**GUIDE 623 – for Consent and Assent for Research Involving Children, Mandatory Reporting**

**Scope**: This guidance includes both adult consent as well as parental and guardian permission, when a child may consent for themselves, types of surrogate decision makers for children and their authority, and required documentation. It also covers:

* Waiver of Parental or Guardian Permission
* Parental Consent and Assent when Research Participants are Children
* Assent
* Special Circumstances
* Parents or Guardian Are Unavailable
* Children Who Are Wards
* Guardians – Restrictions on Authority
* Minors who may Consent as Adults, including Emancipated Minors
* Mandatory Reporting of Child Abuse and Neglect

1. **Consent for Adults**

* The Regulations require the following information, the required disclosures, be provided to each prospective participant in a research project[[1]](#footnote-0):
  1. A statement that the study involves research; an explanation of the purposes of the research; the expected duration of the subject’s participation in the research; a description of the procedures to be followed; identification of any procedures that are experimental;
  2. A description of any reasonably foreseeable risks or discomforts to the participant;
  3. A description of any benefits to participants or others which may reasonably be expected from the research;
  4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to participants;
  5. A statement describing the extent, if any, to which confidentiality of records identifying participants will be maintained;
  6. For research involving greater than minimal risk, an explanation as to any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained;
  7. An explanation of whom to contact for answers to pertinent questions about
     1. the research,
     2. participants’ rights, and
     3. whom to contact in the event of a research-related injury;
  8. A statement that
     1. participation in research is voluntary;
     2. refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled; and
     3. the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and
* The HSP requires the consent form include the name and contact information for the Investigator.
* The Regulations further require one or more of the following additional information, additional disclosures, be provided to each subject, when appropriate[[2]](#footnote-1):
  1. A statement that the particular treatment or procedure may involve risks to participants (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable;
  2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without the subject’s consent;
  3. Any additional costs to participants that may result from participation in the research;
  4. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
  5. A statement that significant new findings developed during the course of the research that may affect participants’ willingness to continue in the study will be provided to the subject; and
  6. The approximate number of participants to be enrolled.
* **Deception in the context of human research** refers to both providing false information as well as to withholding some pertinent aspect of the research that concerns the real purpose or nature of the research. The use of either form of deception is inconsistent with fully informed consent and hence must be scientifically and ethically justified. If the deception/incomplete disclosure impacts the consent process, the deceptive aspects of the study must meet the requirements for waiver or alteration of consent. Any proposal to involve deception or incomplete disclosure must be justified and necessary to carry out the research and must not adversely affect the subjects’ rights and welfare.
  1. **Instances when deception may be allowable**
     1. The use of deception and/or incomplete disclosure in research may be allowable (45 CFR § 46.104(d)(3)(iii)) when the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he/she will be unaware of or mislead regarding the nature or purposes of the research.

Examples of studies that may necessitate the use of deception/incomplete disclosure include:

* + - * Psychology studies examining spontaneous behaviors which would be inhibited by informing the participant of the trait being observed.
      * Psychology studies involving confederate(s) who are used to elicit comments/responses as if to a peer of the participant.
  1. **Instances when deception is not allowable**

The use of deception and/or incomplete disclosure is not allowable when:

* The deception regards significant aspects of the study that would affect the participants’ willingness to participate in the research.
* The deception/incomplete disclosure itself could cause harm to the participants.
* The deceptive techniques are intended solely to entice or lure an individual to participate in a research study.
* False information is incorporated into the consent materials or process.
  1. **Debriefing**

Participants in a study involving the use of deception or incomplete disclosure should be debriefed about the nature of the deception and/or incomplete disclosure after completion of the study unless debriefing is not possible or would cause unacceptable risk to the subjects.

Investigators should include a description of the debriefing process, including any written materials, as a part of the protocol submitted to the IRB. The debriefing process should include a clear description of what information was withheld or false as well as an explanation for why it was necessary to deceive the participant. During the debriefing, subjects must have the opportunity to ask questions about the new information and be given the opportunity to withdraw from the study or have their data removed.

