Specimen Data Management

The data management objectives are to provide state-of-the-art systems and methods capable of supporting the projects of multiple investigators. Study personnel will enter study data into a secure Web-enabled entry system that includes point-of-entry range checks. The accuracy of data transcribed from data entry forms to the database is maintained by complete coding documentation, careful training of key entry operators, and computerized range and valid value checks at the time of data entry. For single-valued observations transcribed from participant data forms, a 0.1 percent initial error rate (i.e., 1 keystroke per thousand) is anticipated based on prior laboratory experience; subsequent audit procedures reduce the error rate to ≤0.01%. Because some data entry errors (such as with participant ID numbers) may affect the referential integrity of the database or may interfere with source document verification, laboratory staff will use additional methods to reduce the error rate. For example each data acquisition form will have a barcoded label that makes the form unique and traceable. Utilities for producing barcodes are available via the Web interface for both data acquisition forms and participant samples. Additionally, online eligibility determination and protocol enrollment functions will be created and deployed, along with a unique participant tracking system that converts the time-oriented schema of a clinical protocol into a participant-specific calendar of events and tasks to be performed.

To connect to the Internet data management system, two passwords are needed. Table- and field-level privileges are used to define and limit who among the personnel may view, edit and download specific data. A backup system copies all files from the database server nightly. Our approach to security and confidentiality is designed to comply with relevant federal regulations and guidelines, including: DHHS/NIH Automated Information Systems Security Program Handbook, current HHS standards for security of person-identifiable health data transmitted over the Internet, and the HIPAA Privacy and Security Rules.

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