Policy Number: 31
Title: Documentation of Informed Consent for Human Subjects Research
Date of Last Revision: 01/21/2007; 01/16/2010; 04/19/2012; 02/06/2013; 04/04/2013; 04/19/2013; 06/05/2013; 10/17/2013; 02/11/2015; 04/10/2017; 06/19/2017; 07/21/2017; 06/27/2018; 08/21/19; 12/04/19; 01/15/20; 04/04/22, 06/24/22, 05/12/23

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that informed consent is documented in writing as determined in the IRB review and approval process.

I. **Three Options for Documentation of Informed Consent**
   A. The IRB may approve procedures for documentation of informed consent that involve either:
      1. A written consent form signed by the participant;
      2. A short form written consent with oral presentation; or
      3. In specific circumstances, a waiver of the signed written consent form.
   B. It is the responsibility of the IRB Committee to determine which of the procedures described below is appropriate for documenting informed consent in research applications that it reviews.

II. ***Option One:*** **Written Consent Form Signed by the Participant or Legally Authorized Representative**
   A. In most circumstances, the IRB should require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative.
   B. This consent form must embody the required elements of informed consent required by IRB Policy # 30, in addition to any applicable additional elements that are required by the Federal regulations.
   C. This form may be read to the participant or the participant's legally authorized representative. However, the Lead Researcher should allow the participant or the legally authorized representative sufficient opportunity to read and consider the consent document before it is signed. A copy of the document must be given to the person signing the form.
   D. The written informed consent document should embody, in language understandable to the participant, all the required elements necessary for legally effective informed consent (See IRB Procedure # 30.B).
   E. Participants who do not speak English should be presented with an informed consent document written in a language understandable to them.

III. ***Option Two:*** **Oral Presentation Using Short Form – Short Form Signed by Participant**

A. Participants Who Do Not Speak English

1. It is preferable that the written informed consent documents for non-English speaking participants embody, in a language understandable to the participant, all the required elements necessary for legally effective informed consent.
2. Alternatively, regulations permit an oral presentation of (long) informed consent information in conjunction with a short form written consent document, written in the language understandable to the participant. A witness to the oral presentation is required, and the participant must be given copies of the short form informed consent document and the IRB approved English version of the consent document.
3. The "short form" method for obtaining informed consent may be used for the **occasional and unexpected enrollment** of a non-English-speaking participant in a study for which no consent form in the participant's language has been prepared. Prospective IRB approval for the use of Short Forms is required.
4. Should a researcher believe that enrollment of non-English speaking participants is due to the nature of the disease or condition being studied and the anticipated study enrollment, study specific justification for the use of short forms must be provided in the IRB Application.
5. When this procedure is used the following steps are required:
   a. The oral presentation and the short form written informed consent document should be in a language understandable to the participant;
   b. A witness who is fluent in both English and the language of the participant should be present. The witness must sign and date both the short form written informed consent document and a copy of the IRB approved English version of the consent document.
   c. The person obtaining consent may not also be the witness to the consent.
   d. The participant must sign and date the short form written consent document.
   e. The person obtaining consent (e.g., the Lead Researcher) must sign and date a copy of the IRB approved English version of the consent document that is presented orally.
   f. Only those study team members who are approved by the IRB to obtain informed consent from research participants may obtain short form consent.
   g. A copy of the Experimental Subject's Bill of Rights (in a language understandable to the participant) should also be provided to all research participants considering participation in a medical experiment, per California Health & Safety Code. These are available on the IRB Forms page under the heading, 'Human Research Protections / Foreign Language Translations' – on the HRP webpage: https://research.uci.edu/human-research-protections/irb-forms/

a. Additional Experimental Subject's Bill of Rights translations may be requested by contacting the HRP office.

h. Once the participant has consented and eligibility is confirmed, the IRB approved English version of the consent document must be translated into the participant 's language by a professional or certified translator.

a. The translated consent form must be provided to the participant *within one month from the date that eligibility is confirmed.*