Debriefing may not be advisable in certain limited situations, for example, if the research reveals information about the participant that s/he might find disturbing (such as a personality disorder, aggressive behavior tendencies, etc.). If an investigator believes that debriefing will be inappropriate, the investigator should explain the basis for this belief in the protocol submitted to the IRB. The IRB will determine whether debriefing is appropriate.

* 1. **Considerations for Consenting Participants in Studies Involving Deception** Consent forms should not include false or misleading information to further the deception. Investigators may, however, be vague as to the purposes of the study or omit information in the consent process in order to maintain the deception or incomplete disclosure necessary for the study.

Investigators should include a statement in the consent form advising potential participants that the information provided in the consent form is not complete and that participants will be debriefed after the research procedures are completed whenever feasible. For example:

“Research designs sometimes require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the purpose of the study and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you might have about the study and the procedures used in the study. You may decide to withdraw from the study or have your data removed as well.”

**2. Assent for Children Involved in Research**

**Waiver of Parental or Guardian Permission**

• FDA regulated research is not eligible for waivers (unless the emergency exception applies.)

• For non-FDA regulated research, the IRB may waive parental or guardian permission if:

1. regular conditions for waiver of consent are met (see 45 CFR 46.116(c) or 46.116(d)); or
2. parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted; for example, if the study:
   * focuses on a condition or is a study of such a private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or
   * involves a subject population such as abused or neglected children. [45CFR 46.408(c)]
3. A request for a waiver (or partial waiver) will be considered for research conducted in a classroom, if the research is minimal risk and meets the other waiver requirements.
4. Research is *generally not suitable for a waiver* if it involves:
   * parental political affiliations or beliefs,
   * mental or psychological problems,
   * sexual behavior or attitudes,
   * illegal/antisocial/self-incriminating behavior,
   * appraisals of other individuals with whom the minor has a familial relationship,
   * relationships legally recognized as privileged (lawyers, doctors, clergy), or
   * religious affiliations or beliefs.

#### Parental Consent and Assent when Research Participants are Children

Parental permission must be provided by at least one parent or guardian in non-exempt research involving children. In instances where the research presents more than minimal risk and provides no direct benefit to the subject, is required, with exceptions discussed below.[[3]](#footnote-2)

##### **Is Permission from Both Parents Required?**

Permission by one parent or the guardian may be sufficient when

1. the research involves no more than minimal risk; or
2. the research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.[[4]](#footnote-3)

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, when

1. the research involves greater than minimal risk and no prospect of direct benefit to the individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition; or
2. the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

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| **Assigned To One of Four Risk Categories** | **# Parents Consent Required** |
| 1. Research not involving greater than minimal risk | 1 or both parents |
| 1. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects | 1 or both parents |
| 1. 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 | Both parents required1 |
| 1. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (the research needs approval from the HHS Secretary or the FDA commissioner). | Both parents required1 |
| *1Unless 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.* | |

##### When May the IRB Waive or Alter the Requirement of Parental Permission?

1. The IRB may waive or alter the requirement of parental permission if informed consent could be waived or altered in accordance with 45 C.F.R §46.116(c), (d).[[5]](#footnote-4)  i.e., to waive or alter the requirement of parental permission, the IRB must have found and documented that
   1. the research meets the following:
      1. The research involves no more than minimal risk to the subjects;
      2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
      3. The research could not practicably be carried out without the waiver or alteration; and
   2. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

or

* 1. the research is on Public Benefit or Service Program such that
     1. The research is conducted by or subject to the approval of state or local government officials, and designed to study, evaluate, or examine
        1. public benefit or service programs,
        2. procedures for obtaining benefits or services under those programs,
        3. possible changes to the programs, or
        4. possible changes in methods or levels of payment for benefits or services under the programs; and
     2. The research could not practicably be carried out without the waiver or alteration.

1. Parental permission may also be waived if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). It may waive the permission requirements provided that the Investigator has instituted an appropriate mechanism to protect the children-subjects, and that the waiver is consistent with law. The choice of an appropriate mechanism would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.[[6]](#footnote-5)

##### **The Order of Parent Permission and Child Assent**

The Regulations do not specify the order in which the Investigator should seek parental or guardian permission and child assent. The IRB has the discretion to determine the appropriate order given the research and the context in which it will be conducted.[[7]](#footnote-6)

In general, parental or guardian permission should be sought before seeking the assent of a child, particularly in more than minimal risk research, unless the requirement for obtaining parental or guardian permission can be waived. There may be some cases, however, involving no more than minimal risk research, where it would be reasonable to seek child assent before seeking parental permission.

