UNIVERSITY OF SOUTH ALABAMA

IRB SOP 702
Informed Consent Documentation

Purpose

This Standard Operating Procedure (SOP) document describes the policies and procedures for documenting informed consent from human research subjects. It does not address the topics of parental permission, assent from children, or the emergency exception provision.

Scope

This SOP applies to all activities associated with the process of obtaining and documenting the informed consent process under the auspices of the University of South Alabama.

Policy

1.0 Written documentation of consent

Researchers are required to obtain written documentation of consent, unless this requirement is waived by the IRB. This means providing subjects with a written version of the required elements of consent and obtaining the subjects' signature or other mark on a written document as documentation of their decision to participate in the research.

2.0 Consent is a process, not a document

Obtaining consent is an active ongoing process that involves more than the documentation of consent. The process involves an information exchange and on-going communication that takes place between the researcher and the prospective subject.

2.1 Obtaining a signature on a consent form does not necessarily complete the consent process. For example, researchers are required to provide subjects with any new information that arises during the study that may affect the subject's

decision about whether to continue participation.

3.0 Who signs the consent form

3.1 The subject or the subject's legally authorized representative (LAR) must sign and date the consent form at the time of the consenting process and only after all questions are answered and s/he agrees to participate in the study.

3.2 It is USA IRB policy that the person who has obtained consent from the subject must also sign and date the consent form. This person may or may not be the researcher. This signature cannot pre-date the subject's signature.

3.3 Witness signatures are required by federal regulations in very limited circumstances. They can also be required by the IRB to assure an adequate informed consent process for some research studies.

4.0 Copy for the subject

It is USA IRB policy to provide the subject with a copy of the signed and dated consent form, unless the researcher requests otherwise and the request is approved by the IRB. A signed copy of the consent is not required for exempt research studies.

5.0 Records retention

The original signed consent form is considered a research record. The researcher is required to retain consent forms for a minimum of three years after the completion of the research (per federal regulation). The University retention period required by University of South Alabama is longer. See the USA Records Disposition Authority Policy. FDA regulated studies must keep records for two years after the approval of the last IND.

6.0 Consent Document

6.1 Regulatory requirements

The consent form is considered to be the written expression of the required elements of consent (listed and described in the *SOP 701: Informed Consent*). The consent form is required to conform to the general requirements for consent (e.g., in a language understandable to the subjects) and to contain all of the applicable specific elements of information (e.g., a description of the research procedures).

6.2 USA IRB Consent Form Templates

Though it is not an absolute requirement, researchers are encouraged to use one of the USA consent templates when drafting a consent form. Use of the templates ensures compliance with federal and state regulatory requirements as

well as USA-specific local context language. At its discretion, the USA IRB may require elements in the consent that exceed federal requirements.

6.3 Combination consent forms

It is acceptable to combine consent forms, when appropriate. For example, it is often efficient and easier for subjects to combine the parental permission for a child subject with the consent form used to obtain consent from the parent.

6.4 Consent and HIPAA Authorization

It is USA policy that documentation of consent and HIPAA authorization for the release and use of Protected Health Information (PHI) be included in one consent document, when the medical records are being obtained from USA Medicine or any of its affiliates.

6.5 Secondary studies and additional specific procedures

Some studies have secondary ("sub") studies or procedures that are related to the main study but not required for it. Examples include: drawing an extra sample of blood and analyzing it for a genetic marker; asking subjects to join a registry for being contacted about future studies; asking subjects for permission to put their data and/or specimens into a repository.

6.5.1 The IRB has the authority to determine whether these can be considered part of the main study, or whether they should be considered a separate study (with a separate IRB application). The issues that the IRB considers are:

- The degree of overlap with the already-approved study.
- Expectations about the future modification activities of the study, based on past experience with the study and the investigator.
- The impact of the additional activities on the complexity of the file and the study, and the IRB's consequent ability to adequately track and oversee the study activities.
- Whether the additions involve significant additional risk to subjects.