6. In general, for studies that involve greater than minimal risk a request for Short Forms will require full committee review. The IRB Chair or Vice Chair's has discretion on a protocol-by-protocol basis however and may decide that review of a request for Short Forms can occur at a subcommittee level. The reason for the level of review (full committee or subcommittee) should be appropriately documented in the IRB Checklist.
7. In the instance that the UCI IRB has approved Short Form use but the specific foreign language translation of the English Short Form *is not immediately available* on the UCI HRP webpage, UCI researchers may use the appropriate language translation of the Short Form *and Bill of Rights*, as available, and as found on the WCG IRB or Central IRB for the National Cancer Institute (CIRB) websites. In addition, other UC IRB translated Short Forms and Bill of Rights documents may be used, with agreement from the UC program Director or designee.

IV. ***Option Three:*** **Waiver of Documentation – No Participant Signature**

A. The IRB may waive the requirement for the Lead Researcher to obtain a signed consent form for some or all participants if the IRB finds either:
   1. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (Note: When the IRB waives the requirement for documentation under this condition, each participant must be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern); or
   2. That 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.

B. **For FDA regulated research**, when the clinical investigation involves no more than minimal risk, **an alteration of consent (e.g., waiver of documentation of consent) may be granted when**:
   1. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   2. The clinical investigation could not practicably be carried out without the waiver or alteration; and
   3. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

C. In cases in which the documentation requirement is waived, the IRB may require that the LR provide participants with a written statement regarding the research (e.g., Study Information Sheet).

V. **No Verbal Consent** - Verbal agreement to participate in a research study is not permitted unless the documentation or process of informed consent is waived by the IRB.

VI. **Use of Facsimile, Mail or Electronics to Document Informed Consent**

A. The IRB may approve a process that allows the informed consent document to be delivered by mail, facsimile or electronically to the potential participant or the potential participant's legally authorized representative and to conduct the consent interview by telephone when the participant or the legally authorized representative can read the consent document as it is discussed.

B. In addition, there may be times when the use of an electronic consent documentation process is most appropriate. The consent may be electronically delivered to the potential participant's legally authorized representative (e.g., via DocuSign). Again, the consent process may be conducted by phone or video, while the participant or the legally authorized representative read the consent document as it is discussed.

C. OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required.

D. FDA regulations set forth the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper (see 21 CFR 11.1(a)). In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under 21 CFR part 11. The electronic system must also capture and record the date that the participant or participant's LAR provides consent (see 21 CFR50.27(a)).

E. All other applicable conditions for documentation of informed consent must also be met when using any of the above procedure.

References:

45 CFR 46.111
45 CFR 46.116 and 46.117
21 CFR 50 and 56
21 CFR 11
OHRP Guidance Document, "Informed Consent, Non-English Speakers" dated November 1995.
FDA Information Sheets, "Guidance for Institutional Review Boards and Clinical Investigators", 1998
FDA Information Sheet, "IRB Waiver of Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects", July 2017: https://www.fda.gov/media/106587/download
OHRP "Use of Electronic Informed Consent: Questions and Answers": https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html#tocq6

Procedure Number: 31.A
Title: Procedure for Documentation of Informed Consent for Human Subjects Research

Procedure:
The purpose of this procedure is to provide guidance on documentation of prospective, legally effective informed consent from research participants or their legally authorized representative.

I. **Lead Researcher (LR) Responsibilities**

A. All informed consent documents (full written documents, oral scripts, Study Information Sheets, short forms, and assent forms) will be submitted to the IRB with the new study submission.

