

University of North Texas Health Science Center
Office for the Protection of Human Subjects
Institutional Review Board

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.

“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, hard copy documents containing subject data, identifiers and linked data will be stored in secure document 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.”