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Tissue Resources Core Facility

Policies of Operation

Only discarded human tissues may be obtained by the Human Tissue Procurement Facility (HTPF) and its Case Comprehensive Cancer Center's (Case CCC) Tissue Resources Core (TRC) for research. No fetal tissue can be collected, due to federal and state statutes, as well as local ordinances. Surgical procedures are not altered in any way to obtain additional tissue for research. Authorization must be obtained from a Surgical Pathologist for the release of remaining surgical tissue not needed for diagnosis. Samples are for research purposes only and may not be used for clinical diagnosis or implantation into humans. No biospecimens are provided by the HTPF or TRC for direct incorporation or further processing into commercial products. Patient confidentiality is strictly maintained by de-identifying or de-linking samples and data. Patient identifiers are not released to the researchers, with the exception of those individuals having separate IRB-approved Protocols permitting access to this information. Clinical information relating to the samples and donors are collected and maintained in a secure database in the event that follow-up data or additional samples are requested.

Institutional Review Board (IRB) Oversight of Facility

Collection and research uses of human tissues from living individuals are conducted in accordance with the policies of the U.S. Office for Human Research Protections (OHRP). The facility complies with federal regulations applying to human subjects research (45 CFR 46, or the "Common Rule"). Remnant biospecimens are prospectively collected from surgical procedures, autopsies and clinical laboratories by the HTPF and TRC under UH-IRB Protocol 01-02-45 (CWRU4Y02). Blood and bone marrow specimens are collected for the Biorepository by the Hematopoietic Stem Cell Core Facility (HSCC), which operates under UH-IRB Protocol 09-90-195. The Biorepository and access to clinical archive materials are covered under IRB Protocol CASE 10Z07. The UH Institutional Review Board (IRB) operates under the Federal Wide Assurance of Compliance number 00003937. The HTPF and Biorepository protocols include waivers of separate informed consent for discarded tissues, in accordance with UH and its IRB policy. Consent is provided in the general procedure consent form. The facilities operate with waivers of HIPAA authorization.

Recruitment and Selection Criteria

Patients are not recruited to be donors of discarded tissues for the HTPF. No contact with the donor patient or family members is permitted. In some studies a researcher may have IRB approval to directly interact with patients through a consented protocol; the HTPF is not involved in any way with these interactions.

Discarded tissues may be obtained from individuals of any age. No gender, minority, or special class restrictions are placed on the pool of potential donors. Data identifying patients as members of special classes of individuals are not available to the HTPF. No individual groups of people are selected for tissue collection. The HTPF does not knowingly collect biospecimens from individuals with infectious agents such as HIV, tuberculosis, and hepatitis C.

Requirements for Biospecimen Distribution

Application Overview

A Tissue Research Application, HTPF Application and Agreement, and copy of the current IRB approval or exemption to conduct the work are generally required in order to receive biospecimens. A Data Use Agreement is also required for de-identified data or Limited Data Sets. Most requests for cancer specimens are reviewed by the Case CCC's Multidisciplinary Clinical Disease Teams and the Tissue Research Review Committee. Researchers will receive specimens after final approval by the Principle Investigator and Director of the HTPF.

IRB Approval

A researcher's IRB approval or exemption is required to obtain tissues from the HTPF and TRC for a study. Research involving the use of anonymous or anonymized (de-linked) specimens generally does not qualify as human subject research, but the IRB must be contacted to obtain verification in writing that the project does not require IRB review.

Priority

Researchers have prioritized access to tissues and services, depending on their affiliations with CWRU/UHCMC, the Case CCC, or whether they are from an outside organization. Cancer Center members receive first priority access to the tissues through the TRC. Priority of access to TRC resources is determined during the Multidisciplinary Disease Team and Tissue Research Review Committee review process, taking into consideration the Case CCC's focus areas and initiatives. Non-Case CCC members affiliated with CWRU/UHCMC receive second priority. Tissues not utilized by internal researchers are made available to external researchers. In practice, most tissues are generally available in sufficient quantity and frequency to meet the needs of all internal researchers and many researchers not associated with CWRU/UHCMC.

Access to Clinical Archives

The Division of Surgical Pathology at UHCMC has clinical archives of paraffin blocks that can be made available through the TRC for retrospective research studies under the approval of the Vice Chair for Clinical Affairs at UHCMC. Surgical Pathologists associated with the TRC are responsible for determining which blocks can be made available and how much material can be removed from the blocks.

Specimen Transfers

Biospecimens provided to investigators for research, and derivatives thereof, may be transferred along with associated de-identified pathology reports by the researcher to collaborators for further study, provided that the following conditions are met: (1) an explanation of the need to transfer the materials and benefit to the researcher's study is reviewed and approved by the Director of the HTPF/TRC; (2) a copy of the Agreement Page from the HTPF Application is signed both by the collaborator and authorized Agency Official and forwarded to the HTPF for approval; and (3) a copy of the collaborator's IRB approval to use the biospecimens or their derivatives in research is provided to the HTPF, unless the collaborator is covered under the IRB approval granted for the project in the researcher's application.

External Academic and Commercial Users

Prospectively collected biospecimens and those stored in the Biorepository that are found not to be needed for in-house research may be provided to external academic and commercial researchers for research and development projects. Each researcher is required to obtain his/her local IRB approval for the study. In addition, the Case CCC's Multidisciplinary Clinical Disease Team and the Tissue Research Review Committee must approve each researcher's formal application for access to Biorepository samples.

Data and Links to Patient Information

Standard Data

Patient confidentiality is strictly maintained through the use of sample code numbers. Researchers are provided with requested biospecimens and corresponding coded Surgical Pathology or Autopsy Reports. Standard information that is made available includes patient age, race, gender, final diagnosis, and sample type and weight. The samples and data are either de-identified or de-linked as appropriate before release to the investigator.

Additional Data Available

Chart reviews can be performed to obtain additional clinical information associated with the biospecimens. These data are provided to the investigator in de-identified manner unless the researcher has specific IRB approval to gain access to the patients' identities and medical records. De-linked specimens are not traceable, and as such no further information can be obtained for these samples.

Quality Control

Quality control is performed on representative sections of tissues collected for research by experienced clinical Surgical Pathologists to confirm that the diagnoses associated with the samples are correct, to ensure that the QC sample results re-confirm clinical data in the Final Pathology Reports (i.e. no cancer cells are found in QC slides when clinical pathology results are negative), and to determine the suitability of the samples research (e.g., the samples are not excessively necrotic). Exceptions are made for the QC of certain tissues, including normal skin, tonsils and bone, since grossly normal tissues of these types rarely have pathologic abnormalities.

Access to Histology and Immunohistochemistry

Histology and immunohistochemistry (IHC) services are generally offered on a first come first serve basis, regardless of order size; however, a research assistant may only spend up to 50% of their time on one particular order a day. Surcharges are placed on rush orders. A formal application is not required to obtain Histology or IHC services, but it is requested that new facility users complete a New Investigator Information Sheet available in the Forms section of this website. All users are required to drop off tissue with an accompanying Histology Record Sheet, which lists the specifics of work to be performed.