For example, a school-based study of minimal risk (e.g., investigating children’s responses to music), could be posed to children in the school setting. Children could be asked if they want to participate and if so, sent home with a request for parental or guardian permission. In all cases, except when the requirement for obtaining parental or guardian permission can be waived, parental or guardian permission, even if sought after child assent is provided, is required before the child can be enrolled in the study.

##### **The Priority of Parental Permission and Child Assent**

If a child is capable of assent and the IRB requires that assent be sought, it must be obtained before the child can participate in the research activity.[[8]](#footnote-7) Thus, if the child dissents from participating in research, even if the child's parents or guardian has granted permission, the child’s decision prevails.

However, the regulations state at 45 C.F.R. § 46.408(a) that the IRB may waive the assent requirements if the intervention or procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of research. Conversely, if a child assents to participate in research, and parental permission has not been waived by the IRB, the permission of the parents or guardian is also required before the child can be enrolled in the research.

##### **How Should Assent Be Documented?**

The Regulations do not require documentation of assent.[[9]](#footnote-8) 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 should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent’s assent. If young children are involved who are unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not required.

**Assent**

The IRB must determine whether researchers have adequate provisions to solicit assent, when the children are capable of providing it. The researcher must inform the IRB how the affirmative assent of the child will be documented, e.g., by signature on assent form, documented by the researcher, or other. In Hawaii, a researcher for an experimental drug study must normally obtain the assent of any child participant 7 years or older. For studies involving children 7 to 17 years, the IRB recommends that researchers document the child's willingness to participate with a signed assent document. A child’s capacity to assent must be evaluated on an individual basis.

**Assent Document**

* Should include any information that can affect a child’s decision to participate - an explanation of the proposed research procedures (procedures that are not part of the child's care should be described as optional), the research purpose, and any discomforts.
* Should use language that is geared to the cognitive level of participating children. The language used in the parental consent document might also be suitable for an older teen.
* Might more appropriately be obtained orally (omission of signature) for younger children (younger than 7 years but old enough to be consulted about participating in research).

See Assent Form Template on the Human Subjects Research website.

**Assent Not Required or Waived**

At the request of a researcher, the IRB may determine no assent is required in one or more of the following circumstances (including FDA regulated protocols):

* Children are not capable of assenting, after taking into account the ages, maturity, and psychological state of the children involved, either for all the children or for each child.
* 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.
* Customary conditions for waiver or alteration of consent are satisfied (45 CFR 116 or 21 CFR 50.55(d)).

**Special Circumstances:**

1. **Parents or Guardian Are Unavailable**

Generally, a researcher may not involve a child in research if the parent(s) or guardian are not available to provide permission and the IRB has not waived parental or guardian permission. In Hawaii, a researcher may be able to involve children for research involving treatment:

* Under certain circumstances where (i) the child is residing with a non-parent relative, (ii) the care of the child has been entrusted by a parent or guardian to an adult, or (iii) the child is in the custody of foster parents, a juvenile court, a social worker or probation officer, and
* When certain conditions are satisfied, e.g. completion of a “Caregiver’s Authorization Affidavit,” issuance of a court order.

**These laws are complex:** Contact the University of Hawaii (UH) General Counsel’s Office for guidance.

1. **Children Who Are Wards**
   * Laws limit research with children who are “wards” of the State or other agency, institution or entity.
   * The IRB may approve a protocol that involves wards and research involving greater than minimal risk with no prospect of direct benefit to participants (under 45 CFR 46.406 or 21 CFR 50.53) or not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (under 45 CFR 46.407 or 21 CFR 50.54) only if the study is:
     1. related to their status as wards,
     2. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the participating children are not wards.

If the research is approved under the above conditions, the IRB shall 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 in a study.

***Note:*** The above does not apply for research approved under 46.404 or 405, 50.51 or 52.

**Who may be an advocate?** An advocate: i) has the background and experience to act in (and agrees to act in) the best interest of the child for the duration of the research, and ii) is not associated in any way with the research (except as an advocate, or member of the IRB), the researchers, or any guardian association.

