

University Health Network Policy & Procedure Manual Clinical – Analysis, Research, Use & Retention of Human Tissue

Policy

1. Mandatory Submission of Tissue to Pathology Laboratory for Analysis

- 1.1 Unless specifically authorized by the VP Medical Affairs, where [tissues](#) or non-biological materials are removed from a patient during a [surgical procedure](#) of any kind, the [surgeon](#) performing the surgical procedure shall send, or cause to be sent, all tissues and non-biological materials removed from the patient, together with a short history of the case and a statement of the findings from the surgical procedure, to the [pathology laboratory](#) for examination and report.
- 1.2 Despite the provisions of item section 1.1 and unless specifically required otherwise by the VP Medical Affairs, where the tissue removed in the surgical procedure is a lens, toenail or tooth, the surgeon is not required to send the tissue to the laboratory for analysis but may choose to send such tissue to the laboratory for examination and report if he or she is of the view that this would be beneficial in the circumstances.
- 1.3 If tissue removed from patients in the normal course of surgical procedures is to be used for research purposes, the tissue must still be submitted to the pathology laboratory for examination and report in accordance with the requirements of [section 1.1](#), unless the tissue in question falls within the exceptions set out in section 1.2. Any such tissue may only be removed from the pathology laboratory for research use following the completion of the examination and report, and only with the specific permission of the pathologist-in-chief or his/her delegate.

2. Informed Consent for Research

- 2.1 If tissue removed from a patient in the normal course of a surgical procedure is to be collected or stored as part of a current research protocol for later analysis, the principal investigator of the specific research project for which the tissue is to be used, or his/her delegate, is responsible for ensuring that the patient from whom the tissue is being removed has given informed consent to that specific use and has signed a specific consent form to that effect.
- 2.2 The consent form to be used for the purposes of complying with section 2.1 shall include:

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- i. The specific use which is being made of his/her tissue;
 - ii. The type and amount of tissue to be collected (if possible to determine ahead of time);
 - iii. How the tissue will be collected;
 - iv. Safety and invasiveness of acquisition;
 - v. Whether the tissue will be stored as a coded sample or data, linked or unlinked anonymised sample, what this means in lay terms, and what safeguards are in place to ensure **that** the sample is stored under these conditions;
 - vi. How the use of the tissue could affect privacy;
 - vii. If participation in the research could reasonably place that individual at risk of criminal or civil liability;
 - viii. Reasonable likelihood, if known, that the uses for the material will lead to a commercial product;
 - ix. If donors will or will not share in the profits should the tissue lead to a commercial product assuming there is a reasonable likelihood that the uses for the tissue will lead to a commercial product. If the investigator might benefit from such commercial usage, this must be disclosed in the consent form; and
 - x. If donors are given an opportunity to withdraw their consent, they should be advised they might contact the UHN Research Ethics Board (REB) for that purpose.
- 2.3 If a patient's surgeon proposes to remove, in the normal course of a surgical procedure, more or different [tissue](#) than is medically necessary for research purposes, the surgeon is responsible for ensuring that the patient from whom the tissue is being removed has given informed consent to that removal and has signed a specific consent form to that effect.
- 2.4 The consent form to be used for the purposes of complying with section 2.3 shall include all items listed in [section 2.2](#), if applicable, and in addition shall:
- i. Reflect the patient's knowledge that additional tissue, beyond that which is medically necessary for the purposes of conducting the surgical procedure, is being removed by the surgeon in the course of the surgical procedure;

