Guidance for Using Leftover Surgical Specimens in Research

This guideline explains UConn Health's position on the use of specimen or tissue samples obtained in a medical/surgical procedure for research purposes. It clarifies in which instances medical/surgical specimens can be linked to medical data and used for research purposes.

The Authorization for Medical/Surgical Procedure form (i.e., surgical consent) states that the hospital may retain tissue removed during the procedure for research purposes provided that ***all links to the patient's identity have been destroyed and cannot be reconstructed***. As such, **samples collected under this consent** and used for research must not be identifiable and would not be able to be linked to medical record data. Thus, it is not permissible for researchers to link clinical data to the medical/surgical specimen without obtaining patient's explicit consent, even if the person linking the sample and data is not otherwise involved in the research.

As such, studies planning on utilizing existing surgical specimen or tissue samples linked with corresponding medical record data must first obtain the patient's informed consent. Once consent has been obtained, researchers may request available medical/surgical specimens or tissue samples and corresponding clinical data.

Leftover samples obtained under a surgical consent may be used for research purposes without obtaining patient informed consent only when used within the limitations of the surgical consent authorization (i.e. without any identifying information or medical data).

Procedures for studies looking to link clinical data to surgical samples:

1. The study protocol should allow for consenting of patients who may meet initial study eligibility criteria. Only patients who provide consent to participate in the study and agree to have their clinical data linked to existing surgical specimens may be included.
2. Pre-screening of potentially eligible participants may be conducted if the IRB approves a Partial Waiver of HIPAA authorization. Patients who meet eligibility criteria may be invited to participate (recruitment and screening materials should be provided for IRB review and approval).
3. Patients who agree to participate should be scheduled for an informed consent visit (ICF and HIPAA Authorization Form should be provided for IRB review and approval).
4. The consent process may be conducted remotely following UCH policy on Informed Consent Process (2011-008.1)
5. Once consent is obtained and documented as required, participant samples and linked medical data may be obtained for those individuals, if such samples exist.

If some patients may be deceased, the study protocol should describe procedures for documenting the patient status. In the case of patients who are confirmed to be deceased, a full HIPAA Waiver may be requested to obtain permission to use the samples with linked datasets, if such samples exist.