization must either destroy or return the information

## It is not the responsibility of the IRB to enforce this regulation however it is the researcher’s responsibility to ensure that the regulatory requirements are met if the regulation applies.

# PPRA

## The Protection of Pupil Rights Amendment (PPRA; sometimes also called the Hatch Amendment, the Grassley Amendment, or the Tiahrt Amendment) and the No Child Left Behind Act are federal regulations that require schools (and researchers who perform these activities at or in connection with the schools) to: 1) Notify parents of the activities, in advance; 2) Make the survey, analysis, or evaluation materials available for inspection by the parents, upon request, before the materials are administered or distributed to students; 3) Obtain consent from a parent for his/her minor child’s participation or allow the parent to opt the child out of participation. This parental consent specific to these circumstances cannot be waived.

## PPRA is applicable when research involves students (below age 18) participating in a survey, analysis, or evaluation that reveals information concerning:

## Political affiliations or beliefs of the student or the student’s parent

## Mental or psychological problems of the student or the student’s family

## Sex behavior or attitudes

## Illegal, anti-social, self-incriminating, or demeaning behavior

## Critical appraisals of other individuals with whom the students have close family relationships

## Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers

## Religious practices, affiliations, or beliefs of the student or student’s parent or

## Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

## It is not the responsibility of the IRB to enforce this regulation however it is the researcher’s responsibility to ensure that the regulatory requirements are met if the regulation applies.

# COPPA

## The federal COPPA (Children’s Online Privacy Protection Act) applies if a researcher is: 1) Operating a website or an online service directed toward children; 2) Actively collecting or maintaining personal information from or about the users of or visitors to that website or online service; and 3) The users or visitors are likely to include children under the age of 13.

## COPPA requires the researcher to:

## Obtain verifiable parent permission for the collection, use, or disclosure of the personal information;

## Provide notice on the website of what information is collected, how it will be used, and disclosure practices;

## Provide to a parent, upon request, a description of the specific type of personal information collected from the parent’s child and the opportunity to refuse to permit your further use or maintenance in retrievable form the child’s personal information.

## It is not the responsibility of the IRB to enforce this regulation however it is the researcher’s responsibility to ensure that the regulatory requirements are met if the regulation applies.

# IRB/HSD Responsibilities

## The IRB is responsible for determining the category of risk for involvement of children in research and document accordingly.

## The IRB is responsible for determining if waivers for assent, one-parent permission, two parent permission, or waiver of parent permission are justified and to document accordingly.

## When determining whether children are capable of assenting, the IRB should take into account the age, maturity, and psychological state of the children targeted for the study population. This determination may apply to all children involved in the study, or on a case-by-case basis, as deemed necessary by the IRB.

## The IRB also needs to determine the appropriate ages for assent and the method of documentation of assent.

## The IRB needs to assure that special protections afforded to children found in Subpart D have been met for this population.

## HHS-funded or supported studies determined by the IRB to meet 45 CFR 46.407 for children, will be given a “deferral” status until a determination by the Secretary of the Department of Health and Human Services (DHHS) is received.

## The HSD Director will notify the HHS Office of Human Research Protections (OHRP) when the IRB determines a study meets 45 CFR 46.407. Documentation sent to the Secretary includes:

### IRB minutes from the convened meeting documenting the IRB findings;

### The complete IRB application and informed consent documents;

### The relevant protocol and/or grant application; and

### Any supporting material including the Investigator’s Brochure, if applicable.

## If OHRP grants approval under Category 46.407, then the IRB may grant final approval. If OHRP requires changes in the process of approval, or any other changes are made after the IRB “conditional approval”, a modification must be submitted for review and approved by the IRB Chair or designee, unless the IRB Chair or designee determines the changes submitted are major, which require IRB review

## FDA regulated clinical investigations determined by the IRB to meet 21 CFR 50.54 for children, will be given a “deferral” status until a determination by the Commissioner of Food and Drugs is received.

## The Executive Director will notify the FDA when the IRB determines a study is determined to meet 50 CFR 50.54. Documentation sent to the Secretary will include:

### IRB minutes from the convened meeting documenting the IRB findings;

### The complete IRB application and informed consent documents;

### The relevant protocol and/or grant application; and

### Any supporting material including the Investigator’s Brochure, if applicable

### If FDA grants approval under Category 50.54, then the IRB may grant final approval. If FDA requires changes in the process of approval, or any other changes are made after the IRB “conditional approval”, a modification must be submitted for review and approved by the IRB Chairperson or his or her designee, unless the IRB Chairperson determines the changes submitted are major, which require IRB review.