* Researchers are responsible for: i) informing the IRB when the study intends to include children who are wards; and ii) compliance with any relevant requirements of the competent court, agency, institution, or entity of which the child is a ward.
* For *research involving medical care* for wards of a court, an order from the judge is often required, in addition to permission from the person charged with the care of the child

1. **Guardians – Restrictions on Authority**

**Medical Care (no research involved):** In Hawaii, a guardian normally has the same authority with respect to the child as a parent having legal custody, except as limited by statute or court order (e.g. the legal document establishing the guardianship).

**Research Involving Medical Care: A guardian’s authority to consent is restricted** in the following circumstances (in the absence of an affirmative court order):

* terms of any letters of guardianship issued by a court (a certified copy of which should be obtained and placed in the medical record),
* surgery on a child 14 years or older, unless (i) the child also consents, (ii) the guardian obtains a court order, or (iii) the guardian has determined based on medical advice that an emergency exists in which the child faces loss of life or serious bodily injury if the surgery is not performed,
* administering an “experimental drug”; e.g., FDA investigational drug), unless a 7 years or older child also consents and the drug is related to maintaining or improving health or obtaining information about a pathological condition of the child,
* authorizing electro-convulsive treatment,
* admitting the child to a “mental health treatment facility” without the child’s consent,
* authorizing antipsychotic drugs except under certain circumstances,
* authorizing an elective procedure performed primarily for the purpose of rendering the child sterile (i.e., not treatment which secondarily results in sterilization),
* authorizing psychosurgery under any circumstances.

See Resources below for applicable CA laws.

1. **Minors who may Consent as Adults, including Emancipated Minors**

***In Hawaii****,* minors may consent to participation in research without parental or guardian permission if legally emancipated and in certain treatment circumstances. An “emancipated minor” may consent to participation in any type of research.

In addition, *for research involving treatment* certain **un**-emancipated minors may consent to research involving specific types of medical treatment, including:

* Outpatient mental health treatment for a minor 12 years or older when certain criteria are met,
* Hospital, medical or surgical care related to prevention or treatment of pregnancy for minors (any age),
* Medical care related to diagnosis/treatment of a communicable reportable disease or condition,
* Hospital, medical or surgical care related to rape for a minor 12 years or older,
* Hospital, medical or surgical care related to sexual assault but must attempt to contact parent/ guardian unless reasonably believe involved,
* Care for alcohol or drug abuse. See Resources below for applicable CA laws

**Mandatory Reporting of Child Abuse and Neglect**

UH has strict requirements for the reporting of child abuse and neglect. Researchers should be aware of UH requirements and their obligations under Hawaii law. See Resources below.

Resources:

**FDA**

• 21 CFR 50 Subpart D Additional Safeguards for Children in Clinical Investigations

• 21 CFR 50.55(d) Waiver or alteration of consent

**OHRP**

• 45 CFR 46 Subpart D Additional Protections for Children Involved as Subjects in Research

• 45 CFR 46.116(c) or 46.116(d) General requirements for informed consent.

• 45 CFR 46.408(c) Requirements for permission by parents or guardians and for assent by children

• Children Involved as Subjects in Research: Guidance on HHS 45 CFR 46.407 ("407") Review Process

*The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question. (AAHRPP Element II.4.B)*

If you have questions, contact the UH Human Studies Program at 808.956.5007

1. 45 C.F.R. § 46.116(a). [↑](#footnote-ref-0)
2. 45 C.F.R. § 46.116(b). [↑](#footnote-ref-1)
3. 45 C.F.R § 46.408(b). [↑](#footnote-ref-2)
4. Id. [↑](#footnote-ref-3)
5. Informed Consent FAQ, supra note 73 at Questions 28, 29. [↑](#footnote-ref-4)
6. 45 C.F.R. § 6.408(c). [↑](#footnote-ref-5)
7. Children FAQ, supra note **Error! Bookmark not defined.** at Question 15. [↑](#footnote-ref-6)
8. Id. at Question 16. [↑](#footnote-ref-7)
9. Children FAQ, supra note **Error! Bookmark not defined.** at Question 14. [↑](#footnote-ref-8)