

Pediatric Division of the Cooperative Human Tissue Network (pCHTN) Data Management and Sharing Plan (April 2025)

The Cooperative Human Tissue Network (CHTN) is a National Cancer Institute (NCI) funded 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 biospecimens, have no oversight or responsibility for the research performed, and have no agreement for return of data generated from research from the biospecimens. The CHTN only collects data on its operations. The Pediatric Division of the CHTN (pCHTN) is one of the six Divisions and is housed at the Biopathology Center (BPC), part of the Abigail Wexner Research Institute at Nationwide Children's Hospital (NCH).

Data types

- **Data types and amount collected for the CHTN:** Data commonly 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.

Data preservation and sharing: Data provided by all CHTN Divisions regarding investigator requests, institutional affiliation, and numbers and types of biospecimens shipped in fulfillment of the requests are collected and preserved in the CHTN Investigator System housed at the CHTN Western Division (Vanderbilt University Medical Center). Data associated with biospecimens procured at the pCHTN is stored in its custom Laboratory Information Management System (LIMS) known as STARS (Specimen Tracking and Reporting System). 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. Protected Health Information (PHI) related to specific biospecimens is not shared publicly by the CHTN. The CHTN reports on its biospecimen sharing activities in bulk, and on publications utilizing its biospecimens, at its website: <https://chtn.cancer.gov/>.

- **Metadata and documentation:** Metadata on biospecimens procured for the pCHTN Division are stored in the BPC-based STARS 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.

Related tools/software and/or code: For tracking biospecimens, the pCHTN currently uses STARS, which was developed specifically for the processes taking place in the BPC. STARS uses a combination of web and database technologies to perform key specimen procurement and distribution services. All components of the application are managed by the NCH Enterprise Information Services team.

Data Standards: Histologic classification and clinical staging of tumor specimens conform to the current edition of the AJCC Cancer Staging Manual.

Data Preservation, Access, and Associate Timelines: 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.

Data Access, Distribution or Reuse Considerations: Access to the CHTN Investigator database is confined to active pCHTN personnel and designated pCHTN Coordinators at the BPC for data entry and

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reporting. Access to the BPC-based STARS is confined to personnel of the pCHTN Division and designated IT specialists for software 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 the biospecimens procured by the CHTN have donor consent that allows for genetic studies and release of data into public repositories. A subset of the samples is procured under waiver of informed consent and are not appropriate for genetic research. CHTN investigators are made aware of these circumstances and 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.

Oversight of Data Management and Sharing: The pCHTN is supported by the NCH Enterprise Information Services team including security, backup, privacy, network monitoring, and other subdepartments. Similarly, the pCHTN also has oversight from the NCH Office of Compliance and Integrity.