# IRB Documentation of involvement of children in research

## When it has been determined that children are involved in a research study under review by the UW IRB, the IRB should review and document the regulatory considerations using the appropriate sections of the Master Checklist:

### **Research with Children:** To be completed if children, ages 0 through 17 years are involved in a research activity. This includes those activities in which no interaction will take place (i.e., record review) whether as the sole focus of the study or for pre-screening/eligibility purposes.

### **Parental Waivers:** To be completed if children, ages 0 through 17 years are involved in a research activity. This includes those activities in which no interaction will take place (i.e., record review) whether as the sole focus of the study or for pre-screening/eligibility purposes.

### **Washington State Law and Minors:** To be completed if children, ages 0 through 17 years are involved in a research activity that occurs in the State of Washington. This includes those activities in which no interaction will take place (i.e., record review involving Washington state held records) whether as the sole focus of the study or for pre-screening/eligibility purposes.

### **Assent by Children: To** be completed if children, ages 0 through 17 years are involved in a research activity. This includes those activities in which no interaction will take place (i.e., record review) whether as the sole focus of the study or for pre-screening/eligibility purposes.

### **Children who are Wards:** To be completed if children, ages 0 through 17 years are involved in a research activity that has been determined to fall under the regulatory category for involvement of children in research 406 or 407 and are considered wards of the state.

# HSD Staff Responsibilities

## HSD staff should ensure that the following actions are completed when research involving children is reviewed and conditional approval or approval is secured:

### Document that all items on the Master Checklist are appropriately addressed by the IRB, with appropriate determinations and documentation, either by convened IRB review or expedited review;

### For Zipline applications: upload the checklist to “supporting documents” following review and determination;

### For paper applications, append the checklists to the minutes document to which they pertain;

### For paper applications: make appropriate entries in the DORA participant tab: select “minors” under “special populations” and mark the level of risk determined at review.

# Definitions

## **Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

## **Children:** 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.

## **Guardian:** “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)) The role of a guardian in the context of research involving a child who is a ward is to provide permission, in lieu of a child’s biological or adoptive parents, for the ward to participate in the research (45 CFR 46.402(c)).

## **Parent:**Achild's biological or adoptive parent.

## **Permission:**The agreement of parent(s) or guardian to the participation of their child or ward in research.

## **Ward:** A person who has a guardian appointed by the court to care for and take responsibility for that person. A governmental agency may take temporary custody of a minor for his/her protection and care if the child is suffering from parental neglect or abuse or has been in trouble with the law. Such a child is a "ward of the court" (if the custody is court-ordered) or a "ward of the state."

# Related Materials

#### CHECKLIST Regulatory [*HSD staff access only*]

#### [GUIDANCE Human Subjects Regulations](https://www.washington.edu/research/policies/guidance-human-subjects-regulations-2/)

#### [WEBPAGE Consent Guidance](https://www.washington.edu/research/hsd/guidance/consent/)

#### [WORKSHEET Children](https://www.washington.edu/research/forms-and-templates/worksheet-children/)

# References

### Office for Human Research Protection, 45 CFR 46, including subpart D

### Food and Drug Administration, 21 CFR 50, including subpart D

### OHRP FAQs on involvement of children in research

### RCW 13.64.010

### RCW 26.28.010

### RCW 26.28.020

### RCW 26.50.020

### RCW 70.24.110

### RCW 70.96A.095

### RCW 71.34.500

### RCW 71.34.530

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.9 | 01.30.2025 | 01.30.2025 | Update regulatory citations for 2018 Common Rule |
| 1.8 | 06.25.2024 | 06.25.2024 | Revise reference to CHECKLIST Regulatory |
| 1.7 | 10.02.2023 | 10.02.2023 | Revise reference to list of RCWs pertaining to age of majority; add version table |
| 1.6 | 10.08.2021 | 10.08.2021 | Move information about parental permission and assent to GUIDANCE Consent and/or WORKSHEET Children |
| 1.5 | 08.25.2017 | 08.25.2017 | Updated per new FDA guidance regarding waiving consent for minimal risk studies |
| Previous versions |  |  | Previous versions are beyond records retention requirements |

**Keywords:** Children; Vulnerable populations