Guidance and Procedures for Investigators

Topic: Data Storage and Security Recommended Language

The following UNTHSC recommended language should be incorporated into the protocol synopsis, and can be modified as appropriate for each IRB submission.

Procedures

"Research data, in hard copy or electronic form (CDs, DVDs, digital or magnetic tape, hard-drives, flash-memory drives, etc.) will be stored and managed in a secure manner following NIH guidelines and according to state and institutional policies and practices. Further, research documents including electronic documents containing subject data, identifiers and linked data will be securely stored in locked containers (file cabinets, lockers, drawers, etc.) in accordance with standard document management practices. At all times, only listed key personnel specifically designated and authorized by the Principal Investigator shall have access to any research related documents. All such personnel will be properly trained and supervised regarding the management and handling of confidential materials. The Principal Investigator assumes full responsibility for such training, supervision, and conduct."

Guidance

The Principal Investigator shall maintain all documentation (hard copy or electronic form) relating to research once the study is complete. This includes portable data storage devices such as flash drives. Refer to section 7.6 Record Keeping Requirements for Investigators in OPHS – IRB Policies and Procedures Manual for record retention requirements. Co-mingling of personal data with research data creates opportunities for breach of confidentiality by allowing access to research data by non-research personnel. Flash drives containing personal data and personal information should not be used to store UNTHSC research data at any time during the study. Instead a dedicated research-only flash drive designated for research data should be used to store research data.