Guidelines For Submission of Excess Biologic Material to Tissue Banks

The following guidelines apply to banking of extra tissue obtained at the time of clinically indicated surgical procedures, for the purpose of future research. Included in this definition is the submission of tissue to centralized tissue banks. These guidelines do not apply to tissues obtained solely for research purposes (that is, not obtained at the time of clinically indicated surgical procedures) or additional tissue obtained at the time of a clinically indicated surgical procedures.

Storage of Tissue with Patient Identifiers

Excess tissues may be collected as part of an addendum to a therapeutic protocol, or as a free standing non-therapeutic protocol. If the collection of excess tissues is an addendum to a therapeutic study, the collection of these tissues cannot be requirement for participation in therapeutic study unless studies performed on these tissues are an integral part of the protocol. In this case, the consent form should describe the tests to be completed, and the risks and benefits of these tests. Collection of excess tissues for "tissue banking" for as yet unplanned studies cannot be a requirement for participation in a therapeutic trial, since these studies, by definition, cannot be integral to the therapeutic study.

1. Local Tissue Banks

For submission of excess tissue to a "local" tissue bank, investigators can use the generic tissue banking consent form (either addendum consent, or full consent). A "local" tissue bank is defined as a facility at the University of Nebraska, or operated entirely or in part by an investigator affiliated with the University of Nebraska. Prior to the banked tissue being is used, the investigator must submit a full protocol to the UNMC IRB describing the specific research to be performed. This protocol will include information regarding the sharing of results with the subject, or an explanation why results will not be shared. In rare cases where the UNMC IRB believe patient's rights and welfare may be affected by use of their tissues in these studies, the IRB may require that the investigator contact patients for reconsent prior to utilization of these samples.

2. Centralized Tissue Banks (Non-Local)

For submission of excess tissue to any non-local tissue bank (such as the CHTN, or a Cooperative Group associated tissue banks, or a bank operated out of another University) investigators can use the generic tissue banking consent form (either addendum consent, or full consent). The UNMC IRB recognizes that the investigators at UNMC will not have control over what studies are performed through these tissue banks, and will only require that investigators obtaining tissue from these banks have the approval of their local IRBs.
**Storage of Tissue without Patient Identifiers**

Research involving the collection or study of existing pathological specimens in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects is exempt from IRB review, under 45CFR46.101(b)(4). Investigators must still complete an IRB Request for Exemption Form prior to collection of these tissues, or use of these stored tissues in research.