

University of New Mexico Health Sciences Center
Office of Research
Policy for the Oversight of Human Tissue in Research

1. Applicability

This policy applies to all tissues collected from volunteers and from nonliving human subjects for the purpose of research. Oversight of this policy and these tissues are the responsibility of the University of New Mexico Health Sciences Center (UNMHSC) Office of Research through its Research Protections Division. The Office of Research governs the collection, storage and dissemination of human research tissues using an administrative structure jointly sponsored by the Department of Pathology and the Cancer Research and Treatment Center (CRTC). A central human tissue repository, a tissue repository database, and the human tissue holdings in all satellite UNM human tissue repositories and the electronic connections between these satellite repositories and the central repository is hereinafter referred to as the Human Tissue Repository (HTR). The UNM Office of Research oversees the HTR for compliance with federal and state laws and regulations.

2. Role of the Human Tissue Oversight Committee (HTOC)

A Human Tissue Oversight Committee (HTOC), and Chairperson, will be appointed by the Senior Associate Dean for Research, with approval of the Dean of the School of Medicine (SOM) and the Vice President of the Health Sciences Center (HSC), to serve in a governing and advisory role to the HTR. The HTOC will not govern the administration of the satellite tissue repositories, but has authority over the collection, reporting and distribution of the tissues held. Membership will consist of at least ten (10) members to include the following eight (8) voting ex officio members: The Chair of the Department of Pathology, the Director of the CRTC, a representative from the hematology-oncology division of Internal Medicine, a representative from at least one of the satellite tissue repositories, the Chair or Executive Chair of the Human Research Review Committees (HRRC), a representative from SEER, the Director of Research Protections, and a representative from the Ethics Institute. The term for members, other than appointments based on specific positions such as Chair of Clinical Pathology, shall be three years, with one additional term permitted by mutual agreement of the Senior Associate Dean for Research and the HTOC member. Members can designate an alternate member who may attend meetings and vote as proxy for the member. The HTOC is responsible for developing new policies and making changes in all standing policies for the HTR, approving the appointment of the Director of the HTR, enforcing policy as needed, approving annual budgets, approving requests for funding submitted to the Office of Research or SOM Dean's office, and other duties as assigned.

3. Definition and categories of "Research Tissues"

Tissues are defined as body fluids, solid tissues, bone, and cellular constituents derived from tissue including, but not limited to, DNA, RNA and proteins. Tissues removed for diagnosis ONLY are NOT included in this policy statement, because they do not constitute tissues for research. A computer-based mechanism shall be developed to capture the data that correlates with each sample collected, listing where the sample is to be stored and whether appropriate permission or waiver of permission has been obtained before dissemination. The database system shall capture the essentials of the permission, including categorizing the type of

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permission as Type A, B, C or D (see definition below), whether permission has been granted for future contact of the volunteer and/or permission to do future, undescribed research, including DNA studies. Compliance with applicable HIPAA privacy regulations is required. Tissue categories are defined as follows:

- a. Type A. Tissue collected for possible future diagnostic purposes. Thus HRRC oversight or informed consent is not required, because the tissue was collected for medically necessary diagnostic study.
- b. Type B. Tissue obtained for known HRRC- approved active research project with HRRC-approved consent status.
- c. Type C. Excess tissue alternatively prepared for tissue banking for unknown future research project with consent of patient for such storage.
- d. Type D. Excess tissue alternatively prepared for tissue banking for unknown future research project with waiver of informed consent, waiver of HIPAA authorization, HTR as honest broker for identifiers, and dispensed as de-identified samples.

4. Where research tissues will be held

Tissues entered into the database and available for research as outlined in Policy Statement 3 above shall be banked in either the central HTR, managed by the Department of Pathology and CRTIC, or in an approved satellite tissue repository. Tissues for which volunteers have given informed consent (HRRC-approved) are generally the only types of tissues that may be stored in satellite tissue repositories. However, exceptions may be made if the satellite repository has sought and received specific HRRC approval for this type of collection. All faculty members shall complete full disclosure of human tissues stored in satellite tissue repositories and seek permission from the HRRC for their maintenance (if they have not already done so). Faculty members who do not wish to seek HRRC approval for continued storage and participation in the HTR must transfer the tissues to the UNM central HTR. Once the UNM HTR software is operational, all tissue in the satellite repositories will be entered into the central database.

