Community Healthcare System

The Review

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The Process of Informed Consent

Legally effective informed consent is a *PROCESS*, not a form. It is the knowing consent of an individual or his authorized representative that is obtained without undue inducement or coercion. Informed consent is designed to provide information to the potential subject about the research and the subject's involvement. The consent form is a valuable means of documenting the voluntary consent of the subject. However, the process of obtaining consent involves discussions between the investigator and/or key study personnel and the subject before, during and after the form is signed. The discussion may be accompanied by a demonstration of the procedures, showing an informative video, in addition to eliciting and answering questions. The entire process may take several hours and should be divided into smaller, manageable sessions so as not to overwhelm the participant.

The use of the most recently approved Investigational Consent Form (ICF) with the CHS CIRB date stamp is crucial to the conduct of the informed consent process. Earlier versions of the form may not include the most up-to-date information about the study and therefore would not adequately inform participants about increased or newly identified risks or changes in the protocol.

All consent forms must be signed by the participant (or legally authorized representative) and the member of the study team who obtains consent. The participant should receive a signed copy of form while the original is held in the confidential study file.

Financial Disclosure

The consent form should also state whether the institution and/or the investigator is receiving reimbursement for conducting the study. Reimbursement to the investigator for providing oversight during the study is considered a reasonable cost. However, there are occasions where the investigator holds an equity interest, receives a salary or has an agreement that would entitle sharing any commercial proceeds of the technology being evaluated. It is necessary to inform potential subjects that these financial relationships exist and the possible consequences to allow them to make an informed decision regarding their participation. The investigator will be required to use a Financial Interest Disclosure Form during the consent discussion.

CONSENT FORM INFORMATION

There are resources and guides on the CHS CIRB web site to assist the investigator when developing or reviewing consents. The guide "Formatting an informed Consent Document" and "Informed Consent: Additional Model Language" follows the criteria set forth in the federal regulations. They also contain suggested language that the CHS CIRB has found helpful and understandable for research participants. The "HIPAA Authorization Template" is based on required language and can be used if the information is not adequately covered in the main investigational consent. A "Glossary of Lay Terms" is available to "translate" the ICF into language that is easily understood by the participant.

Policy IRB 15: Informed Consent
Policy IRB 15.1 Barriers to Informed Consent

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