6.5.2 Consent for secondary studies and procedures can be documented in the following ways. The IRB has the authority to require the method it believes is most appropriate.

6.5.2.1 A separate consent form
Using a separate consent form may be best if there is

relatively little overlap with the main study, or if there is significant additional information (procedures, risks, etc.) to convey to the subjects.

6.5.2.2 Initials or signature on a section of the consent form
It may be most appropriate for the subject to document consent to secondary procedures by initializing or signing a sub-section of the study consent form. If this method is used, it must meet the following:

- The distinction between the main study and the secondary procedures is very clear and obvious – for example, the secondary procedures may be described within a labeled text box.
- The consent process must be an "opt in" process, not an "opt out" process. That is, if the initial/signature line is left blank, it is assumed that the subject did not agree to the additional procedures.

6.6 Who is listed on the consent form

The only research team members who must be named (identified) on the consent form are the lead researcher (principal investigator) and the subject contact person.

6.7 Signatures and dates on consent forms

The consent form should contain signature blocks or sections for each of the following, as appropriate for the study. Each signature block should include: a space for a clearly printed name. the signature, and the date of the signature.

6.7.1 The subject must sign and date the consent form at the time of the consenting process and only after all questions are answered and s/he agrees to participate in the study. Rare exceptions include blind or illiterate subjects and subjects unable to consent for themselves.

6.7.2 Legally-authorized representative (LAR)
LARs may provide consent when subjects are unable to do so.

- This signature should be obtained in a separate signature block entitled "Legally Authorized Representative". The LAR should not sign the subject's name, nor should s/he sign on the subject's signature line. However, the subject's full name should be supplied in the subject printed name block.

6.7.3 Research involving Children

Refer to *SOP 703: Informed Consent: Research Involving Children* for more information about the signature requirements for research involving children.

6.7.4 Researcher signature

The person who obtained consent from the subject must also sign and date the consent form if the research involves more than minimal risk to subjects. The signature cannot pre-date the subject's signature, but can occur after the subject has signed (for example, when the signed consent form is mailed to the researcher). The purpose of the signature is to document that the person has explained the research to the subject and answered the subject's questions.

6.7.3.1 This person may or may not be the lead researcher. If someone other than the lead researcher obtained the consent, then the lead researcher should not sign the consent form.

6.7.3.2 This signature section is not required if a one-on-one consent process will not occur. Examples: web surveys; questionnaires with consent forms that are distributed and returned by mail.

6.7.5 Witness signatures

Witness signatures are required by federal regulations in certain circumstances. They can also be required by the IRB if necessary to assure an adequate informed consent process. The witness signature means that the requirements for consent have been satisfied, and that consent is voluntary and freely given by the subject or legally-authorized representative.

6.8 Signatures and dates on forms: Methods

The standard expectation is that signatures will be handwritten using a permanent medium (such as ballpoint pen). However, the following alternatives are acceptable per federal regulations and USA policy:

6.8.1 Electronic signatures

Federal regulations allow electronic signatures if approved by the IRB. It is USA IRB policy to accept the use of a secure system for electronic or digital signature that provides an encrypted identifiable "signature." The USA IRB may approve other electronic methods under limited circumstances.
The IRB considers:

- How the electronic signature is being created.
- Whether the signature can be shown or verified to be legitimate (for example, an identified witness was present who can provide verification).
- Whether the consent document can be produced for review by the potential subject.

6.8.2 Returning a completed questionnaire or survey sent to subjects by mail/email/social media.

Under certain conditions, this can be considered an acceptable way of obtaining consent (if approved by the IRB). It is sometimes (incorrectly) referred to as "implied consent". However, it does not meet the requirements for documentation of consent. The IRB would need to waive the requirement for documentation of consent as part of its approval.

6.8.3 Subjects should not be required to initial and date each page unless it is an explicit requirement of the study sponsor.

6.8.4 Subjects who are unable to read or write can provide documentation of consent by **making a mark** in place of a signature on the consent document, when consistent with any applicable local law. See Section 6.0 below, for a more detailed discussion of obtaining consent and documentation from illiterate subjects.

