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 ĵ[• 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 vŇ(Ő š Z šŒ]• µŒ]vP šZ •šµ Ç, š(Z šZ • µ i š[•

decision about whether to continue participation.

3.0 Who signs the consent form

3.1 dØs } Œ Z • µ i š [• o P o o Ç Œ E µ ‰ š Œ } Œ E] y š > š] Æ À µ • š] P v 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-

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

[illegible] } Œ ‰ Œ } µ Œ Œ E š Z s } 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 [illegible] oversee the study activities.
- Whether the additions involve significant additional risk to subjects.

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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 t for example, the secondary procedures may be described within a labeled text box.
- The consent process must be an ‰] vprocess, not an ‰ } µ š‰ Œ } • • X • dUZZ[v] š] o l •] Pv] š µ Œ• 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 ‰ Z ‰ Œtuhen su1E>32-4 30.00001 6(e)2 (c)3 (o)-1< (s)11 (p)-444 >

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) (œE š } • ^] u ‰ o}]v • v š _ X , } Á À • Œ v U } u š] š š š Z
requirement for documentation of consent. The IRB would need to (foro

(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.

x 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

6.10.4.1 Sufficient white space around tZ u Œ P]~ví•_ margin) and between headings and paragraphs
6.10.4.2 Use of subheadings, bulleted lists, tables, etc. to improve readability
6.10.4.3 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.
1.3 Researchers are required by USA IRB policy to use copies of the approval-stamped consent form when obtaining documentation of consent from subjects, unless the IRB has approved an exception to this policy (for example, when

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 subject, and