

Oversight of Human Tissue in Research

Title: Oversight of Human Tissue in Research		
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Owner(s) (Name and Title): Vice Chancellor for Research	Revision Date: April 11. 2016	Applies To: HSC Investigators

I. PURPOSE

Unprecedented advances in health care technology have greatly increased the power and precision of analytical tools used in research. Human tissue specimens that are analyzed using these new and developing technology platforms have emerged as a critical resource for basic and translational research. Standardization of human tissue resources using state-of-science approaches has become a pressing need across the research enterprise. The UNM HSC policy for the **Oversight of Human Tissue in Research** sets forth the policies, standards, procedures, and guidelines with respect to the receipt, collection, storage, dissemination, and transfer (both intra-institutionally and to entities outside of the UNM HSC) of human tissue specimens to support research conducted by UNM HSC investigators. In general, all tissues and data obtained or maintained under the auspices of the UNM HSC are assumed to be the property of the UNM HSC unless a formal agreement with the UNM HSC designates otherwise. One of the intents of this Policy is to allow for Research Tissue exchange for collaborative research under the auspices of the UNM HSC’s research policies, procedures, and processes but not to allow for Research Tissue donation, purchase, or sale outside of those research policies, procedures, and processes. The UNM HSC has robust compliance systems to ensure research conducted at the UNM HSC involving Research Tissues comports with applicable state and federal laws, rules, and regulations and the ethics in research that they seek to further.

II. APPLICABILITY

This policy applies to all Research Tissues collected at the UNM HSC, including those obtained by UNM School of Medicine, Department of Pathology faculty members at the OMI, from volunteers and from nonliving Human Subjects for the purpose of Research. Human tissues removed for diagnosis **ONLY** are NOT included in, or subject to this Policy, because they do not constitute Research Tissues.

III. DEFINITIONS

“Collaboration” means an equal partnership between two researchers who are pursuing mutually interesting and beneficial research.

“Collaborative Agreement” means an agreement between two or more researchers that sets forth the nature of their working relationship in a research project. The agreement may include provisions concerning the intent of the parties to share data, research materials and facilities, and to publish research findings. Since collaboration agreements are usually executed between researchers, they are typically not documents that legally bind the researchers' institutions to a commitment of any resources.

“Collaborative Research” means researchers working together, often under the auspices of a Collaborative Agreement, to achieve the common goal of producing new scientific knowledge.”

“Donate” means giving away of something of value where the donor expects nothing in return. In the context of Research, neither the donor nor donee are actively involved in Collaborative Research.

“Honest Broker” means an individual who has access to the desired data by virtue of his or her UNM HSC responsibilities and who is not involved as a listed researcher on the respective research study.

“Human Subject” is defined per U.S. Department of Health & Human Services regulations as “living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.” 45 C.F.R. § 46.102(f).

“Human Subjects Research” means Research involving one or more Human Subjects.

“Human Tissue Repository” or “HTR”: A central human tissue repository, a tissue repository database, and the human tissue holdings in all satellite UNM human tissue repositories.

“HTOC” means the Human Tissue Oversight Committee established, described, and chartered as set forth in Section IV.2 and IV.3 of this Policy.

“Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

“Research Tissues” means any biological product or byproduct obtained from a living or deceased individual that is sufficient in type and quantity to permit an analysis of its physical or biochemical properties. This includes body fluids, solid tissues, bone, and cellular constituents including, but not limited to, DNA, RNA, proteins and human embryonic stem cells (hESCs).

IV. POLICY STATEMENT

1. In General.

Oversight of this Policy and the Research Tissues are the responsibility of the University of New Mexico Health Sciences Center (UNM HSC) Office of Research through its Human Research Protections Office. The UNM HSC 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 UNM Cancer Center UNM Cancer Center. The UNM HSC Office of Research oversees the HTR for compliance with federal and state laws and regulations. The UNM HSC adheres to high ethical principles and complies with all applicable laws, rules, and regulations. The UNM HSC requires ethical review and, in most cases, a prior informed consent of the donor before collection, acquisition or use of Research Tissues. In many cases, applicable laws, rules, and regulations do not provide clear or comprehensive guidance on the use of Research Tissues; accordingly, this Policy sets a minimum standard.

2. Establishment of the HTOC; Authority; Membership

a. *Establishment and Authority of the HTOC*

With this Policy, the HTOC is established to serve in a governing and advisory role to the HTR and any satellite Research Tissue repositories. The HTOC has authority to oversee the collection, reporting, distribution, and transfer of the Research Tissues held in those repositories, whether intra-institutionally or with researchers or entities outside of the UNM HSC, and ensure compliance with this Policy.