6.9 Method for communicating consent document

Federal regulatory agencies have provided guidance that subjects may provide the signed consent form to researchers by any of the following methods: face-to-face, delivery, email, mail, fax, text message, and any other social or electronic media.

The participant or their legally authorized representative must be provided with a copy of the consent form prior to engaging in the informed consent conversation. This will allow ample time for the potential participant to review the consent and to use it as reference during the conversation.

6.10 Additional requirements

6.10.1 Language

The consent form must be in a language understandable by the subject.

6.10.2 Reading level

Most consent forms should be written so they are understandable to a lay audience. This means 8th grade reading level. However, a higher reading level may be acceptable depending upon the study population (for example, a study population of physicians or other highly educated individuals).

6.10.3 Include a version number and/or the date of creation/revision, usually in a header or footer. This USA requirement is important for ensuring that the IRB is able to follow the evolution of consent forms and the use of multiple consent forms in a single study. However, the IRB has the authority to revoke this requirement if it wishes. The decision to do so should be documented in correspondence (email or letter) with the researcher.

Adding a version number and/or creation/revision date is an administrative change that does not require submission of a modification and does not require re-submission of the consent form to any other IRB that may have already reviewed and approved the consent document.

- Missing version numbers and/or dates are not sufficient reasons in and of themselves for the IRB to grant Conditional Approval instead of Approval. Providing these missing elements is an administrative change, and the stamped approved consent document may be provided to the researcher when the corrections have been made.

6.10.4 Reader-friendly formatting

Consent documents should use reader-friendly formatting, including:

- Sufficient white space around the margins (1" margin) and between headings and paragraphs
- Use of subheadings, bulleted lists, tables, etc. to improve readability
- Use of clean, black, 12 point font (preferably times new roman) for easy reading by subject population

Procedures

1.0 Researcher responsibilities

1.1 Documentation of informed consent must be obtained prior to initiating any research activities, including screening procedures or extracting information

from records.

1.2 Researchers are required to use the current approved version of the consent process and form. Researchers are required by USA IRB policy to use copies of the approved, stamped consent form when obtaining documentation of consent from subjects, unless the IRB has approved an exception to this policy (for example, when electronic consent materials are being used).

2.0 Translation and interpretation

As part of each consent discussion, the researcher has an ethical and legal obligation to assess (informally or otherwise) the subject's understanding of the consent information to ensure that consent is truly informed. When the researcher and the subject do not speak the same language, the researcher must depend on the accuracy of the translated consent documents and the qualifications of an interpreter. In addition, the researcher's familiarity (or lack of it) with the subject's culture affects the communication. See the *SOP 705: Translation and Interpretation* for detailed information and USA IRB policies on this topic.

3.0 Standard method of documenting consent

Documentation is obtained by having the subject (or LAR) read and sign a standard consent form that meets all of the requirements described above in Section 3, including the requirement that the consent form is in a language understandable to the subject (or LAR). The person obtaining consent also signs the form.

4.0 Short Form consent document for Non-English Speaking Populations

For research participants who do not speak and/or read English, a short form consent should be used (Office of Human Research Protections 45 CFR 46.117(b)(2) and FDA 21 CFR 50.25; 50.27(b)(2)). This is a generic document stating that the required elements of consent (unless waived by the IRB) have been presented to the subject in the subject's language. A pre-approved English version, called TEMPLATE: Consent Form (Short), English is posted on the USA Human Subject's website or in IRBNet forms and templates.

Literate subjects should have the opportunity to read this form, in the subject's own language. (This means that a translated version of the Short Form must already be available to the researchers.) When the subject is illiterate, a qualified interpreter reads the Short Form to the subject in the subject's own language.

4.1 Summary document

Federal regulations require that there be a "summary" document that contains the specific information provided to the subject. The approved English language

consent document is almost always used for this purpose.