1. It is highly recommended that UCI informed consent templates be used to draft all written informed consent documents. Biomedical and Social/behavioral templates are located on the IRB website at https://research.uci.edu/human-research-protections/irb-forms/ and under the heading "IRB Consent Forms."
2. Informed consent documents (ICD) will be written in language that is at the appropriate reading and comprehension level for the targeted population. Generally, a sixth to eighth grade reading level is recommended for adult consent documents.
3. **When considering which researchers names should be included on the ICD as those who are capable of *finalizing* the consent process (i.e., those authorized to obtain verbal or written consent from participants), the following guidelines apply:**
    a. **For minimal risk research, the LR must list their name on the ICD.**
    b. **For greater than minimal risk research, the LR and Co-Researchers (CR) who are approved by the IRB to finalize consent must be listed on the ICD.**
    c. **For greater than minimal risk research that involves the application of an investigational drug, device, or surgical procedure, only a United States (US) licensed medical doctor or US licensed nurse practitioner may finalize the consent process.**
        (1) We realize and appreciate that Departments may have specific policies related to consent that may be more restrictive. Researchers should be aware of these policies and adhere accordingly.
4. The IRB recommends that the informed consent documents apply to the following division of target populations:
    a. Age 18 or older utilizing the adult informed consent document;
    b. Ages 13 to 17 utilizing a combination assent/parental permission form, in the same language as the adult informed consent document;
    c. Ages 7 to 12 utilizing an assent form written simply and at a comprehension level appropriate for a 7 year old; and
    d. Less than 7 years of age utilizing an oral script in very simple

language appropriate for children of this age group.

B. Obtaining Informed Consent

1. The LR will provide a copy of the currently approved and IRB date-stamped informed consent documents to the participant or his or her legally authorized representative.
2. A surrogate decision-maker may grant permission for an individual to participate in research provided that use of the surrogate consent process has been requested by the LR and approved by the IRB.
3. The LR will provide the participants or his or her legally authorized representative adequate time to read the consent, ask questions, and consider the risks and/or benefits to participation in the research study prior to obtaining their signature.
4. Assent or dissent and documentation of such are to be obtained as directed by the determination of the IRB Committee.
5. Participants or the participant's legally authorized representative will provide a signature and the date of signature on all informed consent documents, unless a waiver of documentation has been requested by the LR and approved by the IRB.
6. For FDA-Regulated Studies using an electronic process to document consent, the LR must use DocuSign Part 11 for obtaining signatures on the Informed Consent Form.

C. Non-English Speaking Participants

1. Translation of English Language ICD and all recruitment material: Participants who do not speak English should be presented with an informed consent document and recruitment materials written in a language understandable to them.
   a. Translations for targeted populations that are non-English speaking must be submitted for review and approval. The LR may wish to delay translation until IRB approval is granted for the English version informed consent documents (including recruitment materials) to avoid extra translation costs.
   b. Translation Requirements:
      (1) Greater than minimal risk studies: professional or certified translation of ICD and recruitment materials is required for studies that pose more than minimal risk to participants.
      For a professional translation the LR must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. Include any credentials, certifications, education, native language fluency, etc. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials.
      (2) **Minimal risk studies:** Studies that are eligible for expedited review also require translation of ICD and recruitment materials; however, certified translation is not required. The IRB will accept documents translated by an individual fluent (i.e., can speak, read, and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. A letter from the translator describing their qualifications must be provided with the translation documents.
2. Use of Short Form Consent Document

a. Investigators requesting the short form consent process must request this use via the IRB application.
b. When informed consent is documented using the short form consent procedure for non-English speaking participants, the following is applicable:
    (1) The IRB approved English version of the consent document and the short form consent documents will be provided in a language understandable to the participant.
        (a) This includes a verbal translation of the English version of the consent form (i.e., the "long form"), along with a hard copy of the short form, written in a language understandable to the participant;
    (2) A copy of the Experimental Subject's Bill of Rights should be provided to all research participants considering participation in a medical experiment (provided in a language understandable to the participant);
    (3) A witness who is fluent in both English and the language understandable to the participant should be present; and
    (4) Once the participant has consented and eligibility is confirmed, the IRB approved English version of the consent document must be translated into the participant's language by a professional or certified translator. *The translated consent form must be provided to the participant within one month from the date that eligibility is confirmed.*
c. Required signatures for short form consent procedures include:
    (1) The short form document should be signed and dated by the participant;
    (2) The IRB approved English version of the consent document should be signed and dated by the person obtaining consent as authorized under the protocol; and
    (3) The short form document and the IRB approved English version of the consent document should be signed and dated by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.
d. It is important to note that the FDA states that investigators should carefully consider the ethical/legal ramifications of enrolling participants when a language barrier exists. If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective.