The HTOC is responsible for developing new policies and making changes in all standing policies for the HTR, enforcing policy as needed, approving requests for funding submitted to the Office of Research or SOM Dean's office, and other duties as assigned.

b. *Appointment, membership and terms of the Members of the HTOC*

The Vice Chancellor for Research has the authority to appoint, evaluate and remove members of HTOC and ensures that composition of the HTOC is in compliance with this policy. The HTOC will be chaired by the Senior Associate Dean for Research or his designee.

The HTOC 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 UNM Cancer Center, a representative from the hematology-oncology division of Internal Medicine, a representative from at least one of the satellite tissue repositories, a Chair or Executive Chair of the Human Research Review Committees (HRRC), a representative from the Surveillance, Epidemiology, and End Results (SEER) Program, the Director of Human Research Protections, and a representative from the UNM HSC Institute for Ethics. 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 Vice Chancellor for Research and the HTOC member. Members can designate an alternate member who may attend meetings and vote as proxy for the member.

2. Acquisition of Research Tissues

The UNM HSC will not acquire Research Tissues from others (i.e., outside entities) without their contractual and/or written assurance that the Research Tissue being acquired was collected in accordance with applicable informed consent (and assent, where appropriate) requirements and in accordance with all applicable laws, rules and regulations. With respect to Research that utilizes "fetal tissue" as defined in the National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43 (the "NIH Act"), the UNM HSC will not acquire such fetal tissue from outside entities (a) without contractual and/or written assurance that the fetal tissue being acquired was collected in accordance with a process that separates the informed consent for the abortion procedure from the informed consent to donate such fetal tissue to the UNM HSC for Research, and (b) where there is contractual assurance that the terms of the acquisition complies fully with Section 112(a) of the NIH Act (42 U.S.C. § 289g-2(a)). In addition, the contractual assurance contemplated in this Subsection 2 must indicate that there are no legal, ethical, or other restrictions against transferring the Research Tissues to the UNM HSC, nor against the UNM HSC's use of them. In addition, with respect to Research Tissues whose obtainment would fall within the coverage of the Jonathan Spradling Revised Uniform Anatomical Gift Act, Section 24-6b-1 et seq., NMSA 1978, as amended (the "JSRUAGA"), the UNM HSC will obtain such Research Tissues in

accordance with the provisions of the JSRUAGA and/or with contractual assurance that it was obtained in accordance with the JSRUAGA.

3. Where Research Tissues will be held and the Method and Manner by which it will be Stored and Maintained

Research Tissues entered into the database and available for research as outlined in this Policy shall be banked in either the central HTR, which is managed by the Department of Pathology and the UNM Comprehensive Cancer Center, or in an approved satellite Research Tissue repository. Research Tissues for which volunteers have given informed consent (HRRC-approved) are generally the only types of Research Tissues that may be stored in satellite Research Tissue repositories. However, exceptions may be made if the satellite Research Tissue 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 Research 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 Research Tissues to the central HTR.

Daily and long-term responsibilities essential for efficient Research Tissue management, either in the central HTR or in satellite Research Tissue repositories, can be diverse and include organizational considerations, space planning and functional design, resource development, evaluation and solidification of infrastructure requirements, constant and consistent review of operational issues, and regular resource evaluation. When executed and practiced in harmony, all of these factors can dramatically improve success in managing and operating a high-quality, highly utilized, and valuable research resource. To this end, the UNM HSC endeavors to meet the standards enunciated by the National Cancer Institute's *NCI Best Practices for Biospecimen Resources* (the "NCI Best Practices"), which incorporates key aspects of the *Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research*, published by the International Society for Biological and Environmental Repositories (Third Ed. 2012) (the "ISBER Best Practices"), relative to organizing, managing, storing, securing, accessing, shipping, and receiving Research Tissues, whether in the central HTR or in satellite Research Tissue repositories. The HTOC, by and through the HRPO, will develop standard operating procedures, to implement these best practices, which cover the following areas:

- Equipment monitoring, calibration, maintenance, and repair
- Control of Research Tissue collection supplies
- Research Tissue identification and labeling conventions
- Research Tissue collection, handling, processing, and preservation methods
- Procedures for storage and retrieval of Research Tissue
- Packaging, shipping, and receiving
- Laboratory tests performed in-house including Research Tissue quality control
- Research Tissue data collection and maintenance (Informatics)
- Biosafety
- Training of employees
- Administrative, technical, and physical safeguards

4. Eligibility criteria for investigators to withdraw Research Tissues from the HTR; Transfers of Research Tissues

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 Research Tissues from the HTR. Samples collected by UNM HSC faculty and stored in the HTR are derived from humans who have signed informed consent forms stating that the tissue may be used by the investigator for Research purposes. These consent forms do not include the right to sell tissues to other entities for profit, and in fact, certain federal laws, rules, and regulations expressly prohibit and make it a crime to transfer Research Tissues for a profit.

