

HLC Accreditation **Evidence Document**

Title: Human Tissue Oversight

Office of Origin: Health and Sciences Center

Description: Information on the oversight structures in place for the dealing with of human tissue in HSC activities. This includes mention of the Human Tissue Oversight Committee (HTOC) and the UNM HSC Human Tissue Repository (HTR).

Date: 2018

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Human Tissue Oversight

UNM HSC Policy for the Oversight of Human Tissue applies throughout the HSC to "tissues" that are collected for research. "Tissue" has been broadly defined and includes but is not limited to tissue, blood, body fluids, cells, derivative nucleic acids, and proteomic materials. It creates the UNM HSC Human Tissue Repository (HTR) which includes the Central Human Tissue Repository (jointly sponsored by Department of Pathology and UNM CRTC), the human tissue holdings in all satellite UNM human tissue repositories and requires the creation of a database/informatics infrastructure to link them, forming a Virtual Tissue Repository.

The HTR is accountable to the Office of Research through the Human Tissue Oversight Committee (HTOC), which reports to the Senior Associate Dean of Research. The policy defines the HTOC membership that provides guidance and oversight to the Director of the Human Tissue Repository. The policy defines the categories and types of research tissues; where research tissues will be held; eligibility criteria and the process by which investigators can withdraw tissues from the HTR, including determining availability of tissue and submitting a research proposal to use tissue from the HTR. The policy defines the function and membership of the human tissue Scientific Review Committee (SRC) and scope of SRC review; the review of proposals for the use of unique, rare or nearly exhausted tissue samples; the suspension or termination of SRC approval; the veto and appeals process and the relationship of the UNM Human Tissue Repository to cooperate tissue procurement efforts such as the Gynecologic Oncology Group and Children's Oncology Group.

Scientific Review Committee Submission Information

Resources:

Oversight of Human Tissue in Research (Policy: RC.05.002.PP). Dated April 11, 2016.

Guidance on Policy Related to the Collection, Use and Storage of Human Tissue.

<u>Human Embryonic Stem Cell</u> <u>Research</u> (Policy: RC.05.001.PP). Dated February 18, 2015.

OHRP Guidance - Issues to Consider in the Research Use of Stored Data or Tissues.

OHRP Guidance - Research Involving Coded Private Information or Biological Specimens

Secretary's Advisory Committee on Human Research Protections (SACHRP) -FAQs, Terms and Recommendations on Informed Consent and Research Use of Biospecimens (pdf)

UNM HSC WORKSHEET: HRP-310 Human Research (This worksheet should be use by the designated reviewer to determine whether an activity is Human Research or how it is regulated.) (doc)