

Obtained via FOIA by Judicial Watch, Inc.

operations. This was followed by another set of standards developed by the NCI in 2007 (National Cancer Institute best practices for biospecimen resources: [http://biospecimens.cancer.gov/global/pdfs/nci\\_best\\_practices\\_060507.pdf](http://biospecimens.cancer.gov/global/pdfs/nci_best_practices_060507.pdf)). The HSTB repository has maintained these documents as reference material and follows these practices in its daily operations. These practices would be continued, extrapolated, refined and implemented for the HUB efforts.

### 5. Ischemia time is minimized

We record the warm ischemic time on our samples and take steps to keep it at a minimum to ensure the highest quality biological specimens [30, 31]. We get feedback from our users and utilize this feedback to tailor our collection processes on a case-by-case basis to maximize the needs of investigators. All warm ischemic times are recorded within Biospecimen Inventory and Operations System (BIOS).

### 6. The proposed HUB has an established track record of being highly collaborative

The HSTB has been a core facility for the University of Pittsburgh Cancer Center for the past decade, providing biological specimens and research pathology support. We receive some funding from the NCI as a Shared Resource as part of the Cancer Center Support Grant (CCSG) for the University of Pittsburgh Cancer Institute. This is the 27th year of funding for CCSG (Core PI: (b)(6) P30 CA047904). In this capacity, HSTB works closely with a multitude of investigators and handles a variety of biospecimen requests both locally and nationally.

### 7. HSTB has a track record of very effective engagement in National and International initiatives

A. The Cancer Genome Atlas (TCGA): This is a collaboration between the National Cancer Institute (NCI) and National Human Genome Research Institute (NHGRI). TCGA generated large datasets of genomic changes in major types and subtypes of cancer. TCGA accrued matched tumor and normal tissue specimens from 11,000 patients; from 33 cancer types and subtypes [32], including 10 rare cancers. The University of Pittsburgh was the second largest contributor to the TCGA Project, with over 800 qualified cases.

B. The Clinical Proteomic Tumor Analysis Consortium (CPTAC): This is a comprehensive and coordinated effort to accelerate the understanding of the molecular basis of cancer through the application of robust, quantitative, proteomic technologies and workflows. HSTB was part of the initial pilot and has been selected as a collection site for the ongoing expanded phase targeting 2000 cases spanning 10 tumor types.

C. The Cancer Human Biobank (caHUB): This is a biorepository and biospecimens derived program that carried out specialized biospecimens and data procurements to support biospecimens science activities. HSTB participated in the caHUB initiative focused on biopreservation variability [33, 34]. HSTB was the largest contributor to this initiative and provided samples and data from approximately 6000 cases; covering four tumor types.

D. SPORE Initiative: HSTB is the biospecimen and research Pathology services resource for our four funded SPORE initiatives: 1. lung, 2. head and neck, 3. skin, and 4. Gynecologic cancers [10, 15]. We have provided samples and data to many investigators outside of the University of Pittsburgh, as part of SPORE driven multi-institutional efforts.

### 8. Identification of late gestation procurement sites

We have not previously collected tissues from cases later than 24 weeks gestation. We are in the process of altering our IRB and autopsy consent forms to permit the collection of tissues from these cases and allow for deposition of these tissues in our tissue bank. We have developed a relationship with the International Institute for the Advancement of Medicine (IIAM) ([iiam.org](http://iiam.org)) who already provide neonatal tissue samples to the NIH initiative LungMap ([LungMap.org](http://LungMap.org)). The IIAM contains a national tissue bank that will allow for the acquisition of genitourinary tissue from 25-42 weeks of gestation. This tissue bank receives on average 20 neonatal cases a year (see letter of support from IIAM). The neonatal tissue will undergo stringent quality assurance and quality control by HSTB, similar to the quality assurance and control (QA/QC) performed for our in house fetal tissue, before being banked or distributed to the requesting, qualified GUDMAP atlas projects.