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.