Policy: Governance of Use and Transfer of Human Biological Materials in Health Sciences	Replaces policy: **Management, Use, and Transfer of Human Biological Materials.**
Original Review: 2/23/2005	Revised: 12/16/2008, 2/21/2012, 7/31/2019

I. **Premises of Policy:**

A. The principle underlying this policy is that the University of Pittsburgh ("University") has the responsibility to ensure that any use or transfer of Materials (as defined in B, below) is done in accordance with applicable laws. The specifics of this Schools of the Health Sciences policy are defined by those laws and regulations as well as the Mission of the University defined in its non-profit charter.

B. The University owns all human biological specimens, samples, isolates, and their derivatives collected by the University's personnel or transferred from UPMC to University researchers ("the Materials") in accordance with consent forms, material transfer agreements, or other contractual obligations, as applicable.

C. Materials may only be used or transferred based on the specific terms of the consent and the IRB or CORID protocol by which the materials were obtained, including UPMC consents and policies if applicable; the consent takes precedence for proposed use.

D. Materials may only be used in a manner consistent with the education and research mission of the University of Pittsburgh, unless the consent by which the samples are collected specifically allows for the proposed use.

E. Materials may only be transferred to external institutions under the protections of relevant contractual agreements (*e.g.*, Collaborative Research Agreement, Clinical Trial Agreement, and Material Transfer Agreement).

F. Financial reimbursement may be made for the transfer, when appropriate and permitted by University policy.

II. **Governance:**

A. The use and transfer of Materials are governed by this policy. The policy describes the procedure for obtaining approval for sharing Materials and the circumstances under which explicit approvals are not required.

B. The University's Human Biological Materials Committee (HBMC), acting on behalf of the Senior Vice Chancellor for the Health Sciences, is responsible for the administration of this policy.

C. The Material Transfer Approval Process (MTAP, see section IV, A) must be followed for all external use and transfer of human biological materials.

D. The HBMC has the authority to deny approval of the transfer of Materials governed by this policy.

III. Basis of Review for Requests to Transfer Material

A. The University places its highest priority for transfer of Material to University researchers.

B. Transfer of Material within the University does not require HBMC review. Such transfer, however, must be allowed by the consent under which the Materials were collected.

C. The University may approve the transfer of Materials to external entities ("Receiving Entity"). The following outlines the external entities and circumstances that define eligibility to receive Material from the University, including the type of review required of the HBMC.

   i. Transfer of Material for research, educational, or other non-commercial purposes is eligible for "Administrative Review" when transferred to:
      1. *NIH funded tissue banks*
      2. *Academic Institutions* that are accredited with the Association of American Universities (AAU) or the Liaison Committee on Medical Education (LCME)

   ii. Transfer of Material is eligible for Administrative Review where the aims of the use or study are aligned with the educational and research mission of the University and the proposed use represents a *bona fide* research collaboration (see definitions, section V) with a University researcher, when transferred to:
      1. *US Not-for-Profit Entities*
      2. *US For-Profit or Industry Entities*

   iii. Transfer of Material is not eligible for only Administrative Review and requires full HMBC review and approval when the transfer is to:
      1. *Not-for-Profit Entities* where no *bona fide* research collaboration exists with a University of Pittsburgh researcher
      2. *International Entities* regardless of whether the research is collaborative or non-collaborative
      3. *For-Profit or Industry* where no *bona fide* research collaboration exists with a University of Pittsburgh researcher
      4. Entities and other circumstances not described hereunder.

   iv. For transfer requests that require full HBMC review, transfer of Material may be allowed when the specific use or study is consistent with the educational and research mission of the University and when the consent by which the samples were collected allows the proposed use.

D. Materials transferred under this policy shall not be re-transferred to third parties unless allowed by a contractual arrangement between the University and Receiving Entity.

E. This policy does not govern the transfer of data and images of Materials. A Data Use Agreement may be required to transfer data and images, if such transfer is allowed under relevant policies and contractual arrangements/agreements.

IV. **Procedures**

A. **Establishment and Registration of Human Biological Materials Repositories**

Human biological materials shall be collected and maintained in accordance with University of Pittsburgh policies, which include but are not limited to the policies of the Human Research Protection Office (HRPO) and the Committee on Oversight of Research and Clinical Training Involving Decedents (CORID). The processes used for collection and maintenance of Materials shall also comply with UPMC policies, as applicable. Faculty Members who establish new or manage existing repositories are required to:

i. Register the repository with the HBMC at https://is.gd/PittBiorepositoryDatabase (the repository must be registered for a transfer request to be approved). If the biorepository that contains the samples that are being transferred has already been registered, then provide the Biorepository ID. You can search for your biorepository and obtain the Biorepository ID at www.pbd.pitt.edu; and,

ii. Appoint a custodian or an oversight committee whose responsibilities include the initial approval of requests from the registered biorepository for the transfer of biological materials that are in compliance with this policy, applicable informed consents, and University policies and protocols.

B. **Material Transfer Approval Process**

i. Requests for the transfer of Material must always be initiated by the Faculty Member or by the person authorized by the Faculty Member at the University of Pittsburgh through the Office of Research (OOR) via MyRA or contract/agreement.

ii. The OOR will request review by the HBMC of any request to transfer Materials pursuant to a contract or agreement.

iii. In addition to HBMC review and approval, approval must be sought from the following offices or committees, as applicable, OOR and IRB or CORID.

iv. The HBMC or OOR may request additional information if needed to determine whether a request will be approved or denied.

C. **Faculty Member leaving the University**

i. If the Faculty Member is leaving the University and wishes to take human biological materials with him/her, the Faculty Member must contact: the person overseeing the Repository that houses the requested samples, the principal investigator of the study that collected the samples (if different from the Faculty Member requesting transfer) and the principal investigator's Department Chair or Institute Director.

ii. Refer to the link, http://rcco.pitt.edu/checklist-investigators-leaving-unversity, for the procedural checklist.

V. **Definitions**:

A. **Administrative Review:** This is defined as a project that is clear cut and fits into predefined categories as defined in section II.C., the transfer request will require only rapid review by an HBMC member.

B. **Collaboration**: This is defined as the situation that occurs when the University is sharing Material with an external entity to work together on a mutually developed project as documented in a University approved agreement. This project must include active involvement by both parties and research results that are shared and may result in a joint publication. For purposes of clarification, Material being used for a research project that does not include University intellectual activity is not considered a Collaboration under this policy.

C. **CORID**: This refers to the Committee on Oversight of Research and Clinical Training Involving Decedents.

D. **Consent**: This refers to the written authorization by the donor to collect and use biological materials for research or education. Use of materials must be entirely consistent with the consent under which the biological material was collected.

E. **Full Review**: This is defined as the situation when a project meets specific criteria or is not sufficiently clear cut to allow for an Administrative Review, then a discussion and review by the all the HBMC members will be initiated.

F. **Human Biological Materials**: This refers to all human biological materials including, but not limited to, tissue, organs, blood, plasma, serum, DNA, RNA, proteins, cells, urine and other body fluids collected by the University's personnel or transferred from UPMC to University researchers in the course of research studies or for the purpose of creating a bank for research or education.

G. **HRPO**: This refers to the Human Research Protection Office.

H. **IRB**: This refers to the University Institutional Review Board.

I. **MTA**: This refers to the Material Transfer Agreement that is executed by the University Office of Research.

J. **OOR**: This refers to the Office of Research.