5. Eligibility criteria for investigators to withdraw tissues from the HTR

Only faculty members of UNM or a bona fide researcher from outside of UNM under the sponsorship of a UNM faculty member are eligible to request/receive archived specimens from UNM HTR. Investigators must submit requests for archived specimens to the Scientific Review Committee (SRC) before submitting the corresponding proposal for review by the HRRC. Decisions of the SRC may influence subsequent review of the proposal by the HRRC if, for example, the SRC deems the proposal to lack merit sufficient to release the tissues, especially those tissues which are valuable to the investigator holding the tissue. Access to

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archived specimens will be granted if, and only if, the research proposal is approved by the HRRC or if the HRRC determines that the proposed research is exempt from review.

6. Determining availability of tissue for research investigation

The investigator interested in the use of tissue for research must provide the UNM HTR a description of the tissue of interest needed for the research project. The investigator may either search the UNM HTR website or request the UNM HTR to search their database for availability of their tissue of interest. The search may be based on type of specimen (block, slide, blood, etc.), the anatomical site of origin, histological diagnosis, relevant patient characteristics (as applicable), including sex, race/ethnicity, age at diagnosis and residency at diagnosis for population-based studies, number of samples required to address research objectives of proposed study and other relevant selection criteria. Upon receipt of the request, the UNM HTR staff will query the database of archived tissue to determine their availability. If the tissue is available from the UNM HTR, the investigator must make appropriate application to the Human Tissue Scientific Review Committee (SRC) to gain access to the relevant specimens. If any of the tissue was originally acquired specifically for diagnostic studies and stored as a slide, paraffin block or frozen tissue for possible future diagnostic/prognostic study through the Department of Pathology, the HTR and SRC can facilitate the use of the tissue but will require that an appropriate pathology faculty member be part of the study to assure that all tissue will be used appropriately and the head of the appropriate Section/Division or his/her designee must verify that the tissue to be used will not exhaust the tissue nor compromise future use for patient care. No further action is required if the tissue of interest is not available from the UNM HTR. However, with an HRRC-approved protocol, the PI must request that the UNM HTR collect the tissue prospectively.

7. Research proposal to request use of tissue from the HTR

Proposals to utilize archived specimens must be submitted to the SRC. Proposals should include 1) background, rationale and significance; 2) research objectives with specific aims; 3) specific methods, including a detailed description of tissue to be acquired, i.e., numbers of samples and types of requested tissue (block, slide, etc.), anatomical site of origin, histology; a detailed description of protocol for handling and processing each specimen, i.e., tissue procurement and handling; tissue processing; tissue tracking; plans to return remaining tissue to archive; and statistical considerations, including statistical power of the study to achieve research objectives, as appropriate; 4) personnel involved; 5) facilities; and 6) any relevant references. Documentation of funding and other pertinent information should also be attached, but would not need to fit within the five page limit. If a proposal is approved, but additional samples are needed for the proposed study, for example, increased numbers or tissue of a different type, an amended version of the proposal must be submitted to the SRC.

