Informed Consent and Assent

Informed consent is an ongoing process that begins with the initial presentation of a research activity to a prospective human participant by the Investigator, or a member of the study team, and continues through the end of the research activity. The process of informed consent is fundamental to ensuring the continuous and adequate disclosure of research risks and benefits before agreement to participation.

209.1 Requirement for Informed Consent

Unless waived by the IRB, legally effective informed consent must be obtained from participants or their legally authorized representative(s) as a condition for their research participation. All pertinent requirements in the OHRP’s 45 C.F.R. §§ 46.111 and 46.116, and the FDA regulations in 21 C.F.R. §§ 50.20, 50.25, 50.27 and 56.1111 that are applicable to the consent process and the consent document to be used for the research must be satisfied prior to approval of the protocol or proposal.

Assessing research compliance includes the evaluation of informed consent requirements. This is operationalized by:

1. The IRB review of the informed consent process information and document(s) provided by the Investigator.
2. Survey and comparison of signed and dated consents with the IRB-approved consent documents during review process by the Compliance Specialist.
3. Observation of the consent process, performed either as a periodic review function of the Compliance Specialist, or as request by the convened IRB.

209.2 Elements of Informed Consent

Legally effective informed consent includes the eight (8) basic required elements of disclosures and the six additional elements of disclosures specified in 45 C.F.R. 46.116 and 21 C.F.R. 50.25. See GUIDE 608: Informed Consent Requirements Checklist for the list of elements of disclosures.

Informed consent requirements for vulnerable and other special populations are addressed in Section 209.6.

209.3 Additional Consent Requirement

New Findings: During the process of obtaining informed consent, the Investigator must provide participants with a statement that significant new findings developed during the course of the research
which may relate to the participants’ willingness to continue participation. The Investigator must also provide that information to already enrolled participants.

The UH OGC provides assistance to investigators and the IRB in resolving any conflicts among applicable laws.

1. Hawai’i Law
2. HIPAA
3. HIV Testing/ Research on AIDS
4. Biospecimen and Biorepositories
5. International Research
6. Other Federal Agencies

1. Hawai’i Law

Under Hawai’i Law, there are specific requirements regarding the informed consent process under certain situations.

**Hawai’i Law on Health-Care Decisions Act:** Under the Hawai’i Uniform Health-Care Decision Act a guardian, an agent, or a surrogate may make health-care decisions on behalf of a patient. If a patient is determined to lack capacity by the primary physician and no guardian, agent, or surrogate has been appointed or reasonably available, the primary physician must make reasonable efforts to locate as many interested persons as practicable. If the interested persons present could not come to consensus, any of the interested persons may seek guardianship through guardianship proceedings.

A health-care decision by a guardian takes precedence over that of an agent. A surrogate may make health-care decisions if the patient has been determined incapacitated and no guardian or agent has been appointed or reasonably available.

**Legally Authorized Representative (LAR):** The issue as to who can be an LAR is determined by the laws of the jurisdiction where the research is conducted. Hawai’i law does not specifically address the issue who can consent to participate in research on behalf of another individual. OHRP would consider an individual as an LAR under the Regulations if the law of the jurisdiction where the research is being conducted provides reasonable basis for authorizing an individual to consent on behalf of a prospective subject to participate in the research procedures.

Therefore, if research is conducted in Hawai’i, a guardian, an agent under a power of attorney, or a surrogate of a prospective subject may be the LAR to consent on behalf of the subject to participate in studies if the subject has been determined to lack capacity to consent. If research is conducted outside of Hawai’i, local law determines who may be an LAR.

**Guardianship:** Under Hawai’i law, "guardian" is defined as a person who has qualified as a guardian of a minor or incapacitated person pursuant to appointment by a parent, spouse, reciprocal beneficiary, or by the court. The term includes a limited, emergency, and temporary substitute guardian

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but not a guardian ad litem. The guardian may consent to medical care for the minor. This power of the guardian fits the definition of "guardian" under the Regulations. The IRB adopts the policy that a duly appointed guardian under Hawai‘i law is a guardian for the purpose of human participant research.

