

## Data Retention Policy

### **General Information**

The CHTN project at UPENN is a federally sponsored grant. It is the policy of the CHTN ED to abide by both the federal CFR.200.334 Retention requirements for records; )“*Financial records, supporting documents, statistical records, and all other [non-Federal entity](#) records pertinent to a [Federal award](#) must be retained for a period of three years from the date of submission of the final expenditure report.*”) ; and the UPENN Research Administration Records policy.

### **Responsibility**

The policies and procedures of the CHTN ED at the University of Pennsylvania are issued by the CHTN ED principal Investigator, Kathleen Montone, MD. This policy applies uniformly to all employees of the CHTN ED and is designed to be of use to the CHTN ED employees for the purposes of carrying out their stated CHTN-related responsibilities.

### **Record Retention Timeline**

Records, both paper and electronic will be retained at a minimum, as indicated in the following table:

Administration records	Up to 7 years after completion of Research and submission of the final Financial Statement Report.
Financial records	Up to 7 years after completion of Research and submission of the final Financial Statement Report.
Scientific, Biospecimen and QMS records	Up to 7 years after completion of Research and submission of the final Financial Statement Report.
IRB and regulatory records	Up to 7 years after completion of Research and submission of the final Financial Statement Report.
MTAs	Up to 7 years after completion of Research and submission of the final Financial Statement Report.
Informed consent documents	Permanent retention in the UPenn University Archives.
ED Investigator applications and agreements	Permanent retention in the UPenn University Archives.
Grant Protocols	Permanent retention in the UPenn University Archives.

Employee records including staff training completed in the UPenn online training portals are managed by the University Human Resources department and are maintained consistent with UPenn document management policies.

When the CHTN Project is eventually terminated, all records (paper and electronic) that are not to be stored permanently, will be archived for a period of seven (7) years after the submission of the final Financial Statement Report. At that time, they will be destroyed consistent with UPenn policy for both paper and electronic records.

If the current CHTN ED is not refunded during the next funding cycle. Records relevant to CHTN investigators and any other pertinent documents will be provided to the NCI Program officer or to another funded CHTN division at the direction of the NCI Program Officer.

**ED Information Management**

The CHTN ED information management system consists of databases and applications which span servers across several physical locations. Data and systems that reside on dedicated secure, encrypted servers behind the UPHS firewall are maintained and are compliant with UPHS IT policies. Additionally, servers within the ED office/labs are backed up using industry-compliant protocols and stored in an environmentally monitored facility

Biospecimen data is maintained in our secure biospecimen management system ScienceServer(SS), which has been developed to manage and support our workflows in collection, specimen annotation, QMS, storage and distribution of biospecimens. Data that is provided to the CHTN researchers is provided as de-identified information.

**CHTN Network-wide Data Management**

The Informatics Subcommittee (ITS) is responsible for all areas of CHTN information storage and transmittal within and outside the CHTN and for providing other groups and organizations with structure and coding of the current version of the CHTN database. Subcommittee responsibilities primarily involve the design, maintenance, modifications and operation of the Cooperative Human Tissue Network investigator database, the sharing of electronic data within the CHTN, the collection of data for reports on CHTN operations and day-to-day function of the CHTN investigator database. Together with the other subcommittees, the ITS plans future developments in the CHTN database, website, and other areas related to information usage, distribution, storage and format.

**Data Quality Assurance / Data Quality Control**

Data quality reports of SS are automatically generated and sent to the ED Informatics Director for review and verification. These weekly reports provide data on the server health, SSL expiration dates, validation of user access and firewall implementation.

Data validation is also performed on a random basis through the data audit reports available in the SS Report Module. This includes a wide variety of data points which are reviewed by the ED leadership for data and workflow quality assurance. When appropriate, these edits are tracked in the internal SS ticketing system.

A critical part of all audit and assessments is to determine if any deviations or unexpected data are found in the audits that may require corrective actions. If corrective actions are required, this information is documented including what actions should occur and how they should be implemented. Identification of the root cause of the deviation or unwanted actions will be documented as well as implementation of preventive actions to deter reoccurrence.

**Correction of Laboratory Records**

Laboratory/biospecimen data are no longer retained in paper format. All data for biospecimens are recorded in SS. The SS application tracks and stores data within a secure database. Access to the database is controlled as noted in the SS User Guide. Any edits or corrections to data in SS can be traced back to identify the time of the edit, the values changed and the user that performed the modification. Requests for change history of data may be made to the ED IT Director.



CHTN - Cooperative Human Tissue Network

ED – Eastern Division

NCI – National Cancer Center

SS – ScienceServer. The CHTN ED biospecimen database.

UPENN – The university of Pennsylvania

UPHS – University of Pennsylvania Health System

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