

## 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 the UW Medicine’s costs of acquisition, preparation, storage, annotation and distribution of the specimen;
3. An in kind exchange as part of a mutual effort to promote biomedical research is permitted and not restricted by (2);
4. Any transfer of a biological specimen to an entity outside the University is accomplished under a Material Transfer Agreement (MTA), the form of which is prescribed by the Center for Commercialization (C4C), or through an agreement under the auspices of the Office of Sponsored Programs (OSP), such as a Sponsored Research Agreement (SRA) or Clinical Trial Agreement; 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 or research purposes;
  - b. The recipient shall not be granted any property rights in the human biological specimen transferred;
  - 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. Research data obtained through recipients use of the human biological specimen shall be made available to the research community, consistent with the NIH Data

Sharing Policy and NIH Research Tool Policy unless otherwise agreed to in writing;

- 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.*, a cell line or xenograft, has received a specific name designated by the UW originator, the recipient shall use, without modification, only that name in reference to the biological specimen in any written or oral communication.

**Compliance with all other applicable laws and policies.**

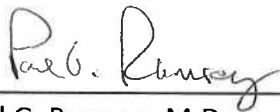
In addition to the foregoing, any transfer of human biological specimens must also comply with:

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 University policies, rules and procedures, including but not limited to those applicable to human subjects research, confidentiality of healthcare information, biohazard and related regulations of EH&S, 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.

Reviewed by: Medical School Executive Committee, August 2011

Approved by:



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Date Approved