2. Health Insurance Portability and Accountability Act (HIPAA)

If the research involves protected health information (PHI) as defined by HIPAA, then HIPAA authorization may be included in the consent process. HIPAA authorization is an authorization to use or disclose PHI, and must be executed by a separate signature. The UH IRB accepts the HIPAA policies and language provided by the covered entities where the research will be conducted.

3. HIV Testing/ AIDS Research

Public Health System (PHS) Funded Research: If the research is supported financially by the DHHS and includes testing for HIV, the consent documentation must state that identifiable participants will be informed of their results and provided with the opportunity for counseling. The IRB requires this except in cases where it is not required by PHS policy.

4. Biospecimen and Biorepositories

The NIH Guidance on Data and Tissue Repositories provides pertinent information for investigators who collect data or tissues of participants for repositories, and HSP staff and IRB reviewers who review such protocols.

When such repositories collect individual identifiable health information from participants, the HIPAA privacy regulations in 45 C.F.R. parts 160 and 164 must also be met. This may require either a written HIPAA authorization from the participants or a waiver of authorization by the IRB.

5. International Research

When conducting research in certain communities or social contexts, whether domestically in the U.S. or abroad, it may be inappropriate to document consent by using the standard written and signed consent document. Other consent procedures may be more culturally or socially sensitive and may provide better protection to participants.

Investigators may request IRB to approve a waiver or alteration of some of the mandatory elements of consent (45 C.F.R. § 46.116(d)), or a waiver of documentation of consent (45 C.F.R. § 46.117(c); 21 C.F.R. § 56.109(c)) as appropriate for the research. Such waiver or alteration of consent or documentation of consent must be approved by the IRB before the Investigator utilizes such documentation or process for obtaining consent.

6. Other Federal Agencies

Additional requirement may apply, depending on the sources of support/ funding. See GUIDE: Other Federal Agencies: - Additional Requirements.

71 § 560:5-102. HRS
72 § 560:5-208(b)(4), HRS.
209.4 Documentation of Informed Consent – Signature Requirements

Documentation of informed consent refers to a participant, or the participant’s LAR, signing and dating an IRB-approved, dated consent document, which includes the eight basic elements of informed consent and the six additional elements of informed consent, when appropriate (45 C.F.R. § 46.116; 21 C.F.R. § 50.25(a),(b)).

Documentation of Informed Consent – Signature Requirements

When a person agrees to be a participant in a research study, signing the consent document indicates that they have participated in the consent process, and understand the information provided to them. Documentation requirements for informed consent are specified in OHRP in 45 C.F.R § 46.117(a),(b) and FDA 21 C.F.R. § 50.27(a),(b).

In order to approve research, the IRB must determine that informed consent will be appropriately documented, unless the IRB waives documentation under OHRP or FDA regulations (see Section 209.5 below.). If a participant lacks the capacity to consent, then consent for research must be obtained from the participant’s LAR (See Section 209.6 below).

Consent is documented through the use of a written consent document signed and dated by the participant or the participant’s LAR that includes all the required elements of informed consent (see Section 209.2). Only the IRB-approved informed consent document and/or process may be used, and unless the requirement is waived by the IRB, the consent document must be signed by the participant (or the participant’s LAR), and a copy must be provided to the person who signed the form. FDA regulations required that the signature on the consent form also be dated.

Short Form Consent Process – Additional Signature Requirements

If a short form written consent document (see Section 209.5 on Short Form Consent) with the requirements and process specified in OHRP 45 C.F.R. § 46.117(b)(2) and the FDA regulations in 21 C.F.R. § 50.27(b)(2) is approved for used by the IRB, the following signatures are required to obtain legally-effective consent to participate in the study:

On the short form consent document (translated):
- Participant or the participant’s LAR
- Witness (the interpreter may act as the witness)

On the summary form (English):
- Person obtaining consent
- Witness (the interpreter may act as the witness)

For more detailed information on using the short form consent process see GUIDE 622: Informed Consent Process for Non-English Speakers and Persons with Limited Literacy.
Documentation of Informed Consent and Assent for Research Involving Children as Participants

In general, research involving children as participants requires the consent of the parents, or the legally appointed guardian. If the IRB deems that the children participants in a particular research are capable of providing assent, the committee may determine whether and how assent must be documented. See the following for further guidance:

- Children as Participants under Section 209.6
- GUIDE 623: Consent for Adults and Assent for Research Involving Children Requirements (includes children)
- Templates on HSP website for parental consents and assent forms

209.5 Types of Informed Consent Process and Documentation

The IRB requires the use of a full written consent form on research involving human participants. However, federal regulations permit a waiver or alteration of some of the mandatory elements of consent, or a waiver of documentation of consent with prior approval from the IRB.

