Guidelines for the Clinical Use of Data Generated from Human Tissue in the Innovative Translational Research Shared Resource (ITR)

Background: The ITR works with clinical and laboratory investigators to assist in making research discoveries that can be translated into patient therapies. Often, this type of research requires the use of human tissues.

Purpose: The purpose of these guidelines is to clarify the need for CLIA-certified laboratory test confirmation of data generated in the ITR if the test results are to be used for the diagnosis, prevention, or treatment of disease or impairment of, or the assessment of the health of, human subjects.

Guidelines: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for clinical laboratories to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed (57 FR 7139, Sec. 493.1). This provision defines clinical laboratory as a facility for the "biological, microbiological, serological, chemical, immune-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings". Under these amendments, if researchers wish to provide diagnostic results to subjects or use test results to alter care, they should have laboratory tests performed under the auspices of a clinical laboratory that has been certified in accord with CLIA.

The ITR is NOT a CLIA-certified laboratory; therefore data generated in the ITR cannot be used for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

If you have any questions please contact Kimberly Dahlman for more information at 936-6589 (office) or Kimberly.b.dahlman@vanderbilt.edu.