Institutional Handbook of Operating Procedures Policy 11.01.05	
Section: Research Policies	Responsible Vice President: Vice President and Chief Research Officer
Subject: General Research	Responsible Entity: Vice President and Chief Research Officer

I. Title

Existing Clinical Human Biospecimen Use and Transfer

II. Policy & Procedures

A. Transfer of Existing Clinical Biospecimens to Not-for-Profit Entities

The UTMB Investigator may transfer Existing Clinical Biospecimens for research purposes to external individuals at an academic institution or a not-for-profit entity by utilizing a Material Transfer Agreement (MTA) or research agreement that clearly delineates the transfer of the Existing Clinical Biospecimens to the recipients. UTMB Investigators must contact the UTMB Department of Legal Affairs/Office of Technology Transfer for the negotiation and execution of the MTA. The MTA must be completed and signed by all relevant parties before any transfer can take place. Transfers of existing clinical specimens to not-for-profit entities are considered related to the mission of UTMB to further biomedical research and education and/or patient care if:

- The recipient institution shares the same or similar mission as UTMB;
- The transfer is for the recipients' institutional purposes; and
- The specimens are not subsequently transferred to a for-profit entity;

When the activity only involves the transfer of Existing Clinical Biospecimens and the Research is not being conducted at UTMB, handling and shipping of biospecimens shall be handled by the staff of the UTMB Institutional Biorepository, or a delegate chosen by the Manager of the Biorepository.

Such transfers of Existing Clinical Biospecimens must be reviewed and approved by the UTMB IRB and meet such other requirements and processes as are determined appropriate for said transfer.

B. Transfer of Existing Clinical Biospecimens to For-Profit Entities

For transfers to for-profit entities, every Existing Clinical Biospecimen transfer must be covered by an appropriate MTA or Research Agreement that has been specifically reviewed, approved, and signed by all relevant parties. Agreements regarding the transfer of Existing Clinical Biospecimens will be reviewed using the following criteria:

- The agreement may include appropriate payments to support the research collaboration as determined by either the Office of Clinical Research or the UTMB Biorepository.
- When the activity only involves the transfer of Existing Clinical Biospecimens and the Research is not being conducted at UTMB, handling and shipping of biospecimens shall be handled by the staff of the UTMB Institutional Biorepository, or a delegate chosen by the Manager of the Biorepository.

- The only permissible payments are for reimbursement to the UTMB Institutional Biorepository for costs, as accrued, of handling and shipping the Existing Clinical Biospecimens.

• The required agreement shall not have the expressed or implied intent or the effect of providing any payment to UTMB or the Investigator in exchange for the Existing Clinical Biospecimens other than those required for handling and shipping.

III. Definitions

Existing Clinical Biospecimen(s): tissue, blood products, serum, DNA, and other biological materials or specimens that are obtained from UTMB clinical patients for clinical purposes and are either stored or will be discarded.

Material Transfer Agreement (MTA): a contract that governs the transfer of tangible research materials between two organizations.

Transfer: biospecimens sent outside of UTMB.

Research: means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)) or, under FDA regulations, an activity that (1) involves a drug, other than use of a market drug in the course of medical practice, or (2) the use of a device to evaluate safety and effectiveness of that device, and (3) data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product. If the activity is designed to improve internal practices, it is not research.

Research Agreement: a contract detailing the obligations of two or more parties over the course of a research or services project. The term "Research Agreement" shall include but is not limited to, clinical, nonclinical, sponsored, or collaboration agreements.

IV. Relevant Federal and State Statutes

45 CFR Part 46
21 CFR Part 50

V. Additional References

UTMB Institutional Review Board (IRB)
UTMB Office of Clinical Research
Material Transfer Agreements

VI. Dates Approved or Amended

Include origination date, dates of major or minor revisions and dates reviewed without changes.

Originated: 07/02/2024	
Reviewed with Changes	*Reviewed without Changes*

VII. Contact Information

Vice President and Chief Research Officer
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