The following are permitted variations of informed consent processes and documentation requirement:

1. Written informed consent by the subject or the subject's LAR;
2. Short form of consent documentation;
3. Waiver or alteration of the consent process; and
   a. Waiver or alteration of informed consent in non-emergency situations; or
      i. Research involving deception,
      ii. Research involving children: waiving parental permission,
   b. Waiver of informed consent for emergency research; or
      i. Planned Emergency Research,
      ii. Emergency Use of a Test Article,
4. Waiver of consent documentation requirements.

Written Informed Consent

In most circumstances, a written consent form, also called long form of consent documentation, is required, and only the current IRB-approved consent document may be used. If the long form of consent documentation is used, the Investigator must satisfy the following procedures:73

1. The consent document must include the required and appropriate additional disclosures;
   a. Research subject to FDA requirements need to include the additional following disclosures in the consent document:
      i. Statement noting the possibility that the FDA may audit the records that will be provided to each participant; and
      ii. Statement that a description of the clinical trial will be available on

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73 45 C.F.R. § 46.117(b)(1).
ClinicalTrials.gov as required by U.S. law.

2. The participant or the participant's LAR signs the consent document;
3. The Investigator must give the participant or the participant’s LAR adequate opportunity to read the consent document before he/she signs; and
4. The Investigator (or person obtaining informed consent) gives a copy of the consent document to the person signing the consent document.

If the majority of the potential participants to be enrolled do not speak English, the consent document shall be translated to the primary language of that majority and provided to those potential participants (see Short Form below for alternate option).

When necessary, the written consent form shall be read to the subject or the subject’s LAR. The original consent document shall be maintained by the Investigator.

Short Form of Consent Documentation

When only a small portion of potential participants will not be able to understand the consent document in English, short form consent documentation may be used for non-English speaking potential participants.

If the short form of consent documentation is used, the Investigator must satisfy the following procedures:
1. The short form of consent document states that the required and appropriate additional disclosures have been orally presented to the participant or the participant’s LAR;
2. A written summary must embody the required and appropriate additional disclosures;
3. The Investigator orally presents the required and appropriate additional disclosures to the participant or the participant's LAR;
4. A witness must be present during the oral presentation;
5. If the participant or the participant’s LAR does not speak English, the witness must be conversant in English and the language that the participant or the LAR speaks;
6. The participant or the participant’s LAR signs the consent document;
7. The witness signs the consent document and a copy of the written summary;
8. The person obtaining the consent signs the copy of the written summary;

A copy of the signed consent document and the signed written summary is given to the participant or the participant’s LAR.

Waiver or Alteration of Informed Consent Requirements

FDA regulations do not provide for a waiver or alteration of the informed consent process. The only exceptions to the informed consent requirement are for specified situations of emergency use of a test article (see section here, and SOP 121: Emergency Use of a Test Article), and waiver granted for planned emergency research (see SOP 122: Planned Emergency Research, and GUIDE 624: Planned Emergency Use Research). Aside from emergency research, the remainder of this section’s discussion below applies only to non-FDA-regulated research:

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74 45 C.F.R. § 46.117(b)(1).
75 45 C.F.R. § 117(b)(2).
1. Waiver or Alteration of the Consent Process
   a. **Non-Emergency Situation**
      i. Research Involving Deception
      ii. Waiver of Parental Permission/Guardian Consent
   b. **Emergency Research**
      i. Planned Emergency Research
      ii. Emergency Use of a Test Article

2. **Waiver of Consent Documentation** ("waiver of signature")

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**Waiver or Alteration of Informed Consent in Non-Emergency Situations**

Under OHRP 45 C.F.R. §§ 46.116(c) (d), and (e), IRBs have authority to alter or waive the requirement to obtain informed consent.