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- ii. Reflect the patient's knowledge that the tissue removed in the course of the surgical procedure, or some portion of it, is being used for research purposes;
 - iii. Reflect the patient's knowledge of the specific research use which is being made of his/her tissue; and
 - iv. Reflect the patient's consent to this removal of additional tissue and to the specific research use.
- 2.5 Where tissue being removed from a patient during a surgical procedure is to be stored or banked for future research purposes, the surgeon who is removing the tissue, or his/her delegate, is responsible for ensuring that the patient from whom the tissue is being removed has been provided the [Medical Research at UHN](#) (Form 3281) and has been given the opportunity to ask questions which have been answered.
- 2.6 The consent form to be used for the purposes of complying with section 2.5 is [Consent for Use of Tissue, Blood and Body Fluids for Future Research](#) (Form 2019K) and shall specify:
- i. That the tissue removed during the course of a surgical procedure will be stored or banked in order to be available for use in future research, possibly including genetic research;
 - ii. How it will be stored (coded sample, linked or unlinked anonymised sample);
 - iii. The research on his/her sample is not designed to produce information that would be medically useful to the patient;
 - iv. None of the research results will be placed in the patient's health record unless they give explicit permission in the future for the results to be placed on their record;
 - v. Research carried out on his/her tissue may lead to the development of marketable treatments, devices, new drugs or patentable procedures, and that the patient will not be entitled to benefit financially from any such commercial developments, and that any benefit from commercial products will remain with the University Health Network and its research partners;
 - vi. The patient may give or refuse permission for researchers from UHN to contact them in the future to invite the patient to participate in other research;

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- vii. The patient may refuse to provide a sample to the tissue [bank](#) for future research purposes and that this decision will not affect their medical care in any way; and
 - viii. The patient may withdraw their consent for the use of their tissue for future research, at any time in the future by contacting REB for that purpose.
 - ix. Reflect the patient's consent to this banking and subsequent use of his/her tissue for research purposes.
- 2.7 Where tissue removed from a patient is collected or stored as part of a current research protocol, where the purpose of the research is known, the principal investigator of the specific research project for which the tissue is to be used, or his/her delegate, is responsible for ensuring that the patient from whom the tissue is being removed has given informed consent to that specific use and has signed an REB approved consent form to that effect.
- 2.8 Where tissue has been removed from a patient during a surgical procedure and stored in a tissue bank prior to the implementation of this policy and where consent for the storage and use of tissue has not been obtained;
- i. Where the identification of the donor is possible through linked anonymised samples or data and coded samples or data researchers shall seek to obtain free and informed consent from him or her for the use of the previously collected tissue.
 - ii. If it is impracticable to obtain consent from the donor the coded sample or linked anonymised sample may still be used if the REB has reviewed the protocol and agrees that there are minimal risks or the REB may agree that it is acceptable to use the sample provided the identifiers are removed.
 - iii. When identification of the donor is not possible through an unlinked anonymised sample or data, if there are minimal risks, the donor does not need to provide informed consent and the sample may be used, provided REB consent has been obtained.
- 2.9 The requirements of [sections 2.1 to 2.8](#) inclusive apply, with any necessary modifications, to blood or any other bodily substance or fluid which is to be used for a research purpose and which is removed or obtained from a patient in the course of, or incidental to, a surgical procedure.

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3. Ethics Approval, Conflict Disclosure & Commercialization Issues Relating to Research Using Tissue

- 3.1 Any research involving the collection, use or examination of tissue, blood or other bodily substances or fluids removed from patients, including any research involving the use or examination of tissue stored in a tissue bank, must be approved by the REB before the collection, use or examination of such tissue or blood can occur. If the contemplated use of the tissue involves a third party with commercial interests, the Research Business Development Office must also approve the use.
- 3.2 The principal investigator for any research project of the nature described in section 3.1 must disclose to the REB, in the course of seeking its approval of the research, any direct or indirect financial interest the investigator or any other personnel involved in the research have, which could conflict, or be perceived to conflict, with the interests of the patients from whom the tissue is being removed.
- 3.3 Once REB approval has been obtained and the research is proceeding, the principal investigator for any research project of the nature described in section 3.1 shall continue to be responsible to disclose both to the REB and the patients any direct or indirect financial interest which he/her has, or which any other personnel involved in the research have, which could conflict or be perceived to conflict with the interests of the patients from whom the tissue is being removed.
- 3.4 If a principal investigator, or any other personnel involved in a research project carried out in whole or in part at the [Hospital](#), proposes to pursue commercialization of the research project, this effort must be coordinated through the UHN Research Business Development Office.
- 3.5 The provisions of section 3.0 apply to all tissue, blood and body fluids which are being used for research purposes, including tissue which falls within the exceptions regarding pathological examination in report as outlined in [section 1.2](#).

