

UMAB's Procedures for Keeping Electronic Data Security and Confidentiality

- All study participants PHI data is kept and tracked in secure relational tracking database. Each user is setup with a unique role, user and password to access and modify the data.
- The database is housed on a secure server behind a second firewall and users must log on using a VPN account with encrypted sessions.
- The database generates unique identifier for each participant and the unique identifier is used to communicate between UMAB and the LHC remote site and any documents that users use on the field (questionnaire, forms etc.)
- Principal Investigators at LHC request data on a regular basis from UMAB for statistical analysis. All data sets go through a very detailed process of removing any PHI information before they get sent to LHC using the 18 PHI variable rules.
- Tissue collection follows the same rules. All Tissue collection for participants is registered in a secure relational Tissue Data tracking system. Again the system generates a unique identifier that represents the participant and their tissue collections.
- Users bar code these samples with the unique identifier and send the tissue to LHC.
- NDI data is de identified before sent to LHC and only the unique identifiers are used to link multiple sets with all the related data.
- The data on the server is backed up daily and a copy is sent to a secure remote location. Data recovery was tested successfully.
- All computers that users accessing data are located in secure locked offices. Users log off after completing their sessions and before walking away from their desks. In addition all computers are set up with a screen saver and password to lock any active sessions for any keyboard inactivity.
- Critical documents are scanned and digitized and stored on the HIPAA server and tracked through the database.

UMAB's Procedures for Keeping Participant Data Confidential

- All of those screened are given a study ID and that number is used once the participant is enrolled.
- If specimens are collected an accession number is given to the specimens.
- The linking file of the study ID to the accession number is stored at UMMS.
- PHI is not visible on desk folders, stackable filing trays and shelves binders.
- Any PHI needed on a daily basis is stored in a locked in file cabinets or lock boxes when study staff is in clinic or off campus.
- All study files, questionnaires and study information is kept in locked cabinets. The cabinets are opened in the morning for use and locked in the evening or when no one is in the office.
- Any unneeded documents with PHI will be shredded.
- The office door is locked at all times, regardless of how short the absence is from the office.
- Housekeeping is not allowed in the office unless requested. When they are in the office, all PII will be put away unless it is being worked on by a staff member.
- Any reports containing large numbers of individual study ID numbers and patient names will not be removed from the office. A prospective patient will be assigned a study ID and their name recorded in the computer data base.
- The study ID number will then be recorded on the questionnaire and screener form that is used for the recruitment and enrollment of that patient. The study ID number, medical history number, name, address, and phone number of the patient will be recorded in the questionnaire. Directions will be taken but kept separate from the questionnaire.
- In the field or at a clinic, the study staff records PHI on the study form. All forms will be kept with the study staff member. Any other PHI pertaining to other patients will be kept in a locked cache and placed in a secure location or an available office.
- Questionnaires that are being transported between the University of Maryland and Johns Hopkins Hospital will be kept in a secure locked bag or lock box for transport. They will not be left in a motor vehicle over night.
- When a Study staff member goes to a patient's home for an interview, all PII that does not pertain to that particular interview will be kept in the locked cache and taken into the patient's home.
- All PII will be kept in the locked cache and taken with the study staff member when he or she leaves the vehicle.
- Only if necessary, in the evening, the locked cache-containing PHI will be taken into the study staff member's home for the evening.