

Institutional Policy Regarding Acquisition, Storage, and Distribution of Human Tissue in Basic, Translational and Clinical Research

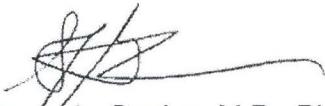
These guidelines apply to biospecimens that are obtained in the course of clinically indicated diagnostic and/or therapeutic procedures. Specimens that are obtained exclusively for research and not as part of a diagnostic or therapeutic procedure are exempt from this policy.

Institutional Policy and Practice:

1. All surgical specimens obtained for clinical purposes must be released by a pathologist or a designated pathology staff member, as required by law, before tissue is acquired, processed or stored for research.
2. The Institution recognizes that human specimens, including tissue, represent a valuable and unique patient resource that must have proper acquisition and custodianship in accordance with best practices for biospecimen resources. This will be accomplished through centrally supervised acquisition, processing, and banking of clinical tissue in a facility co-sponsored by the Department of Pathology and the CTRI or through satellite repositories in facilities that accept the principles set forth in this policy.
3. Human specimens will be collected, banked, and distributed in accordance with Assurance of Compliance and IRB review, when appropriate, and according to equitable practices reviewed by the Human Sample Biorepository Governance Committee (see #5 below). Tissue-specific advisory committees can oversee and ensure that human specimen resources are optimally acquired, processed, stored, distributed and tracked.
4. Tissue banked centrally or in satellite laboratories will be made available to UCSD researchers at a price that offsets the cost of acquisition, processing and storage.
5. A governance committee will be established to oversee the Repository policies and will include the Director of the Human Tissue Acquisition Service, the Chair of Pathology or his/her designee, the Chair of Surgery or his/her designee, the CTRI Director or his/her designee, and the Cancer Center Director or his/her designee. An "at-large" faculty member also will be appointed. Tissue-specific sub-committees can be established to oversee and prioritize requests for specific tissue types, such as breast, GI, or nervous system tumors.
6. Newly banked tissue will be registered and tracked by a centralized database. A de-identified tissue inventory will be web-searchable via UCSD administrative password access so that availability of human tissue samples is known. The Governance Committee will empower tissue-specific use subcommittees to ensure that the use of tissue for research is properly and fairly managed.

7. Tissue released from the Central Repository to for-profit entities will require approval by the central governance committee. Proceeds obtained from this activity may be utilized to offset operating costs for the repository system. Individual PIs who modify stored specimens from the Central Repository, and subsequently release these specimens to the private sector in exchange for financial support should disclose the terms to the Governance Committee to assure compliance with Repository policy and practice.

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