The shared use of archived Research Tissue cannot occur in the absence of a collaborative research agreement between an HSC principal investigator and appropriate investigator at an outside institution or entity and/or an inter-institutional agreement such as a services agreement or a MTA between the UNM HSC and the outside entity or institution. Although use of a collaborative research agreement, an inter-institutional agreement, or a MTA is not required by law, it is considered a best practice for setting forth the terms under which the Research Tissue is shared and/or transferred to an outside institution or entity. Accordingly, commencing April 11, 2016, having in place a collaborative research agreement, an inter-institutional agreement, or a MTA with the outside institution or entity prior to the sharing and/or transfer of Research Tissue, in light of the NCI Best Practices and the ISBER Best Practices, may be a condition precedent to the approval of any such sharing and/or transfer of Research Tissue. In circumstances where a collaborative research agreement exists with another institution or commercial entity, the sharing and/or transfer of Research Tissue with outside investigators and/or institutions requires IRB approval at both institutions and appropriate informed consent from the patients involved. All external IRB approvals must be submitted to the UNM HSC Human Research Review Committee (HRRC) before Research Tissues are shared and/or transferred outside of the UNM HSC.

a. *Principles Guiding the Transfer of Research Assets*

- The UNM HSC will comply with all legal and regulatory obligations.
- The UNM HSC will protect the welfare of participants in research and honor their expectations with respect to the use of their Research Tissues.
- The UNM HSC will protect the value to investigators and their use of Research Tissues for the conduct of research.
- The UNM HSC will protect the value to the UNM HSC of Research Tissues as property and resources of the UNM HSC, and for the development of intellectual property.

b. *Material Transfer Agreement (MTA)*

As indicated previously, from and after April 11, 2016, if an investigator's research involves the collection and use of Research Tissues and the investigator intends to transfer these samples to a location outside of the UNM HSC, a Materials Transfer Agreement (MTA) is strongly advised and should be processed according to procedures in fiscal services. This is because research protocols are not designed to document material transfers and are usually inappropriate for this purpose. An MTA is needed for:

- All transfers that involve Research Tissues; or
- All transfers that involve Research Tissues that may result in the limitation of access to these research resources by investigators at the UNM HSC.

In this connection, such an MTA will be required unless:

- The Research Tissue transfer is part of a contract or grant agreement that adequately specifies the management of the Research Tissues and associated data; or
- A testing, research or professional agreement or collaborative agreement has been approved with a provision that the Research Tissue samples and data will not be retained or used for research purposes other than for the purposes stated in the agreement.

c. *Investigator's Responsibilities*

The use of Research Tissues may only be done as specified in the study participant's consent forms. The investigator is responsible for reviewing the original consent forms to confirm the appropriate use of the samples that the investigator wishes to transfer. Investigators should understand that there are some cases in which the UNMHSC cannot permit transfer of samples to another entity.

5. HRRC and ESCRO Approval

a. *Human Research Review Committee (HRRC) –*

- i. All research involving the use and/or transfer of Research Tissues (whether identifiable or de-identified) must be submitted to the HRRC for review and determination. *Investigators must submit requests for archived specimens of Research Tissues 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 Research Tissues, especially those Research Tissues which are valuable to the investigator holding the Research Tissue or which are deemed rare or exist in limited amounts. Access to archived specimens of Research Tissue 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. If the request involves a transfer of Research Tissues for research purposes outside the UNMHSC, the Principal

Investigator must notify the HRRC. This notice is shared with the HRRC and the HRPO and the HRRC reviews the proposed transfer to ensure the following:

- The intended use is not inconsistent with the consent given by participants under the original collection protocol(s), to the extent applicable.
 - The intended use will not conflict with any pre-existing obligations attached to the samples.
 - The intended use is consistent with the UNM HSC's obligations under federal and state laws, regulations, and guidelines, including HIPAA and IRB guidelines.
- ii. HRRC review and approval is required for the storage of human tissue for human research purposes as defined by 45 CFR § 46. The storage of human tissue for future use in human research studies is considered a separate human research activity from any current or future human research study involving the use of the stored tissue, and requires separate HRRC review and approval.

HRRC approval and informed consent is required to store the following categories of human tissue for future use in human research:

- Identifiable human tissue originally collected for use in human research.
- Identifiable human tissue originally collected for clinical purposes.
- De-identified or coded human tissue originally collected for use in human research.

HRRC approval and informed consent is not required to store the following types of human tissue for future use in human research:

- Tissue collected from non-human subjects as defined by 45 CFR 46.
- De-identified tissue originally collected for clinical purposes (provided, however, that these tissues may be subject to compliance with the repository requirements of this Policy, any guidance published by the HRPO, and any applicable SOPs).

