IRB SOP 702
Informed Consent Documentation

Purpose

This Standard Operating Procedure (SOP) document describes the policies and procedures for

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

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

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