OBJECTIVE:
Describe the process for obtaining and documenting the Informed Consent for all subjects participating in clinical trials.

Principal Investigators are responsible under the Code of Federal Regulations for obtaining and documenting the Informed Consent of each subject who participates in clinical research. Informed Consent is required at the point where a procedure diverges from the generally accepted standard of care (i.e., any activity that is conducted as part of the research process).

REFERENCES:

21 CFR 50	Protection of Human Subjects
21 CFR 312.60	Investigator's Responsibilities
21 CFR 812.100	General Responsibilities of Investigators
ICH E-6, § 1.28	Definitions – Informed Consent
ICH E-6, § 4.8.	Informed Consent of Trial Subjects
45 CFR 46	Protection of Human Subjects
FDA Guidance	A Guide to Informed Consent – 1998
FDA Guidance	Guidance for Clinical Investigators, Institutional Review Boards and Sponsors. Process for handling referrals to FDA under 21CFR 50.54: Additional Safeguards for Children in Clinical Investigations – 2006
OPHS-IRB Manual, Section 9	Informed Consent Requirements

SCOPE:
This procedure for obtaining and documenting Informed Consent applies to all research conducted under the requirements of the Code of Federal Regulations for human research (21 CFR) and or research conducted under National Institute of Health requirements (45 CFR) and/or the University of North Texas Health Science Center requirements. In some cases, this may require documenting Informed Consent to screen potential subjects for eligibility to participate in a clinical trial.

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Certain exceptions apply to the general requirement for obtaining Informed Consent. These are narrowly defined; reference 21CFR 50.23 if you believe such an exception might apply.

The requirements for creating the Informed Consent Form (ICF) and all of the considerations that should be taken into account are beyond the scope of this procedure. Creation of the ICF is the responsibility of the research sponsor, nonetheless, the site should assure that the ICF reflects the governing requirements (ICH or FDA), contains the necessary required elements, and is properly identified, versioned and approved.

Note: UNTHSC's IRB has specific requirements for the Informed Consent document for certain types of studies. Reference the current version of the IRB's procedure to determine the required content of the Informed Consent document.

RESPONSIBILITY:

The Principal Investigator (PI) and/or Key Personnel identified as Authorized Consenting Personnel (ACP) are to obtain and document Informed Consent for any trials meeting the definitions outline in "Scope" above.

The organization sponsoring the research is responsible for creating Informed Consent Forms (ICF) appropriate to the trial being conducted. In conjunction with the research site, all ICFs will be submitting to the applicable Institutional Review Boards (IRB), and specific approval received before any subject is consented. Note that while the sponsor generally creates the ICF, the IRB of record holds the final authority on the content of the ICF.

The sponsor is responsible for providing research sites with any revisions to the ICF and the sponsor and site will assure that any revised ICFs are submitted and approved by the applicable IRB.

The Study Coordinator or other delegate assigned by the PI is responsible for maintaining the currently approved ICF and all prior ICFs in the site's Regulatory Binder. However, it is worth re-emphasizing that the PI is responsible for everything that is done or fails to be done with respect to the clinical study for which he/she acts as PI.

PROCEDURE:

When obtaining and documenting Informed Consent, the PI (or delegate) will adhere to all of the above-referenced policies, particularly Section 9 of the OPHS-IRB Manual.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	08-009	"Patient" removed throughout	Michael V.W. Bergamini (MVWB)
2	08-009	Edited for clarity and style; cross-referenced to OPHS-IRB Manual	MVWB

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