

CHTN Data Retention Policies and Procedures

Introduction:

The Principal Investigator is responsible for the maintenance and retention of research data, except where precluded by specific terms of sponsorships, other agreements or collaborations. Under the CHTN RFA, there is no guidance on data retention during a funding period. Policies, if any, are left to the individual divisions and the respective institutions. CHTN will adhere to OMB Circular A-110 regarding retention of financial data three years from date of final report submission to NIH.

CHTN Western has used 45CFR 164.316 and CHTN Manual of Operations to build a hybrid policy model for data retention policies and procedures. The information contained in this document is a “reasonable” effort to adhere to appropriate policies and procedures.

This document is separated into CHTN divisional functions, CHTN Operational Functions (network-wide) and Institutional requirements, procedures, or policies.

CHTN Western Division at VUMC- Principal Investigator of Record- Divisional

The Principal Investigator must determine and ensure the accuracy and authenticity of the records, define who has authority to access and use the records and describe how the records will be maintained and secured.

There are three levels of access to data at CHTN Western Division based on the employee's role. Each level has access to information about retaining, creating, and exposing data.

The retention time, archival rules, data formats and storage requirements will vary depending on the type of data being retained and stored and the staff or VUMC office(s) that require access to the data.

The sole objective is to organize and retain data so that it can be searched and/or accessed later as well as determine what data can be destroyed or no longer needed per institutional policies, NCI-CHTN RFA and NIH recommendations.

Data contained or stored in a database complies with industry standards.

CHTN Western-Divisional Data- Divisional

CHTN operational areas:

CHTN VUMC Donor Portal-

The CHTN VUMC Donor Portal contains de-identified patient information. Investigators are provided with a unique username and sent a temporary password to access the site. Examples of data contained linked to their Investigator ID includes final pathology reports, chart reviews, CHTN Tissue Quest file, packing slips, digital slides, and a de-identified sample inventory.

*CHTN does not store investigator passwords to the Donor Portal

* Investigators are not allowed to request more than one account and are responsible for the security of their user ID and password.

*CHTN Off site/satellite site Final Pathology Reports- Records are kept for three years after grant/project ends. CHTN VUMC subcontracted with tissue collection sites (local and out-of-state) to obtain de-identified, waived consent tissue and corresponding final pathology reports. These reports are exposed in the same manner as VUMC de-identified data on the CHTN Donor Portal.

CHTN Network-Wide Data

CHTN Donor Quest Tissue Repository Database- (Indefinitely or until project/grant ends).

Investigators are informed that projects, tissue requests and other information contained in their application is considered confidential and will only be shared with other CHTN divisions and the National Cancer Institute/National Institutes of Health. The privacy policies for CHTN-Network-Wide Data can be found on the CHTN Donor Portal or a request can be made to the CHTN division.

*Investigators may be asked to complete yearly questionnaires regarding CHTN services and tissue quality, which will be used as “aggregated data” and is not considered confidential.

*If the investigator chooses to draft support statements for the CHTN website or marketing campaigns, CHTN will not release any information other than his/her comments, statements, name, and professional title. This information is historical data and may be used by other resources and websites, making it “public domain information”. The investigator can request that the comments be removed from the CHTN NCI website.

*Investigators cannot make requests to delete any information pertaining to their application file. The information is kept in our secure database for at least 3 years after the NIH defunds the CHTN as a resource for specimen procurement.

*CHTN does allow for the transfer of specimens to a third party for research purposes only. Instructions and documentation for third party transfer can be found in the CHTN application, page 1.

*CHTN does not collect any personal information on investigators. CHTN collects only data relevant to their application to use CHTN services.

*CHTN does not collect or store financial information, such as credit cards, debit cards or checking account numbers.

*CHTN does collect and store information to process your transactions, such as billing addresses and purchase order numbers. This information is not deleted and will remain part of the investigators file.

*CHTN VUMC utilizes a third party to perform certain tasks on our behalf, such as processing and sending/mailling invoices (Agilent ilabs)

*CHTN email communications re: regulatory elements (IRB, Approvals, Signed Agreements for Use of Tissue, Data Use Agreements) are maintained by the CHTN primary division and any division that the investigator is networked. Each division may have a secure database to house applications and documents. As of June 1, CHTN has moved to a secure database, TissueQuest II, which allows the upload of all CHTN application documents. This information will be kept if

NIH funds the CHTN program. This means that if CHTN VUMC does not obtain funding as the Western Division, but NIH continues to fund the program at another institution, all CHTN application materials will be transferred to the new division.

CHTN VUMC Donor Portal Use- CHTN Investigators may access the CHTN VUMC Donor Portal at any time using their login credentials.

- *CHTN VUMC does not keep passwords on file.

- *Investigators can retrieve a temporary password and are advised to change after the initial login.

- * Should an Investigator leave their institution, their account/access to the CHTN Donor Portal will be removed. Reinstating access to the system will incur a charge for the work involved.

- * Investigators are provided with three different ways to access data (CSV, PDF or Excel).

- *Investigators are encouraged to download the data pertaining to their orders.

- *Information on the Donor Portal will be kept in a secure database for one year after the CHTN VUMC funding ends. Investigators will be encouraged to download all relevant data before the deadline (TBD). Attempts or requests for information or access to the Donor Portal will not be accepted.

CHTN MOO- Operational Policies and Manual of Operations (MOO) are maintained by the CHTN Central Coordinator. The CHTN Coordinating Committee (PI of the division and the coordinator) is responsible for maintaining the content to adhere to Federal regulations and CHTN policies.

- *Investigators may submit a request to view CHTN SOP's, pertaining to the collection and dissemination of tissue and/or data.

- *Requests are reviewed first by the primary division and then submitted to the Coordinating Committee to approve or deny the request for SOPS or sections of the MOO.

Privacy Questions

If you have questions about the CHTN Privacy Policies, please contact the CHTN VUMC Coordinator or if you would like to submit a complain, please contact kay.washington@vumc.org or Kerry.wiles@vumc.org.

CHTN is dedicated to protecting both patient information and investigator information and will review each inquiry or complaint and respond accordingly. Complaints and suggestions that could improve CHTN operations are submitted to the CHTN Coordinating Committee and NCI for review.