

Management and Use of Human Biological Materials for Research Purposes

Definition: *Human Biological Materials:* All human biological samples including, but not limited to, tissue, organs, blood, plasma, serum, DNA, RNA, proteins, cells, urine and other body fluids collected by University of Pittsburgh personnel or transferred from UPMC personnel to University researchers in the course of research studies or for the purpose of creating a bank for research and/or education. (Note: immortalized cell lines are excluded from this policy).

Established University Policy: The University of Pittsburgh maintains ownership and control over all biological materials collected by University personnel for research and/or educational purposes.

Establishment and Registration of Human Biological Materials Repositories: Human biological materials shall be collected and maintained in accordance with applicable University of Pittsburgh (including Institutional Review Board (IRB) and Committee on Oversight of Research Involving the Dead (CORID)) and, when applicable, University of Pittsburgh Medical Center (UPMC) policies and requirements. Personnel who establish new or manage existing human biological materials repositories, regardless of when established or type or quantity of specimens stored, are required to:

1. Comply with all University of Pittsburgh and UPMC policies involving human biological materials
2. Register the repository with the University of Pittsburgh Health Sciences Human Biological Materials Database, using the attached form.
3. Appoint a custodian or an oversight committee to be responsible for approving requests for transfer of biological materials and ensuring that such requests are consistent with the informed consent documents and any IRB or CORID protocols governing the repository.

Transfer of Human Biological Materials: Common types of transfer of human biological materials for the purposes of research collaboration and educational programs include transfers within the University of Pittsburgh, to external academic institutions, and to industry. Such transfers are governed by the following principles:

1. The University of Pittsburgh maintains ownership and control over all human biological materials that are collected by University personnel for research or educational purposes. The University of Pittsburgh Health Sciences Human Biological Materials Committee (HBMC), acting on behalf of the Senior Vice Chancellor for the Health Sciences, is responsible for oversight and regulation of transfers of human biological materials.
2. Outside entities wishing to access human biological materials maintained at the University of Pittsburgh may only do so pursuant to a research collaboration with University researchers (rarely, the HBMC may consider an exception to this requirement, in accordance with the procedures outlined below). These entities

are required to submit a written proposal that shall describe the aims of the research involving the human biological materials, and shall describe the collaborative aspects of the project, including the unique resources supplied by the outside party. Because human biological materials are a limited resource, and because of legal and ethical restrictions that may apply to secondary research use of such biological materials, all proposals for such outside access shall be reviewed and approved by the custodian of, or the oversight committee for, the repository, the Principal Investigator (PI) of the study who collected the samples, the PI's Department Chair or Institute Director (as appropriate), and the IRB or CORID (as applicable). Such transfer must be explicitly allowed in the Informed Consent under which the materials were originally collected, or in the original CORID Submission or subsequent Modification thereto.

An exception to this requirement that research involving human biological materials be conducted at the University may be granted by the HBMC in the following cases:

- a. Where another non-profit educational or research institution wishes to use the samples for non-commercial research purposes;
- b. Where the human biological materials are requested from an NIH funded tissue bank that is specifically designed to provide samples to qualifying parties, and the requesting party fits within the conditions for access to the bank;
- c. Any other exceptional case, where unique equipment or resources are only available at an external location, and where the HBMC approves the specific transfer.

Notes: "Principal Investigator" is defined by the PI listed on the IRB or CORID-approved research protocol. The IRB and CORID will be responsible for making determinations that the transfer of human biological materials is consistent with applicable IRB or CORID-approved informed consent documents and whether there are potential conflicts of interest that must be referred to and evaluated by the University of Pittsburgh Conflict of Interest Office prior to approval. For de-identified samples which do not require IRB or CORID approval, the University Conflict of Interest Office must confirm that there are no significant conflicts of interest related to the proposal. The University Office of Research will ensure that all such approvals are obtained before approving a Material Transfer Agreement for the transfer of such materials.

3. Where there are multiple requests for human biological materials, priority for access shall be given first to University of Pittsburgh researchers. Second priority for access shall be given to scientists from external academic or governmental institutions. Third priority for access shall be given to industry. Transfers to industry must be associated with an agreement that outlines a substantive partnership with University investigators, unless an exception has been granted by the HBMC in accordance with the principles outlined in Paragraph 2, above.

- Human biological materials maintained at the University may not be used by faculty in connection with personal consulting activities.
4. All human biological materials that are transferred to an outside entity must be transferred pursuant to a University Material Transfer Agreement ("MTA") executed by the Office of Research.
 5. Any data generated by use of University of Pittsburgh human biological materials through outside party research collaborations must be shared with the University and must be available for the University's continuing non-profit research and educational purposes.
 6. The University of Pittsburgh Health Sciences Human Biological Materials Committee will hear appeals related to the transfer of human biological materials, as needed.

Allocation and Final Disposition of Biological Materials:

Transfer: If a researcher leaves the University of Pittsburgh to accept employment at another institution, and if he/she wishes to take biological materials collected at the University of Pittsburgh to continue his/her research at that institution, the consent of the Department Chair or Institute Director (as appropriate), Dean of the School, and IRB or CORID (as applicable) shall first be obtained. Transfer requests are subject to all terms of funding agreements under which the tissue was collected or the bank was established. The human biological materials must be transferred pursuant to a University Material Transfer Agreement ("MTA") executed by the Office of Research. As consistent with the conditions of an MTA, material that is taken from the University of Pittsburgh to another institution may not be transferred from that institution to a third institution, without the prior consent of the University, even if the faculty member who has left the University was the principal investigator under which the materials were originally collected.

Disposition: Prior to study completion or end date of a banking period, the approval of the Department Chair or Institute Director, as appropriate, Dean of the School, and IRB or CORID, whichever applicable, shall be secured prior to disposition of materials. Additionally, a review of the terms of funding agreements under which materials were collected or the bank established must be conducted prior to disposition to assure that this activity is appropriate.