In some cases, as in FDA regulated research involving in-vitro diagnostic devices, human tissue specimens are considered to be human subjects. As such, HRRC review and approval is required, but obtaining informed consent may not be possible. Investigators should consult with the HRPO if you plan to engage in this kind of research.

- b. *Embryonic Stem Cell Research Oversight (ESCRO) Committee* – All research involving the use of embryonic stem cells must be submitted to the ESCRO Committee prior to submission to the HRRC. The ESCRO Committee will conduct a scientific and ethical review and provide recommendations to the HRRC. The HRRC will consider the Committee's recommendation in the HRRC's analysis of risk and benefit.

6. Determining availability of Research Tissue for research investigation

The investigator interested in the use of Research Tissue for Research must provide the HTR a description of the Research Tissue of interest needed for the Research project. The investigator may either search the HTR website or request the HTR to search its database for availability of the Research 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 HTR staff will query the database of archived tissue to determine their availability.

If the tissue is available from the 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 HTR. However, with an HRRC-approved protocol, the PI must request that the HTR collect the tissue prospectively.

7. Research proposal to request use of Research 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. Appointment, Membership and Terms of the human tissue Scientific Review Committee (SRC)

The Senior Associate Dean for Research in the School of Medicine shall appoint a standing Scientific Review Committee (SRC) and its Chair. The SRC shall be composed of voting ex officio members and regular members and ad hoc members (principal investigators of satellite repositories). 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 (UNM Cancer Center) 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 UNM HSC 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 UNM HSC 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 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. Function of the human tissue Scientific Review Committee (SRC)

The SRC **assesses** the scientific merit of all Research Tissue proposals for the use of archived specimens. The SRC review can influence subsequent IRB approval of the proposed study.

a. SRC review of proposals

- i. 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.
- ii. The SRC will review proposed use of Research 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 PI that oversees 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 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.
- iii. 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.

- iv. Research proposals will be evaluated by the SRC based on the following criteria:
- (a) Scientific merit of the proposed study, including:
 - i. Context/background of proposed investigation
 - ii. Novel vs. confirmatory nature of proposed investigation
 - iii. Feasibility of proposed study
 - (b) Demonstrated expertise of the investigator/research team to appropriately address the objectives of the proposed investigation, including:
 - i. Record of relevant publications
 - ii. 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:
 - i. Availability of funds specific for this project or reference to existing grant proposal
 - ii. Adequate and appropriate facilities
 - iii. 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.
- b. *Proposals for the use of unique, rare or nearly exhausted tissue samples*

Investigators should understand that the SRC review and approval process will 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.

c. *Suspension or termination of SRC approval*

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.

d. *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. The ad-hoc member may not veto during an appeals process. A second level of appeal may be made to the Vice Chancellor for Research.

10. Relationship of HTR to cooperative tissue procurement efforts

- a. *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 UNM HSC to foster and maintain relationships with Cooperative Tissue Procurement efforts and with Cooperative Groups.
- b. *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).
- c. *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 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.

- d. *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.

REFERENCES/RESOURCES

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National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 42 U.S.C. § 289g-1 et seq.

Jonathan Spradling Revised Uniform Anatomical Gift Act, Section 24-6b-1 et seq., NMSA 1978, as amended.

Title 3 -The President, Executive Order 13505 of March 9, 2009. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. Federal Register/ Vol. 74, No. 46, page 10667- 10668.

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RESPONSIBILITY

1. The HTOC is responsible for developing new policies and making changes in all standing policies for the HTR.
2. The Vice Chancellor for Research ensures that composition of the HTOC is in compliance with this policy.

RESOURCES AND TRAINING

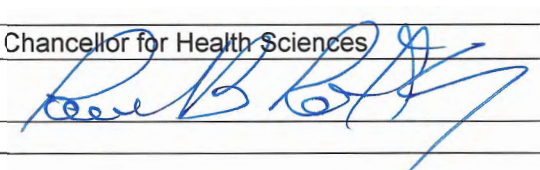


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SUMMARY OF CHANGES

Replaces *Policy for the Oversight of Human Tissue in Research*, Approved by HTOC December 14, 2007 and updated June 3, 2013

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	Vice Chancellor for Research, Office of Research		
Consultant(s)			
Recommender(s)			[Y or N/A]
Committee(s)	Human Tissue Oversight Committee (HTOC) Research Strategic Planning Committee (RSPC)		[Y or N/A]
HSC Legal Office			[Y or N/A]
Official Approver	Chancellor for Health Sciences		Yes
Official Approver Signature		Date: April 11, 2016	
2nd Approver			
2nd Approver Signature (Optional)		Date:	
Policy Origination Date: December 14, 2007, updated June 3, 2012 and September 16, 2015			

ATTACHMENTS

None