D. Waiver of Documentation of Informed Consent
1. The Investigator will assess the proposed research to determine if it meets regulatory requirements for a waiver of documentation of informed consent.
2. The Investigator will complete and submit for review a justification for the Request for a waiver of written (signed) informed consent.
3. When the IRB waives the requirement for documentation of informed consent because the principal risk would be potential harm resulting from a breach of confidentiality, each participant must be asked whether he or she wants documentation linking him or her with the research, and the participant's wishes will govern.

E. Any revisions to the informed consent process or documents will be

submitted to the IRB for review and approval as presented in the amendment policy and procedure (See IRB Policy # 17).

II. **IRB Committee Responsibilities**

A. The LR's plan to obtain informed consent should be assessed by the IRB Committee, the Chairperson, or designee must determine that the appropriate requirements are met.

1. The IRB should consider the nature of the proposed participant population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved);
2. All elements of consent as required by the Federal Regulations, as well as any appropriate additional elements are incorporated into the documents;
3. Provisions have been made if the study is to include non-English speaking participants and the translated documents have been (will be) verified to be in a language understandable to the participant;
4. The IRB Reviewers must assure that provisions for obtaining surrogate decision-maker consent are reviewed for appropriateness, when applicable;
5. The reviewers are to verify that the informed consent documents match the protocol narrative and IRB application. If not, the Reviewer or Committee will request revisions prior to granting approval;
6. The Reviewers will assure that the written language is in lay terms with correct grammar, spelling, and punctuation for readability and understanding.

B. In order to determine that the use of the short form process is acceptable, consider whether the investigator has addressed or acknowledged all of the following criteria as outlined in the IRB Application:

1. Provided a compelling and sound rationale for use of the short form consent.
2. The short form states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
3. A written summary (i.e., IRB approved English version of the consent document) that embodies the basic and required additional elements of disclosure has been included.
4. A witness will be present for the oral presentation.
5. For participants who do not speak English, the witness will be conversant in both English and the language of the participant.
6. The participant or the participant's legally authorized representative will sign and date the short form consent document.
7. The witness will sign both the short form and a copy of the IRB approved English version of the consent document.
8. The investigator or designee actually obtaining consent will sign a copy of the IRB approved English version of the consent document.
9. A copy of the short form consent will be given to the participant or the legally authorized representative.
10. A copy of the IRB approved English version of the consent document will be given to the participant or the legally authorized representative.
11. A copy of the Experimental Subject's Bill of Rights should also be

provided to all research participants considering participation in a medical experiment.

C. The IRB must review all amendments to the informed consent process or documentation. A determination of the necessity of re-consenting participants must also be rendered.

D. When the research includes children, the IRB must determine whether assent is required, for what ages assent is required, and how assent is to be documented.

E. Decisions to waive documentation of informed consent are documented in the IRB approved protocol and IRB minutes, if applicable.

III. **IRB Analyst or Higher Responsibilities**

A. The Analyst will conduct a pre-review of all informed consent documents submitted for IRB review and approval utilizing the informed consent checklist.

B. Correspondence recommending pre-review changes to the informed consent documents are sent to the LR by the Analyst in the electronic IRB submission and management system.

C. Once final approval is granted by the IRB, the informed consent documents will be stamped with current “Date of IRB Approval” (See IRB Policy # 34).

D. Changes to the informed consent process and/or documents are to be completed according to the IRB amendment request policy and procedure.

E. Appropriate electronic IRB submission and management system entries are to be completed.

References:

45 CFR 46.111
45 CFR 46.116 and 46.117
21 CFR 56.109
OHRP Guidance Document, “Informed Consent, Non-English Speakers” dated November 1995.
OHRP IRB Guidebook, “Protecting Human Research Subjects: Institutional Review Board Guidebook"
FDA Information Sheets, “Guidance for Institutional Review Boards and Clinical Investigators”, 1998