**GUIDANCE: Consent Process and Documentation**

**Policy**: It is the policy of UTHSC-H that in obtaining and documenting informed consent, study personnel should comply with Good Clinical Practice regulations and abide by the ethical principles that have their origin in the Belmont Report.

**Key Terms**

**Exculpatory Language -** Language through which the subject is made to waive or appear to waive legal rights, or releases or appears to release the Investigator, the Sponsor, or the institution from liability for negligence.

**Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

**Principal Investigator:**The individual responsible for the conduct of a research study.

**Responsible Personnel:** The consent discussion may be conducted only by the Principal Investigator, collaborator or study staff listed in the approved CPHS Application as the designated individuals for conducting the consent discussion. The Principal Investigator should maintain documentation of delegation of consent responsibilities to appropriate individuals. This may be achieved by maintaining a study responsibility log.

The Principal Investigator should ensure that everyone in the study team who has permission to conduct consent discussions is adequately qualified and trained. They should have access to the most current CPHS approved consent documents. When study staff are authorized to conduct consent discussions, the participant should have access to the Principal Investigator or Co-Investigators to have their questions answered.

The researcher and the research team should plan how the consent process will be conducted and obtain approval from the CPHS. Information on who will conduct the consent discussion, where it will occur and how much time it will take should be included in the CPHS application form. All members of the study team who are authorized to obtain consent should have access to the current approved and stamped version of the consent document and HIPAA documents.

**Consent Process:** The consent discussion must take place in person, unless there is prior approval from CPHS to use an alternate method of obtaining consent such as phone, fax, email or mail. Consent must be obtained before performing any study procedures, including screening participants for study inclusion, unless specifically permitted by CPHS. Consent discussion should take place in a language that is preferred by the participant.

It is not appropriate to approach a participant immediately before a procedure or surgery, while in labor, while under sedation and any other situation where a participant might feel compromised, unless specifically approved by the CPHS. Many research groups approach the consent process as a team effort. The investigator seeing the patient first introduces the research study to the patient. If the patient is interested, the consent discussion is continued by a research staff. This is acceptable as long the investigator is available for answering questions that the participant might have.

Participants should be given adequate time to read the consent document and make a decision about study participation prior to signing the consent document. The term adequate time may differ depending on the research study. For very complex research studies involving greater than minimal risk, it may be advisable to conduct the consent discussion over more than one visit. After the initial discussion, the participant should be advised to take the consent document home and discuss with friends and family.

The study team should have a plan to minimize the possibility of coercion or undue influence when consenting potential participants. One method to avoid undue influence or therapeutic misconception is to have someone other than the attending clinician present the research study to potential participants.

The consent process is not a onetime event, but an ongoing process throughout the participant’s participation in the research. At every visit, the study team should ensure that the participant is aware that he / she is part of a research study and elicits the participant’s willingness to continue participation.

The information to be communicated to the participant should not include exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights; or release or appear to release the investigator, the sponsor, the organization, or its agents from liability for negligence.

**Assessing Comprehension:** If an individual decides to participate in a research study, the person obtaining consent should be satisfied that the individual has a clear understanding of the research. One method of ensuring that the individual understood the research is to ask questions about the research and judge whether the potential participant has a clear understanding. If necessary, the person obtaining consent should go over the areas that the potential participant is unclear about.

**Documentation:** When an individual agrees to participate in a research study, the potential participant, the person obtaining consent asks the participant to personally sign and date the consent document. The person obtaining consent should also personally sign and date the consent document. A copy of the signed consent document should be given to the participant.

A copy of the signed consent document should be placed in the participant’s medical records. It is advisable to have clear identification on each page of the consent document by pasting the patient label or writing the patient name and medical record number to ensure that these documents are not lost. The original signed consent document is to be filed with other essential study documents. It is also acceptable to have two original consent documents – one for the participant and one for the study files.

The person obtaining consent should also document the consent process in the medical records. This documentation should include the protocol title, who obtained consent, if any one was present with the subject during the discussion and whether the subject agreed to participate in the study. If the consent process took place over more than one visit, it is best practice to document the process at every visit. Research teams may choose to use a standardized form to place in the medical records, a template of the form is attached.

**English Speaking Participant Who Cannot Read/Write** - A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document. A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective participant and the specific means by which the prospective participant communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.

**Non-English Speaking Participants** – Consent documents should be in language understandable to the participant (or authorized representative). When the consent discussion is conducted in English, the consent document should be in English. When the study participant population includes non-English speaking people or the researcher anticipates that participants who are not comfortable speaking English will be recruited, a translated consent document must be submitted to the CPHS for review and approval.

**Non-English Speaking Participants** (translated consent document not available) - While a translator may be helpful in facilitating conversation with a non-English speaking participant, routine ad hoc translation of the consent document should not be substituted for a written translation. If a non-English speaking participant is unexpectedly encountered, researchers will not have a written translation of the consent document and must rely on oral translation. Researchers 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.

# Applicable Regulations and Guidance Documents

* 21 CFR 50
* 45 CFR 46.116 and 46.117
* ICH Good Clinical Practice: Consolidated Guideline
* FDA Guide to Informed Consent - Information Sheet (<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116333.htm>)
* "Exculpatory Language" in Informed Consent - Cooperative Oncology Group Chairpersons Meeting November 15, 1996

# References to Other SOPs

* Consent Process
* Consent LAR

# Attachments

* Template for Documentation of Consent Process in Medical Records

**If you find errors in this document, please contact** **clinicaltrials@uth.tmc.edu**

|  |  |
| --- | --- |
| **Document Number:** | 402-013 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | January 1, 2010 |
| **Revision History:** | None |
|  |  |
|  |  |