8. Function and membership of the human tissue Scientific Review Committee (SRC)

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The Senior Associate Dean for Research at the UNMHSC shall appoint a standing Scientific Review Committee (SRC) and its Chair to assess the scientific merit of each proposal for the use of archived specimens. The SRC shall be composed of voting ex officio members and regular members, appointed by the Senior Associate Dean of Research and ad hoc members (principal investigators of satellite repositories). The ex officio and regular member appointments will be approved by the Dean of the SOM and the Vice President of the HSC. There will be at least three (3) ex officio members to include a UNM HTR Director (either a Medical or Scientific Director), a member of the Cancer Research and Treatment Center (CRTC) Medical Scientific Review Committee (MSRC) and a member of the Surgical Pathology Section of the Department of Pathology. Ex officio members shall have ongoing membership with no limits to their term. There will be at least three additional regular members, broadly representative of the clinical and research communities of UNMHSC including at least one epidemiologist or biostatistician familiar with epidemiology research.. Regular members will have a three (3) year term of membership. If no ex officio or regular member of the SRC has expertise relevant to the proposal under review, an appropriate subject matter expert(s) will be identified to participate in the review process by the Chair of the SRC. A subject matter expert(s) may be recruited by the SRC from inside or outside the UNMHSC community to assist in evaluating the scientific merit of the study when those individuals possess expertise relevant to the specific proposal under consideration but this expert will not have a vote. In addition, when a request/proposal involves specimens from a source other than the UNM HTR, the Principal Investigator (PI) who oversees those satellite specimens shall serve as an ad hoc member of the SRC during the review process and shall have a vote on that protocol only. A quorum needed to decide on a particular protocol will be a majority of committee members including voting ad hoc members (e.g., 4 if the committee consists of 6 or 7 members).

9. SRC review of proposals

Each proposal will be assigned a *primary* and *secondary*- reviewer from the membership of the SRC. These Reviewers will (a) conduct a careful and comprehensive review of the assigned proposal prior to the meeting, (b) submit a written review of the assigned proposal to other SRC members, (c) lead discussion of the assigned proposal during review process, and (d) make recommendations regarding approval, revision or denial of the assigned proposal.

The SRC will review proposed use of human tissue at either a convened meeting at which a majority of the members of the SRC are present or electronically wherein the majority of members should certify officially that they have reviewed the proposals and read the reports of the primary and secondary reviewers and indicate same by entering their vote. A face-to-face meeting will be called at the request of any reviewer(s) or the SRC Chair. If the tissue being requested is from a satellite tissue bank, the director of that satellite tissue bank must also be either present at the convened meeting or participate in the electronic review process. In order for the request to be approved, it must receive the approval of a majority of those members present at the meeting. If the tissue (slides, paraffin blocks, frozen tissue or other

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specimen) was initially acquired for diagnostic purposes and might be used for future diagnostic studies for living or deceased patients, then the head of the appropriate Department of Pathology Section/Division must participate in the meeting, review the proposal, and have the power to veto the proposal if he/she deems use of the tissue, as proposed, might compromise future patient care and/or potential use of the resource.

In instances where a subject matter expert has been recruited by the SRC for their relevant expertise, the expert shall serve as *primary reviewer* only if s/he can participate in the relevant meeting of the SRC.

Research proposals will be evaluated by the SRC based on the following criteria:

- a. Scientific merit of the proposed study, including:
 1. Context/background of proposed investigation
 2. Novel vs. confirmatory nature of proposed investigation
 3. Feasibility of proposed study

- b. Demonstrated expertise of the investigator/research team to appropriately address the objectives of the proposed investigation, including:
 1. Record of relevant publications
 2. Record of relevant funding

- c. Demonstrated availability of sufficient funding and physical resources and human resources to successfully achieve the objectives of the proposed study; including:
 1. Availability of funds specific for this project or reference to existing grant proposal
 2. Adequate and appropriate facilities
 3. Personnel with adequate and appropriate experience

- d. Specific statement addressing the potential risk to study subjects vs. the possible benefits to be derived from the proposed project

- e. Certification by signature of the Medical Director of the HTR that the tissue is available and indicate that it is (or is not) rare.

10. Proposals for the use of unique, rare or nearly exhausted tissue samples

The SRC review and approval process shall be more stringent for tissue samples that are unique, rare, or “nearly exhausted”. SRC members must agree that a proposed use of unique, rare, or “nearly exhausted” specimens is of high scientific value and that such research could not be reasonably conducted with other tissue obtained elsewhere. Approval of a request to utilize specimens that are unique, rare, or “nearly exhausted” requires the approval of two-thirds (2/3rds) of those members present at the convened SRC meeting.

11. Suspension or termination of SRC approval

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The SRC has authority to suspend or terminate approval of research that has previously been approved by the SRC. This stipulation protects the HTR's right to return unused tissues to the database to be listed as "available" should the PI not follow appropriate policy or fail to exercise his access within a reasonable period of time.

