**GUIDANCE: Consent by Legally Acceptable Representative**

**Policy:** The UTHSC-H requires that informed consent must be obtained from all human subjects prior to their participation in any research unless the process, or any part thereof, has been waived by the CPHS. *(from CPHS Policy - Informed Consent)*. 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.

**Incapacitated:** Lack of ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to any proposed treatment decisions.

**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.

**Legally Acceptable Representative:** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.

**Assessing Competence**: As a general rule, all adults, regardless of their diagnosis or condition, should be presumed to be competent to consent unless there is evidence of a serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the concept of being a research volunteer, and capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evaluation to determine the individual’s understanding of the information relevant to thedecision; appreciating the information (applying the informationto one’s own situation); using the information in reasoning; and expressing a consistent choice.

In research that involves cognitively impaired persons, CPHS may set qualifications for the person making assessment such as requiring an independent psychiatrist or geriatrician to make this assessment. The independent assessment should be documented by a formal note that is dated and signed.

**Surrogate Consent:** Consent may not be obtained from legally authorized representative unless explicitly approved by CPHS. Texas law allows surrogate consent for treatment for an adult patient who is comatose, incapacitated, or otherwise mentally or physically incapable of communication.

When the CPHS has approved obtaining consent from legally authorized representatives, the investigators should obtain consent either from the patient’s legal guardian with the authority to make decisions regarding medical treatment or a person designated as a surrogate decision-maker by the patient in a medical power of attorney or Advance Directive. In the absence of either of the above, an adult surrogate from the following list, in order of priority, who is available after a reasonably diligent inquiry, may consent on behalf of the patient:

1. the patient's spouse (including a common law spouse);
2. an adult child of the patient who has the waiver and consent of all other qualified adult children of the patient to act as the sole decision-maker;
3. a majority of the patient's reasonably available adult children;
4. the patient's parents; or
5. the individual clearly identified to act for the patient by the patient before the patient became incapacitated, or the patient's nearest living relative.

If a dispute arises as to the right of a party to act as a surrogate decision maker, it may only be resolved by a court of record having jurisdiction under Chapter V, Texas Probate Code. Thus, researchers should not enroll a person in a trial if a dispute arises as to who has the authority to give consent and there is no court order granting such authority to someone (or some entity). There are some limitations on the authority of a surrogate decision-maker. All decisions must be based on knowledge of what the patient would desire, if known. Someone higher on the list can choose not to be the surrogate, in which case you would move on to the next person in the order of priority, however that person may not appoint someone else as the surrogate decision maker. Furthermore, health care providers are obligated to respect the wishes of a patient that are delineated in an Advance Directive or a Declaration for Mental Health Treatment, unless there are statutory provisions granting deviations from said documents.

**Consent Process:** 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. When possible, assent should be obtained from the research subject.

**Consent Documentation:** When an LAR agrees to the participation of the subject in a research study, the LAR and the person obtaining consent should personally sign and date the consent document. A copy of the signed consent document should be given to the LAR. The investigator or designee should document the consent process in the source document. In addition to the information documented in the medical records as per SOP Consent Process and Documentation, the person obtaining consent should also document the relationship of the LAR to the subject and how the individual was determined to be the LAR of the subject.

**Special Consideration:** Informed consent is not a one time event but an ongoing process. In some situations, the research subjects might regain capacity to consent. For example, a stroke patient who was enrolled in a research study when they were not capable to give consent, might become fully capable of giving their consent during the course of the study. The researcher should at this time obtain informed consent from the subject. This consent discussion, like the previous consent discussion with the LAR should be documented in the source documents. The consent process should also be documented by obtaining the subjects signature on a fresh consent document or the same consent document that the LAR signed. Study teams may choose to use an addendum to The signature should be accompanied by a note on the consent document that clarifies the situation including what the subject was agreeing to e.g. continuing studying intervention, data collection or follow up etc.

# 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
* "Exculpatory Language" in Informed Consent - Cooperative Oncology Group Chairpersons Meeting November 15, 1996
* Assessing Decisional Capacity for Clinical Research or Treatment: A Review of Instruments. Am J Psychiatry 163:1323-1334, August 2006

**Applicable Institutional Policies and Procedures**

* Consent Process
* Consent Documentation

**Attachments**

* None

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| **Document Number:** | 402-015 |
| **Author:** | Clinical Trials Resource Center |
| **Effective:** | June 1, 2011 |
| **Revision History:** | None |
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