

UW MEDICINE POLICY ON THE TRANSFER OF HUMAN BIOLOGICAL SPECIMENS

Policy

It is the policy of UW Medicine to permit the transfer of human biological specimens to other entities for legitimate research and educational purposes as determined by UW Medicine provided that the procedures set forth herein are followed.

Definition

“Human biological specimen” means any biological material that comes from a human being (e.g., blood, urine, cells, organs, DNA).

Principles

Human biological specimens may be transferred to an agency, person, company, institution, or entity for legitimate research and educational purposes as determined by UW Medicine only if all the following conditions are met:

1. The donor of the biological specimen has authorized or consented to the use, if such authorization or consent is required by an applicable policy, law, rule or regulation;
2. If the recipient pays a charge for the biological specimen, the charge shall be calculated to recover only UW Medicine’s costs associated with the acquisition, preparation, storage, annotation and distribution of the specimen, in accordance with applicable policies;
3. An in kind exchange as part of a mutual effort to promote biological research is permitted and not restricted by (2);
4. Any transfer of a biological specimen to an entity outside the UW is accomplished under a Material Transfer Agreement (MTA), the form of which is prescribed by the CoMotion, through an agreement under the auspices of the Office of Sponsored Programs (OSP), such as a Sponsored Research Agreement (SRA) or Clinical Trial Agreement, or through an agreement under the authority granted to the School of Medicine (SoM) Vice Dean for Research and Graduate Education; and
5. Any such agreement transferring the biological specimen shall include provisions giving effect to the following principles:
 - a. The human biological specimen is made available solely for educational and/or research purposes;
 - b. The recipient shall not be granted any property rights in the human biological specimen transferred, unless otherwise agreed to in writing by UW Medicine;
 - c. Where possible, UW Medicine’s practice shall support the wide distribution of materials that might be derived from the specimen (e.g. cell lines, xenografts);
 - d. Provision of a human biological specimen as originally isolated and preserved (that has not been substantially modified or improved) shall not confer future intellectual property (IP) rights upon UW Medicine, nor shall UW Medicine seek rights in inventions made by investigators using such specimens;
 - e. UW Medicine encourages recipients of the human biological specimen to make available to the research community research data obtained through recipients’ use

of the specimen, consistent with the NIH Data Sharing Policy and NIH Research Tool Policy;

- f. The recipient shall not sell, redistribute, or otherwise transfer the biological specimen or any progeny or material incorporating the biological specimen or any part thereof, except upon the written approval of UW Medicine and subject to any laws and regulations applicable to the recipient and its operations; and
- g. If the biological specimen (e.g., cell line or xenograft) has received a specific name designated by the UW originator, the recipient shall use, without modification, that name in reference to the biological specimen in any written or oral communication.

Compliance with all other applicable laws and policies

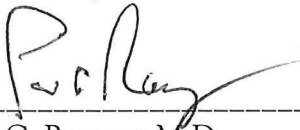
In addition to the foregoing, any transfer of human biological specimens must also comply with:

- 1. All applicable federal and state laws and regulations, including but not limited to those applicable to human subjects research, obtaining informed consent from donors of human biological specimens and confidentiality of healthcare information; and
- 2. All UW Medicine policies, rules and procedures, including but not limited to those applicable to human subjects research, confidentiality of healthcare information, biohazard and related regulations of Environmental Health & Safety, and transfer of tangible materials to another entity.

UW Medicine retains the discretion to refuse to transfer biological specimen to any agency, person, company, institution or entity.

This policy was implemented September 6, 2011 after approval by the Medical School Executive Committee (MSEC) in August of 2011. Revisions to the policy were approved by MSEC on November 2, 2018.

Approved by:



3/19/19

Paul G. Ramsey, M.D.

Date

CEO, UW Medicine

Executive Vice President for Medical Affairs and

Dean of the School of Medicine,

University of Washington