12. Veto and appeals process

The SRC recognizes the special role of faculty members who have invested considerable time, money and effort to develop tissue collections that exist outside of the Tissue Repository. These investigators will be asked to serve as an **ad hoc member** of the SRC when a request/proposal seeks to utilize specimens that are under her/his control. The ad hoc member shall have the option to veto such proposals. A veto by an ad hoc member may also be appealed using the SRC appeals process. A researcher or member of the SRC may appeal a decision of the SRC or a veto by an ad hoc member. Appeals must be submitted in writing and must address, on a point-by point-basis, the appellant's specific disagreements with the judgment of the SRC or veto. The first level for adjudication of appeals is the fully convened SRC (in a face-to-face meeting). The second level of appeal is the UNMHSC Research Council, acting at the discretion of the Vice President for Health Sciences. Any member of the HSC Research Council who was a party to the SRC deliberations shall recuse himself/herself from the appeals process.

13. Relationship of UNM Human Tissue Repository (HTR) to cooperative tissue procurement efforts

Principles: A growing effort at the national level seeks to create a National Biospecimen Collection Network. Such a network would involve regional repositories near cancer referral and academic centers, Cooperative Group tissue collection efforts and a connecting network. A national network would facilitate distribution of specimens to participating institutions. UNM participation in such a network would support a national tissue procurement effort and improve availability of tissue to UNM tissue researchers. It is therefore in the strategic interest of the UNMHSC to foster and maintain relationships with Cooperative Tissue Procurement efforts and with Cooperative Groups.

Role of Surgical Pathology: Proper tissue collection and triage is essential to proper evaluation and triage by UNM Surgical Pathology faculty and staff. Priority is given to diagnostic studies and patient care. See per UNMH policy ("Handling of Specimen, Foreign Bodies, Care and Disposition of", University Hospital and Children's Hospital of New Mexico, Clinical Practice Policies and Procedures). Nonexempt tissues must be submitted to Surgical Pathology for assessment and selection of diagnostic tissue prior to selecting tissue for banking. Surgical Pathology will assist in harvesting as agreed upon between the local PI collecting tissues, Surgical Pathology and the UNM HTR (in its UNM HRRC-approved protocol).

Cooperative Group Protocols: The cooperative effort will ensure tissue is collected, whenever appropriate, for national and local research needs. The UNM HTR may provide a

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trained tech working closely with Surgical Pathology, trained in handling tissues for banking. Close cooperation between Surgical Pathology, the UNM HTR and Cooperative Groups will ensure that tissue is handled and shipped as appropriate to Cooperative Group efforts with documentation for tracking. The UNM HTR will account for technical and administrative services provided in collecting and shipping these tissues, and will charge the research protocol for these services, according to a standardized and approved fee schedule. This usually represents a pass through of funds from the Cooperative Group to the local P.I. The UNM HTR will document tissue collection and shipping for accountability and funding, but will not retain control of the tissue collected for the Cooperative Group. The responsibility and control resides with the Cooperative Group, whether the Cooperative Repository is in Albuquerque or other location. This responsibility includes storage, quality control, and dispensing of tissues. Cooperative Group collections housed at UNM, are not to be maintained in the HTR database as stored tissues, but are entered as collected and shipped. In addition, the UNM HTR will not be involved in the receipt of tissues sent to a Cooperative Group collection housed at UNM. These tissue specimens belong to the Cooperative Group and will be managed by the local P.I., who is also responsible for the HRRC (IRB) approval, consent status, storage, quality control and distribution. The UNM HTR will refer all requests for tissue from the cooperative bank to the administrator of the relevant Cooperative Group.

In the event that a Cooperative Group collection effort ceases due to lack of funding or other reasons, the UNM HTR will consider assuming that collection on a case by case basis, depending on the needs of the UNM HTR and the quality/type of the collection.

Other Cooperative Relationships: The UNM HTR will also consider contractual relationships with external tissue repositories and with virtual human tissue repositories, with full consideration to patient care, ethical, privacy, and conflict of interest issues.