There are circumstances in which the IRB may approve research without meeting all of the required elements of informed consent. The IRB may approve the alteration or waiver of informed consent requirements if the Investigator demonstrates the following:

1. The research involves no more than minimal risk to the participant;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, participants will be provided with additional pertinent information after participation.

*Note:* The criterion, "the research could not practicably be carried out without the waiver or alteration," means that the circumstances make it impracticable to carry out the research if informed consent must be obtained. It does not mean that the circumstances make it impracticable to obtain consent.

Approval for alteration or waiver of informed consent requirement may also be granted if the project meets the criteria under 45 C.F.R. § 46.116(c) for research on certain public benefit or service programs, but such situations are rarely applicable.

To request a waiver or alteration of the informed consent process, the Investigator must address each of the criteria under 45 C.F.R. § 46.116(c) or (d) for a given research protocol or proposal in the **APP 04: New Research for Initial Approval, Non-Exempt Application**.

The IRB must find and document that all regulatory criteria under 45 C.F.R. § 46.116(d) (OHRP) are met and that the research is not subject to FDA regulations for it to approve an alteration or waiver of informed consent process.

**Special Considerations for Research Involving Deception**

In research involving deception, the Investigator may, with protocol-specific justification, request an alteration of the consent process. The IRB may approve the research, including the request to alter the requirement for informed consent if the Investigator demonstrates that deception or incomplete disclosure is necessary and addresses concerns relating to participant protection.

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76 45 C.F.R § 46.116(c), (d).
77 Id.
Use of a debriefing form and specific debriefing procedures is required with the protocol or proposal submission for IRB review and approval before its use. Debriefing forms will be considered as informed consent documentation, and only participants whose signatures are obtained through the debriefing form are considered consented participants.

See guidance documents on informed consents and **TMP 465** for debriefing form template.

**Research Involving Children: Waiver of Parental Permission/Guardian Consent**

Research regulated by the FDA is not eligible for waiver of parental permission, except for the use of an FDA test article meeting the emergency exception (see below).

The IRB may consider a request for a waiver or partial waiver of parental permission for minimal risk research to be conducted in a classroom (exempt category 1) or in situations where the child is a truant (e.g., runaway, refugee).

The IRB may waive parental permission by determining that the criteria for waivers or alterations are met. However, research is ordinarily not suitable for a waiver of parental permission if it involves any of the following issues:

1. Parental political affiliations or beliefs
2. Mental or psychological problems
3. Sexual behavior or attitudes
4. Illegal, antisocial, or self-incriminating behavior
5. Appraisals of other individuals with whom the minor has a familial relationship
6. Relationships legally recognized as privileged (lawyers, doctors, clergy), and
7. Religious affiliations or beliefs.

If the IRB waives the requirement for parental permission, the committee may require an alternative mechanism to protect child participants (e.g., appoint a qualified child advocate).

**Waiver of Informed Consent in Emergency Research**

**Planned Emergency Research**

“Planned emergency research” refers to research planned for emergency settings, including the planned use of a test article. Such type of research requires an extensive approval process, including FDA approval, prospective IRB review, and approval and consultation with representatives of the communities where the research will be conducted and from where participants will be recruited.

Investigators must submit a protocol application including a description of the informed consent process or a request to waive informed consent; often in emergency settings it is not possible to obtain informed consent from a potential participant when there is insufficient time and an LAR is not available.

The IRB may waive the requirement for informed consent in accordance with an exception under 21 C.F.R. § 50.24 (FDA) or 45 C.F.R. § 46.101(i) or 45 C.F.R. § 46.116(f) (OHRP), depending on whether or not the research is subject to FDA regulation, given that all required IRB determinations under these provisions can be made. Under these regulations, the IRB may allow planned research in an emergency setting without the informed consent of the participants or their legally authorized representatives in a limited class of emergent situations where the participant is in need of an emergency experimental
intervention, but cannot provide informed consent due to a life-threatening medical condition and there is not sufficient time to obtain consent from the participant’s legally authorized representative. This waiver does not apply to research involving fetuses, pregnant women, neonates (subpart B of 45 C.F.R. part 46), or prisoners (subpart C of 45 C.F.R. part 46).78

In addition, advance notice of such planned emergency research protocols will be provided to the OHRP pursuant to 45 C.F.R. § 46.101(i).

