IAORC Process - Obtaining Human Derived Material for Research

Overview of Responsibilities and Procedures1

(Office of Academic and Research Affairs – March 7, 2016)

**I. Samples Obtained from Research Subjects**

All research involving human derived material (e.g., tissues, biopsies, fluids, etc.) obtained from living research subjects must be reviewed and approved in advance by the Committee for the Protection of Human Subjects (CPHS). This includes de-identified samples obtained by UTHealth investigators from any location as well as samples obtained from collaborators at other institutions who initially obtained the material (*link to HOOP 200 – Review of Research*). Investigators should contact the CPHS Office for further information on obtaining and using such samples in research (<http://www.uth.edu/CPHS/>).

Certain material obtained from living subjects for research or educational purposes with proper approval may be identifiable as being of human origin by a layperson (e.g., a limb obtained by amputation, bones from a hip replacement, etc.). Such material must be disposed of in an appropriate and respectful manner after the research or educational use is finished. When appropriate, IRB protocols should stipulate that any such material should be transferred to the UTHealth Human Structure Facility for proper disposal in a timely manner after the research or educational use is completed.

**II. Anatomical Specimens**

Anatomical specimens are defined as body parts, including bones and viscera, obtained from deceased human bodies or surgical specimens. Small quantities of tissues and histological sections that would not be recognizable to a layperson as derived from human body parts are not considered anatomical specimens (see *HOOP 97 – Deceased Human Bodies and Anatomical Specimens*).

All requests to obtain and use anatomical specimens for research must be reviewed and approved by the Director of the Human Structure Facility (see:  <https://med.uth.edu/nba/willed-body-program/iaorc/>). This includes specimens to be obtained from the university’s Willed Body Program, from surgical procedures or autopsies performed by UTHealth physicians, and from other universities or organizations.

If requests are approved, the Director of the Human Structure Facility will arrange for specimens to be obtained from the Willed Body Program or instruct investigators how to request specimens from the Pathology Department or other appropriate non-UTHealth source. Approval by the Director of the Human Structure Facility is required, but additional approval(s) may also be required (*vide infra*).

Specimens provided by Pathology or outside sources should be sent directly to the Human Structure Facility for administrative log in and records processing before delivery to the investigator. In special circumstances, samples may be sent from the provider directly to the investigator if approved in advance by the Director of the Human Structure Facility.

**III. Teeth Obtained from Dental Procedures**

Teeth obtained from dental procedures are considered in a separate category (see *HOOP 97 – Deceased Human Bodies and Anatomical Specimens*, Section III. C.3). HOOP 97 stipulates that all teeth acquired from dental procedures are to be received, recorded and dispensed through the Surgical Oral and Maxillofacial Pathology Laboratory and other appropriate venues of the School of Dentistry as determined by its Dean.

**IV. Tissue Samples Derived from Autopsies**

Research using specimens obtained at autopsy must comply with an appropriate Autopsy Consent Form (<https://med.uth.edu/pathology/files/2013/08/66466-Postmortem-Examination-or-Autopsy-Consent-Form.pdf>) as determined by the Director of the Autopsy Service in the Pathology Department and relevant hospital, HIPAA and the IAORC requirements (the latter as per section II. Anatomical Specimens above.) IRB approval is not necessary because research on deceased persons is not within the purview of an IRB. Acquisition and disposition of recognizable body parts must have IAORC approval, but small pieces of tissue unrecognizable as human organs or body parts upon observation by a layperson require neither IRB nor IAORC approval. Investigators are nevertheless strongly encouraged to contact the Director of the Human Structure Facility to confirm whether IAORC approval is required in a specific situation.

Investigators requesting autopsy samples should provide the Director of the Autopsy Service with the following information

* 1. A description of the research, the tissues needed, including how they should be processed, and how patient confidentiality will be maintained and HIPPA requirements will be met.
  2. IAORC approval as needed for recognizable body parts.
  3. Any other documents or materials the Director of the Autopsy Service determines are necessary.

The documents will be reviewed by the Director of the Autopsy Service for compliance with applicable regulations, UTHealth, and hospital requirements. If approved, the prosectors will be tasked with collecting the tissues and transferring to the investigator requesting the material, or to the Human Structure Facility if required.

If analysis of samples by a pathologist is necessary as part of the research protocol, investigators should contact an appropriate Pathology Department faculty member in advance to make needed arrangements. Depending upon the analysis required there may be a fee and co-authorship or other agreed upon recognition may be appropriate.

More detailed guidelines and procedures are provided by the Department of Pathology and should be reviewed in advance by investigators (<https://med.uth.edu/pathology/research/>).

**V. Archival Biopsies and Materials**

All archival biopsies and other materials obtained for examination by pathologists for clinical care are under the control of the Department of Pathology and Laboratory Medicine of the Medical School and the relevant hospital/health care system. Release of material for proposed research can only be done if it will not compromise routine current or future clinical care. While advances in genomics, proteomics, metabolomics, and other technologies have greatly expanded opportunities for research and diagnostic purposes, biopsies are becoming smaller in many cases so less tissue may be available than in the past. In addition, requests and uses of biopsies and other material must comply with some or all of the following regulations and requirements.

1. CLIA (Clinical Laboratory Improvement Amendments) for accreditation of diagnostic laboratories).

2. IRB (Institutional Review Board) for human subjects (defined as a live person(s)) research as necessary.

3. IAORC approval for anatomical specimens if appropriate. (Anatomical specimens are human body parts, including bones and viscera, whether obtained from deceased human bodies or surgical specimens; small quantities of tissue or sections of bone or viscera are not considered to be anatomical specimens as per HOOP policy 97).

4. HIPAA (Health Insurance Portability and Accountability Act), the federal law that protects personal medical information.

In addition, there are strict requirements for the Pathology Department and/or hospital to retain sufficient material for possible future examination for medical or other (e.g., legal review) purposes. For example, Federal law requires that a Pathology laboratory retains paraffin blocks for two years for patient care purposes and CLIA requirements in some cases stipulate that paraffin blocks used for patient diagnostic purposes be kept for as long as 10 years.

To be fully aware of all requirements, which may be subject to change due to periodically altered requirements of regulations, investigators should carefully review the details of procedures for obtaining any needed approval from the Department of Pathology and Laboratory Medicine (<https://med.uth.edu/pathology/documents/2015/08/ut-research-tissue-policy.pdf>). In general this is a two-stage process that involves an initial, small number of key questions to determine if pathology approval is automatic or requires a more complete Pathology review that requires investigators to provide additional information.

Depending upon the study and requested information/analysis certain fees may be required and some type of professional recognition may be appropriate.

1Note: The purpose of these guidelines is solely to provide information about processes, procedures, and required permissions. It is not the purview of the IAORC to evaluate the quality or value of research or educational programs that propose to involve human subjects, anatomical specimens, teeth derived from dental procedures, material derived from autopsies, or archival biopsies or other materials.