

Technical Information Regarding OHSU's Electronic Health Record System

Security

- Unique user IDs and passwords are required to access the system.
- Passwords kept confidential and not shared.
- The system automatically logs off (time-out) the user if the user hasn't used the system for a period of time.
- The location of the data is physically secure
- The system has a virus detection/protection program.

Monitor Access

- Clinical trial monitors may have access to the electronic health records.
- Clinical trial monitors are issued a password for read-only access to the electronic data for subjects participating in the clinical trial.
- Completion of a site-specific access request form is required before accessing the system.

Data Collection

- The system can produce accurate and complete electronic and printed readable copies of electronic records, suitable for review and copying.
- The system is backed-up nightly to prevent loss of data.
- Data backups are made and kept according to OHSU policy, which also addresses disaster recovery.

Audit Trail

- OHSU's system includes a secure, tamperproof, and printable audit trail for capturing changes to information in the electronic system, which contain the following items in the audit trail:
 - user name/ID of who authored the change
 - Date stamp
 - Time stamp
 - Reason for change
 - Original data is accessible within the history of the change
- OHSU's system employs tamperproof electronic signatures which incorporate the following features:
 - User ID
 - Password

- Date Stamp
- Time Stamp
- The meaning associated with the signature (for example: review, approval, responsibility, and/or authorship, etc.)

Procedures, Policies and Training

- OHSU policy governs use of the system. These policies include information regarding:
 - System Administration access vs. user access
 - Maintenance of user ID's and passwords
 - Electronic record retention
 - Data backup and retention
 - Disaster recovery
 - Operations during system downtime
- Documented training is required of all users prior to accessing OHSU's system.
- Change control detailing who has system access and what level of access is documented.
- OHSU electronic records are archived in accordance to local regulations for clinical studies or patient records, whichever is longer.
- There any no changes planned to the system which may affect access of the method in which source data is recorded.