4. Transfer and Disposal of Tissue

- 4.1 Where the research being conducted involves the use or examination of tissue stored in a tissue bank, tissue can only be released from the tissue bank for use in the research following the receipt of REB approval for the specific research project in which the banked tissue is to be used.
- 4.2 If blood or body fluids removed from patients is to be used for research purposes, the blood or body fluid may only be removed from a [clinical laboratory](#) or a [bank](#), if the patient has given consent for that sample to be

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used for research purposes as outlined above **and** with REB approval.

- 4.3 Where tissue is collected as part of a research protocol, Pathology shall not transfer any tissue to anyone or to any group where there are reasonable grounds to believe that it will be used for purposes other than those stated in the research protocol.
- 4.4 In cases where consent to donate tissue has been given for a specified purpose, the tissue may only be used for the particular use or uses authorized by the donor.
- 4.5 All tissue which is subjected to examination and report in accordance with [section 1.1](#) or [section 1.2](#) shall be disposed of by the Pathology laboratory in accordance with all applicable statutory and regulatory requirements.
- 4.6 Despite the provisions of section 4.5, if tissue is being used for a research purpose in accordance with the provisions of [section 1.3](#), [section 2](#) and [section 3](#), it shall be the responsibility of the principal investigator to ensure that any tissue obtained from the laboratory in accordance with section 2.1 which remains in existence once the research is completed, or which is not used in the research, is disposed of in accordance with all applicable statutory and regulatory requirements.
- 4.7 If a principal investigator or anyone else involved in a research project as described in [section 1.3](#), [section 2](#) or [section 3](#) transfers tissue, or causes tissue to be transferred, to any other investigator, physician, researcher, facility or institution, that principal investigator shall remain responsible, in accordance with section 4.6, for ensuring that all tissue remaining following the completion of the research shall be disposed of in accordance with all applicable statutory and regulatory requirements, unless someone else has (in writing) accepted responsibility for disposal. Where tissue is being transferred, all necessary steps to protect the confidentiality of the patient(s) from whom the tissue originated should be taken, including the removal of all patient identifiers attached to the specimen.
- 4.8 If a physician, researcher, investigator, or any other person at the Hospital accepts tissue from another investigator, physician, researcher, facility or institution, that person shall be responsible, in accordance with [section 4.5](#), for ensuring that all tissue remaining following the completion of the research shall be disposed of in accordance with all applicable statutory and regulatory requirements, unless someone else has (in writing) accepted responsibility for disposal.
- 4.9 The requirements of section 4 apply with any necessary modifications, to blood or any other bodily substance or fluid which is to be used for research purposes and which is removed or obtained from a patient in the course of, or incidental to, a surgical procedure.

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Definition

For the purposes of this policy, the following definitions shall apply:

Hospital –University Health Network (UHN) and any site thereof.

Pathology Laboratory – The pathology laboratory at a site of UHN where surgical procedures are performed.

Clinical Laboratory – The Biochemistry, Hematology or Microbiology laboratories.

Tissue – A part of a living body and includes cells, an organ or organs.

Surgical Procedure –An operation or biopsy performed by a surgeon or physician requiring incision through the skin, or involving an aspiration of cells, or a resection of tissue through endoscopic or laparoscopic means, and includes a procedure involving curettage.

Surgeon – surgeon or physician.

Bank – A UHN facility that stores tissue, blood or body fluids.

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