Request for Human Biological Materials for Research

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Intramural Request for Archived Human Biological Material	Reference Lab Requests	TRC Request Form

Purpose and Guidelines

This procedure is written under the direction of the Tissue Resource Committee (TRC). In June 2000, the Medical Executive Committee constituted a Tissue Resource Committee to formulate guidance regarding the procurement and use of human tissues for research. The committee addressed issues of human subjects protections and implementation of a documentation system for tissue acquisition and transfer in the NIH Clinical Center (CC) and to non-NIH investigators. Additionally, the committee sought to delineate the differences in handling tissue specimens obtained for clinical care as opposed to research, and to protect investigators' access to tissues collected under protocols, while providing access of others to the archival CC specimen collection (the Archive) curated by the Laboratory of Pathology (LP). See M01-2 (rev.), "Procurement and Use of Human Biological, "Procurement and Use of Human Biological Materials for Research Materials for Research for the CC Medical Executive Committee policy.

Release of any patient materials from the archive (e.g., specimen, blocks, slides, or reports) for research must be approved by the TRC. The TRC may question the technical approach of any request and may contact the requester for additional information to justify or modify the request. However, it is not the purpose of the TRC to review the scientific merit or ethics of any proposal.

All studies using materials from living patients must have proper Institutional Review Board (IRB) approval or Office of Human Subjects Research (OHSR) exemption. IRB approval is necessary if the request requires samples linked to patient identification or any study that uses patient information other than age, sex, and diagnosis (i.e., clinical outcome).

An OHSR exemption is required for non-protocol material, such as anonymized material (i.e., unlinked, with no patient identifiers and therefore cannot be correlated with patient's clinical course or clinical outcomes, etc.). It is the responsibility of the requestor to obtain the appropriate OHSR approval before requesting resources through LP. Age, sex, diagnosis, and source may be provided for OHSR-exempted requests.

Neither IRB approval nor OHSR exemption is required for materials from deceased patients. For release of material from non-living patients, the requester must certify the expiration of the patient.

The use of tissues for controls in diagnostics tests (e.g., block used as a control for an immunoperoxidase stain) performed for diagnosis (tests performed in a CLIA- or CAP-approved laboratory) is exempted from this process.

Specimens prospectively collected for particular protocols are protected from non-protocol-specific research. General policies are listed below to provide general guidance.

- All specimens that are collected for protocol purposes but for which limited material is available will be unavailable for any research (linked or unlinked) without the consent/collaboration of the principal investigator (PI). Limited material is defined as a single block specimen (includes cytologies and surgicals). Such specimens will be flagged in the SoftPath™ Laboratory Information System (LIS) along with the protocol number.
- Limited medical specimens collected as part of medical care of the patient, but not part of the protocol (e.g., stomach biopsy on a hepatitis patient), will be available for research with the proper ethical approval.
- Non-limited specimens collected for a protocol will be available for research without the consent or collaboration of the PI with the proviso that at least one representative block is set aside and preserved for diagnostic purposes.
- More restrictive use could be flagged on larger (less limited) cases on a protocol-by-protocol basis if the PI notifies LP or notates this on each specimen requisition.
- Restrictions on uses of limited specimens would be lifted five (5) years after the protocol has closed, unless otherwise requested by the PI.
- Investigators placing CRIS orders for our services will have to answer a yes/no question about whether the specimen they are collecting is required or specified by the ordering protocol. (All CRIS orders that non-pathology personnel place already have to be linked to a protocol number). This information will come over to the LIS via the computer interface between the CRIS and LIS. If the specimen is being collected for the protocol, the tech who accessions the case will retype the protocol number in the "F.case#" field on the Specimen Registration screen, which is a searchable alphanumeric field. There are multiple benefits to collecting this information. First, it should reassure investigators worried about their protocol biopsies. Second, it will permit us to easily track these specimens and link specimens to PIs. We will also be able to extract information about which protocols require the most technical work. Right now, this only affects in-house specimens; however, placing this question and a place for protocol number on the paper request forms for submitted cases are under consideration.

Requests for other anonymous tissues require approval from OHSRP. To obtain this approval, requests should be submitted through OSHRP's web-based request for determination system: https://federation.nih.gov/Determination/start.php (NIH Login required).

References