See also:
• Informed Consent Requirements in Emergency Research [OHRP]
• Exception from Informed Consent for Studies Conducted in Emergency Settings [FDA]
• SOP 122: Planned Emergency Research

Emergency Use of a Test Article

Emergency Use of a Test Article refers to the use of a test article on a human patient in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. Unlike planned emergency research, emergency use of a test article does not constitute research under the HHS regulations. Therefore, the patient may not be considered a research participant, and any data derived from the use may not be included in any report of research activities.79

The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each participant, the participant's LAR if the participant remains incapacitated, or a family member if such an LAR is not reasonably available, of80:

• The participant’s inclusion in the study, the details of the research, and other information contained in the informed consent document; and
• The right to discontinue participation in the research at any time without penalty or loss of benefits to which the participant is otherwise entitled.

If an LAR or a family member is told about the research and the participant’s condition improves and regains capacity for informed consent, the participant is to be informed as soon as possible. If a participant is entered into an emergency use situation with waived consent and dies before an LAR or a family member can be contacted, information about the usage is to be provided to the participant's LAR or family member, if feasible.

See SOP 121: Emergency Use of a Test Article for more details on and procedures to implement this type of procedure.

Waiver of Documentation of Consent – ("waiver of signature")

In some situations, a written consent form is used, but the participant or the participant's LAR is not required to sign the consent form. Per OHRP and FDA regulations81, the IRB may waive the requirement to obtain written documentation of informed consent. A waiver of documentation of consent, however, does not preclude the requirements of the consent process.

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79 45 C.F.R. § 46.103(b) (2014); HHS on Emergency Care, supra note 198.
81 OHRP (45 C.F.R. § 46.117 (c)) and FDA regulations (21 C.F.R. § 56.109(c))
Even if a waiver of documentation is granted by the IRB, the Investigator must still provide the participant with all of the necessary information described in Section 209.2. The Investigator is required to develop a complete and appropriate consent process, through an information sheet, or through an oral script in a language understandable to the participants. In all cases in which the requirement for documentation of consent is waived, the IRB may require the PI to provide participants with the written consent document with an option to sign the consent document, or with a written statement regarding the research.

Approval of a waiver of documentation is granted when the IRB finds that the protocol-specific justification for waiving documentation satisfies regulatory criteria. Specifically, the request for waiver must meet one of the following regulatory criteria:

(a) Under OHRP (45 C.F.R. § 46.117(c)(1) only, the IRB must find and document either:
   (1) the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant’s wishes will govern; or
   (2) the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context;

OR

(b) For research subject to OHRP and FDA regulations, the IRB must find and document that:
   (1) the research involves no more than minimal risk to participants; and
   (2) involves no procedures for which written consent is normally required outside of the research context.(45 C.F.R. § 46.117(c)(2), 21 C.F.R. § 56.109(c)(1)).

IRB approval to waive consent documentation must be obtained prior to research implementation.

See GUIDE 625: Findings for Waiver or Alterations of Consent Requirements on the HSP website.

Waiver or Alteration of HIPAA Authorization

In order to waive or alter a HIPAA authorization, the PI must provide sufficient information on which the IRB can determine that it meets the following three (3) findings specified by the Privacy Rule (45 C.F.R. § 164.512(i)(2)(ii):

1. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on;
   a. An adequate plan to protect the identifiers from improper use and disclosure;
   b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
   c. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule;
2. The research could not be practically conducted without the waiver or alteration; and
3. The research could not be practically conducted without access to and use of the protected health information.

