Data management and sharing plan

The CHTN is a biospecimen resource that provides biospecimens to approved investigators through an investigator agreement in which the CHTN and its member institutions make no intellectual claims on research performed with the specimens, have no oversight or responsibility for the research performed, and have no agreement for return of data generated from research from the specimens. **Hence no research data will be generated directly by the grant awardees.** The CHTN only collects data on its operations.

1. Data types
    a. Data types and amount

Data that will be collected includes the numbers and types of biospecimens served to investigators, the number and location of investigators utilizing the CHTN and the institutional affiliation of the investigators. The CHTN also collects information on publications and patents that have utilized CHTN biospecimens. Basic demographic data and clinicopathologic data on biospecimens are obtained as metadata for investigators. Also collected are time stamps to monitor biospecimen procurement processes and histologic quality control data on procured tissue samples.

    b. Data preservation and sharing

Data regarding investigator requests, institutional affiliation and numbers and types of biospecimens shipped in fulfillment of the requests are preserved in the CHTN Investigator System which is managed by the CHTN Western Division at Vanderbilt University Medical Center (VUMC). Metadata associated with biospecimens procured at The University of Virginia for the CHTN is stored in its integrated Biospecimen Information System (iBIS). Data regarding the numbers of investigator requests and the number and types of biospecimens sent to investigators are shared with the NCI through the CHTN Program Office. The identity of the investigators and the nature of their requests are considered confidential information and are not released publicly. HIPPA-compliant attributes of specific biospecimens are not shared publicly by the CHTN but may be shared by investigators in support of their own research data releases. The CHTN reports on its biospecimen sharing activities in bulk, and on publications utilizing its biospecimens, at its website.

For historical data on investigator requests and specimen procurement/shipment at active CHTN divisions, data is held indefinitely in CHTN informatic resources. Upon cessation of funding, data will be held for the minimum specification of the NIH: 3 years from cessation of funding.

    c. Metadata and documentation

Metadata on biospecimens procured for the Mid-Atlantic CHTN division are stored in the UVA iBIS and includes procurement and processing timestamps, quality control metrics, donor demographic data and histopathologic data on tissue samples. Metadata conforming to the basic dataset set forth in the CHTN Manual of Operations (MOO) are released to investigators at the time of specimen receipt. Additional HIPAA-compliant data elements required for the conduct of the research may be obtained by investigators upon request.

2. Related tools/software and/or code

The CHTN Investigator System was developed during previous CHTN funding periods and undergoes constant updating. It is a real-time, centralized web-based system (Java Web Application) that stores and shares investigator information and tissue requests amongst all CHTN divisions. It is housed on Amazon Web Services on an Oracle platform with 24/7 backup and stringent security measures that comply with applicable standards.

For tracking biospecimens procured for the CHTN Mid-Atlantic Division at UVA an integrated Biospecimen Information System (iBIS) is used, which is an extension of the open source Caisis biomedical research information system . Caisis was originally developed at Memorial Sloan Kettering Cancer Center and is available as open-source software (see Section D for more details). It is housed at UVA on a SQL Server with 24/7 backup and stringent security measures that comply with applicable standards.

3. Data Standards

Histologic classification and clinical staging of tumor specimens conform to the 8th edition of the AJCC Cancer Staging Manual.

4. Data Preservation, Access, and Associate Timelines

CHTN data on its investigators and its biospecimen donors is proprietary and/or protected health information and are not linked by the CHTN grant awardees to research data, hence no data generated by this grant mechanism is suitable for release to public repositories of research data. The CHTN divisions support the release of HIPAA-compliant biospecimen metadata by the investigators utilizing this resource when sharing the results of their research studies.

5. Data Access, Distribution or Reuse Considerations

Access to the CHTN Investigator database is confined to active CHTN personnel at approved CHTN sites and designated IT specialists at VUMC for modification and maintenance of this resource. Access to the UVA iBIS is confined to personnel of the UVA CHTN Mid-Atlantic Division, the UVA Biorepository and designated IT specialists for modification and maintenance of this resource.

The release of genetic data derived from or the creation of living cellular model systems from CHTN biospecimens is conditional upon the circumstances of donor consent. The majority of specimens procured by the CHTN have donor consent that allows for genetic studies and release of data into public repositories. A subset of samples are procured under waiver of informed consent and are not appropriate for genetic research. CHTN investigators are made aware of these circumstances are specifically asked to provide information on their research so that appropriate biospecimen matching to consent status occurs. The biospecimens and all metadata are released to investigators in a de-identified manner and all metadata conforms to limited data sets as defined by HIPAA.

6. Oversight of Data Management and Sharing

The data models and informatic systems utilized by the CHTN to track investigator requests and shipments are overseen by the CHTN Informatics Subcommittee, which in turn is overseen the CHTN Central Coordinating Committee (composed of CHTN site PIs, coordinators and an NCI representative). Decisions are made by majority votes. Data resources housed at each CHTN member institution will fall under that site PI's responsibility and/or delegation for adherence to the DMSP.

At The University of Virginia, Jeff Pitts (IT specialist) has been delegated responsibility for monitoring compliance with the data management (e.g., data capture, documentation, quality review, storage and backup) aspects of the approved DMS plan at least annually and, when appropriate, proposing revisions. Research administration/compliance staff will conduct compliance reviews following procedures established by the Office of the UVA Vice President for Research prior to submission of an RPPR.