4.2 Interpreter
The Short Form document is read or presented to the subject by an interpreter who is fluent in both English and the subject's language. The interpreter also facilitates the question and answer phase of the consent process between the potential subject and the researcher (if the researcher is not the interpreter).

4.3 Witness
The witness must be an adult, fluent in both languages, who is *not a member of the research team.* If the interpreter is not a member of the research team, the interpreter may serve as the witness.

4.4 Signatures
The following signatures (or marks) must be obtained:
- 4.4.1 Short Form document: Signed by the participant and by the witness.
- 4.4.2 Summary document: Signed by the witness and by the person obtaining consent.
- 4.4.3 Distribution of copies. The participant is provided with a copy of the Short Form document as well as the Summary document.

5.0 Non-English speaking subjects

When the researcher or the IRB anticipates that the study population will include non-English speaking subjects, it is expected that the consent process will be conducted in the subject's own language.

However, the USA IRB recognizes that there are some circumstances when it is not possible to provide a translated version of the study's consent form. The cost of translations is not sufficient rationale for use of the Short Form process. See the *SOP 705: Translation and Interpretation* for more information.

While an interpreter may be helpful in facilitating the consent process, federal regulations do not allow routine ad hoc translation of the consent document by an interpreter and should not be substituted for a written translation.

6.0 Illiterate subjects

Federal regulations do not specifically address the process for obtaining consent and documentation of consent from illiterate participants (i.e., participants who cannot read the consent materials due to illiteracy).

6.1 The pertinent federal regulation is the requirement that "The information that is

given to the subject or the representative shall in be in language understandable to the subject or the representative." If the participant is illiterate, the written consent form would not be in language understandable to the participant.

6.2 USA IRB generally follows, for all research, the guidance provided by the federal Food and Drug Administration for research involving illiterate subjects (FDA; reference 7.3, section 4.8.9):

The consent materials are read to the subject in the presence of an impartial witness who observes the entire consent process.

6.2.1 Sufficient time is allowed for questions to be asked and answered, to ensure that the subject comprehends the consent information.

6.2.2 Documentation is obtained:

- If capable of doing so, the subject signs, or marks an X, to signify consent.
- The witness signs and dates the consent form. By doing so, the witness attests that the consent information was accurately explained, that the subject apparently understood the information, and informed consent was freely given.
- The person obtaining consent signs and dates the consent form.
- A signed copy is provided to the subject.
- The researcher considers using a video/audio recording of the consent discussion as part of the documentation of consent.

6.2.3 Alternative approaches

Alternative approaches may be used if approved by the IRB and if they satisfy the requirements of the applicable regulations. For example, on rare occasions, the IRB may approve a process that involves reading the consent form to the subject and noting it in some official record that is not part of the research records (for example, in the subject's medical record).

7.0 Subjects who can read but are physically unable to talk or write due to physical limitations

Subjects with these characteristics may be able to participate in research if they are cognitively competent and able to indicate approval or disapproval by other means. The consent form should document the method used for communication with the subject and the specific means by which the subject communicated agreement to participate in the study.

8.0 Obtaining consent remotely

IRB approval is needed for the use of remote consent in situations other than a public health emergency. Intended procedures must be outlined in the IRB application for

review and approval. Remote consent may be obtained through multiple methods including telephone, secure video conferencing, electronic consent platforms, interaction with a website. Consent obtained by these methods must still comply with all regulatory requirements about the process, the consent elements, and documentation of consent unless the requirements are waived by the IRB. When the study does not meet the criteria for waiving documentation of consent, the researcher may propose a consent documentation process as follows:

The participant receives a copy of the consent form in advance. For example, it could be mailed, emailed, or posted on a website. If mailed, two copies must be mailed so the participant or legally authorized representative is able to retain a copy for reference when their signed consent form is returned to the site. Once the research team receives the signed consent form from the participant, the person obtaining consent must sign and date the document using the current date.

The person obtaining consent must document a brief reason for performing the consent remotely, the method remote consent was conducted, the date of the consent discussion, and the date the signed consent form was received. This may be documented either directly on the consent document under the signature line or through an accompanying consent note.