### 209.6 Consenting Vulnerable and Other Special Populations

Special attention is given to protecting the welfare of vulnerable participants, such as children, prisoners, pregnant women, human fetuses and neonates, individuals with decisionally-impaired capacity, or economically or educationally disadvantaged individuals (45 C.F.R. § 46.111(b) and 21 C.F.R. § 56.111(b)). In fact, there are specific regulations governing research involving pregnant women, fetuses, and neonates (45 C.F.R. 46, Subpart B), prisoners (45 C.F.R. 46, Subpart C), and children (45 C.F.R. 46, Subpart D and 21 C.F.R. 50 Subpart D).

### Children as Research Participants

Children, with regards to human participant research, are individuals who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Hawaii, one under 18 years of age is considered a “child,” and may not legally give consent, although there are certain exceptions for emancipated and self-sufficient minors.

**Parental Consent:** As such, parental permission must be provided by at least one parent or guardian in non-exempt research involving children. The documentation of parental permission is similar to that of informed consent for the general population. The IRB may waive the requirement of documentation if it finds the waiver is appropriate under 45 C.F.R. § 46.117. See GUIDE 623: Consent and Assent for Research Involving Children.

**Assent:** The IRB determines whether child assent is required for a study if the children are capable of providing assent. In assessing whether children are capable of assenting, the IRB takes into account the age, maturity, and psychological state of the children involved, and the complexity of the proposed study procedures. The IRB also considers the degree of risk involved in the procedures. This judgment may be made for all children to be involved in a particular protocol, or for each child, as the IRB deems appropriate.

The IRB may waive the requirement of child assent in the following situations:

1. when the IRB finds that the capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. 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, or
3. consent may be waived in accordance with 45 C.F.R. § 46.116.

### Individuals with Diminished Decision-Making Capacity as Research Participants

All adults, regardless of their diagnosis or condition, will be presumed competent to consent to

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82 45 C.F.R. § 46.408(a).
83 See id.
84 45 C.F.R. § 46.408(a); OHRP Children FAQ, at Question 13.
participate in research unless there is evidence that their reasoning or judgment is impaired. Mental
disability alone will not disqualify a person from consenting to participate in research; rather, specific
evidence of the individual’s incapacity to understand and make a decision will be required.

**Assessing Capacity:** For individuals whose capacity appears diminished, there must be an
assessment of the participant’s capacity to consent to participate before the enrollment of the participant
in the study. The IRB may request that an assessment be undertaken by a qualified mental health
professional whose training and credentials are suitable for the assessment, given the nature of the
participant’s illness and the study. The assessor must be independent from the study to avoid the
appearance of conflicts of interest. The research plan must indicate how the capacity will be
assessed. Factors to be considered in the assessment include:

- the ability of the prospective participants to understand the research, and its risks and benefits;
- the prospective participant’s medical condition; and
- the voluntariness of the participant’s consent in the light of the subject's ability to assess the provided
  information and to make informed decisions.

**Consent:** If the prospective participant lacks the capacity to consent to participate in a research
study, consent can only be given by an individual who is the participant's legally authorized
representative (LAR) under the jurisdiction where the research is to be conducted. Officials of the
institution where the incapacitated patient resides are not generally considered as appropriate participant
representatives because their supervisory duties may give rise to conflicting interests. In that case, use of
a participant advocate is recommended.

If a participant’s capacity may become impaired during the course of a study, the protocol and the
consent form will detail the specific mechanisms for monitoring the participant to determine if there is a
decrease in capacity.

**Assent:** The IRB may require the Investigator to obtain assent from the participant and, if so, will
determine whether the plan for assent is adequate.

**Non-English Speakers and Persons with Limited Literacy**

The Regulations require that informed consent information must be presented in a language
understandable to the subject and, in most situations, in writing. When subjects do not speak or read
English, the requirements on documentation of the consent process can be met in two ways:

1. Consent documents written in the subject’s preferred language with all the necessary elements for
   legally effective informed consent; or
2. An oral presentation of informed consent information in conjunction with short form written
   consent.

See GUIDE 622: Consent Process for Non-English Speakers and Persons with Limited Literacy.

