**NMU Human Tissue Use Policy**

**November 2012**

**Background:** This policy has been developed for scientists at Northern Michigan University who use human tissue in research laboratories on the NMU campus. Tissue samples collected from patients for the purpose of genetic research have implications for patients and their families. The potential for sharing genetic information and genetic discrimination necessitate ethical and regulatory protocols for the distribution and use of tissue samples.

Tissue samples are often stored in medical facilities or tissue banks set up specifically for the purposes of utilization in a particular research project. Research projects involving tissues samples are often prospective in nature. The purpose of the specified research protocol may not be known at the time that the sample was collected, resulting in a retrospective research design and the use of pre-existing tissue specimens.

This policy was developed to assist the faculty and the Institutional Review Board (IRB) in reviewing research protocols. In no case will NMU researchers be allowed to collect tissue samples; instead, they will use samples from repositories containing samples previously collected for clinical activities.

**Northern Michigan University Policy Statement:** This policy pertains to scientists proposing to use human tissue in their research. Tissue identification is of particular importance because research on tissue is frequently done to test for genetic characteristics that are correlated with human diseases. The current policy applies to proposals that comply with the following stipulations: a) the human tissue was collected from another institution, and b) the collection of that tissue sample was approved by the collaborating institution for research purposes. If both of these factors are satisfied, then the NMU researcher should submit an application to use human subjects in research (form available at <http://www.nmu.edu/grantsandresearch/node/102>). This application will be completed to alert the IRB that this research will be conducted at Northern Michigan University. Special care should be taken in responding to the query of how confidentially of subjects will be maintained, by noting if NMU faculty, staff, or students will be aware of patient identification, resulting in “identified samples”. If human tissue is removed from a bank or institution for research purposes and the information provided to the institution is in such a format that human subjects cannot be identified, directly or through identifiers linked to the subjects, the research project qualifies for “Administrative Review”, and the researcher should submit the IRB proposal under that designation. If human tissue is removed from a bank or institution for research purposes and the information is provided to the investigator in a manner such that human subjects can be or are identified, the researcher should submit the HSRRC proposal in the “Full Review” category. The NMU policy is consistent with the National Institutes of Health (NIH) policy for persons submitting a research grant proposal. The NIH policy states that even in cases in which the tissue originates from the laboratory of a collaborator, IRB approval must be obtained from the institutions of both the collaborator and the person submitting the grant proposal.

**In addition to the submission of the IRB approval form noted above, the institution from which the tissue was collected must be identified in a cover letter, and the written approval of the tissue use for research purposes from the collaborating institution must be included with the form.**

**Definition of terms:**

1. **Anonymous samples**: Biological samples obtained by an investigator

without any identifying information and without a link to an individual subject source.

2. **Genetic information**: Information about an individual or the individual’s blood relatives obtained from a genetic test.

3. **Genetic research**: Research using human DNA samples, genetic testing or genetic information.

4. **Genetic test**: A test for determining the presence or absence of genetic characteristics in a human individual or the individual’s blood relatives, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.

5. **Identified Samples**: Biological samples obtained by an investigator or a 3rd party that have identifiers attached or a link permits determination of the individual subject through the use of a code.

6. **Pre-existing specimens**: Specimens collected prior to the proposed study for conducting research on human tissue, for which records accompanying these specimens are not in compliance with the Institution’s current IRB Guidelines.

7. **Prospective study**: A study in which the collection of tissue will occur “in the future”; that is, the biological specimen is not “on the shelf” when approval for the research under review is requested.

8. **Retrospective study**: Studies that utilize existing tissue that has already been collected when the IRB request for approval is made.

9. **Tissue**: Any cell tissue, fluid, or excreta from which measures of normal or pathological human physiologic function can be obtained.