The original final consent form must be filed with the research records and a copy of the final consent form, including all signatures, must be sent back to the participant either electronically or as a hard copy.

Additional guidance on strategies research teams may consider when utilizing a remote consent process can be found in the USA IRB Remote Consent Guidance document.

9.0 Other scenarios

Consult with USA IRB Office to determine appropriate procedures that comply with applicable regulatory requirements and conform to the Belmont ethical principles.

10.0 IRB Review and Approval

10.1 What is reviewed

The consent form and documentation process must be reviewed and approved by the IRB. Changes or supplements to approved consent forms must also be reviewed and approved by the IRB, as modifications. Approval must be obtained in advance.

10.2 Criteria for IRB approval

The IRB approves the consent form when the IRB determines that the requirements have been met, unless the IRB determines that the study meets the criteria for waiving documentation of consent.

10.3 Waiver of Documentation of Informed Consent

The IRB may grant a waiver of the regulatory requirement for documentation of consent. This means that consent is still obtained but that it is not documented with a signed form.

10.3.1 The investigator makes a preliminary decision to seek waiver of the documentation requirements for obtaining informed consent, as specified in the protocol submission.

10.3.2 The IRB may waive the documentation requirements to obtain a signed consent if:

- Non-FDA-regulated studies: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Study personnel must ask each subject whether the he/she wants documentation regarding the research; **OR**
- Non-FDA-regulated studies: The research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required (i.e., a cover letter or a phone script). **OR**
- FDA-regulated studies: The research presents no more than minimal risk and involves no procedures for which the IRB normally requires written consent.

10.3.3 When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the investigator will give to the participants. The IRB Office requires investigators use the "Waiver of Documentation of Informed Consent" template. Some federal agencies restrict the use of this waiver.

10.3.4 In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research

10.3.5 If the waiver of documentation of informed consent is part of a protocol submission reviewed by the convened IRB, IRB office staff will document the waiver of documentation of informed consent criteria and approval in the IRB meeting minutes.

10.3.6 If the protocol is eligible for expedited review, a notation will be made in the study file by the expedited reviewer documenting whether the study meets each of the criteria for a waiver of documentation of informed consent.

10.3.7 Consent scripts or similar descriptions

When the IRB has waived the requirement for documentation of consent, the IRB expects the researcher to create a script or other description of how the consent information and elements will be provided to subjects in place of a consent form. The IRB must review and approve the script or process.

10.3.7.1 The script or other description must be sufficiently detailed and specific that the IRB can ensure that all required elements of consent will be adequately included (unless waived by the IRB).

10.3.7.2 For other research, a word-for-word script may not be necessary as long as the researcher can provide the IRB with a sufficient description of how the consent elements will be communicated to subjects in place of the consent form. The USA IRB recognizes that, in some circumstances, reading from a word-for-word script may be inappropriate and could even negatively affect the consent discussion. It is the researcher's responsibility to bring such circumstances to the attention of the IRB, together with an explanation of how the consent elements will be adequately addressed.

10.4 Documentation of IRB approval

USA IRB places a date approval stamp on each page of the IRB approved informed consent document. The approved consent document is published as a board document in IRBNet online management system.

The IRB Office does not stamp consent documents if a study is permanently closed to enrollment, subjects are discontinued from protocol related treatment and remains open for long-term follow-up. If there are significant new findings such as increased risk that may require re-consent, the IRB Office will publish an updated and stamp consent. A change in Principal Investigator may be communicated by letter via the Clinical Trials Office or other administrative unit.

Regulated Documents:
45 CFR 46, 21 CFR 50, and 21 CFR 56

University Related Documents:
SOP 701: Informed Consent
SOP 703: Informed Consent: Research Involving Children
SOP 705: Translation and Interpretation

Related Forms:
Waiver of Informed Consent (located in IRBNet forms/templates)

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Responsible Office:

Office of Research Compliance and Assurance