### 209.7 Consent Templates and Guidance

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85 45 C.F.R. §§ 46.116, 46.117.
86 OHRP, Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English, HHS (Nov. 9, 1995),
The Human Studies Program website provides various consent form templates which address the required elements of informed consent, as well as providing language for various situations (e.g., genetic testing, curriculum studies) and settings (e.g., anonymous online surveys) in which certain additional information may need to be provided to participants. Assent templates are also provided on the website for research involving children.

Guidance on consent documentation and process, including discussion on appropriate reading level and length for the various types of consent or assent, are also available on the website.

209.8 IRB Review of the Consent Process and Documentation

PIs shall refer to the GUIDE 601: Investigator’s Handbook for information regarding the development of an informed consent process and method of documentation appropriate to the type of research and study population.

PIs must submit for IRB review any consent document(s) and explanation of the circumstances under which informed consent will be sought for initial review, and whenever a modification to the consent process or documents is requested.

The New Research Application needs to include information necessary for the IRB to evaluate whether the informed consent process will be conducted appropriately given the research-specific situation (e.g., level of risk, inclusion of vulnerable population) and protects its participants adequately. Approval of informed consent process and documentation for non-exempt research is contingent upon the following four criteria:

1. Prospective participants or their LAR are given sufficient opportunity to discuss concerns and decide whether to participate in the research;
2. The possibility of coercion or undue influence are minimized;
3. The information provided about the research will be in a language that is understandable to the participant or the LAR; and
4. That no informed consent, whether oral or written, may include any exculpatory language, through which the participant or their LAR is made to waiver, or appear to waive, any of the participant’s legal rights, or which releases or appears to release the Investigator, sponsor, or institution from liability for negligence.

Any new information that could impact participants’ risk (e.g., adverse event) or procedure changes shall be submitted as a modification request, along with the consent documents appropriately updated and submitted for IRB review.

The IRB needs to be aware of the relationship between the person(s) who will recruit potential participants and obtain consent and the potential participant, to determine whether that the relationship sets the participants at risk for coercion and undue influence. The IRB requires that the circumstances of the consent process be culturally and linguistically appropriate for the intended participants.

The IRB also reviews any direct advertising (e.g., newspaper, TV or radio ads, posters, flyers, letters or postcards, emails, postings on bulletin boards/ internet/ web), since it is considered by the FDA “to be the start of the informed consent and subject selection process.” In order to approve advertisements, the IRB must determine that the direct advertising is not unduly coercive and does not promise a certainty of
cure or favorable outcome or other benefits beyond what is outlined in the consent and the protocol or proposal.

See

- GPM Chapter 207

Considerations during Full-Board Review

The IRB determines that all basic, and all additional elements of disclosure appropriate to the research, are included in the consent process. All the relevant requirements in OHRP in 45 C.F.R. §§ 46.109(b) and 46.116, and in the FDA regulations in 21 C.F.R. §§ 56.109(b), 50.20 and 50.25, that are applicable to the consent process and the consent document, must be satisfied for IRB approval.

Upon IRB approval, the consent form document must include the approval date and expiration date. If the consent form document was approved between review periods, the expiration date on that consent form shall reflect the expiration date provided in the previous continuing review (or initial review) approval letter.

209.9 Observation of the Consent Process

As part of the IRB oversight responsibilities, the IRB may require that an HSP staff member or an outside third party observe the consenting of research participants to determine:

- Whether the informed consent process has been appropriately completed and documented;
- Whether the participant has had sufficient time to consider study participation, that no coercion has been used by the consenting staff; and
- That the information presented to the participant reflects the content of the consent form and is conveyed in understandable language.

The IRB may require that one or more informed consent process situations be observed for selected protocols or proposals. IRB considerations used to choose such protocols include:

- High risk studies
- Studies that involve particularly complicated procedures or interventions
- Studies involving potentially vulnerable populations (e.g., ICU patients, children)
- Studies involving study staff with minimal experience in administering consent to potential study participants, or
- Situations when the IRB has concerns that the consent process is not proceeding well.

See:

- SOP 110: Quality Improvement Activities
- WKSH 322: Consent Observation Checklist
- WKSH 353: Post Approval Monitoring Checklist for Biomedical, Clinical Research
- WKSH 354: Post Approval Monitoring Checklist for Social & Behavioral Sciences Research