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EFFECTIVE: October 11, 2005	<b>Requirement for Research Ethics Board approval of the use of tissue and biological specimens and cadavers in research</b>		

**1) Review and approval of the UWO Health Sciences Research Ethics Board (HSREB) is required when:**

- a) Tissue and biological specimens are **collected prospectively, specifically for the research project** even though the specimen may have all identifying information removed before it is passed to the researcher.
- Procedurally:
    - i) It is expected that written consent will be obtained from the subject for use of their specimen in this research even though the specimen normally would be discarded. *Exceptions to this requirement will be considered if the researcher makes a compelling case.* Research participants must be told exactly what specimens are to be collected, what testing will be done on the specimen, what identifying information will be used to label the specimen and where the specimen will be tested and stored or disposed of. The use of the general surgical consent is generally not considered sufficient for specific research purposes.
    - ii) Researchers wanting a portion of tissue or specimens originally collected **for diagnostic purposes** must have this request processed by the Pathology Tissue Use committee before the specimens can be distributed to the researcher and/or outside the hospital. Researchers will be required to provide evidence to the HSREB, from the Pathology Tissue Use committee that a) the use of the tissue has been approved or b) approval of the Tissue Use Committee is not required.
    - iii) Researchers wanting to collect tissues or specimens solely for **research purposes** (n.b. these must not be required for diagnostic purposes) do not need to provide evidence of review by the Pathology Tissue Use committee to the HSREB.
    - iv) For tissue specimens **harvested outside a hospital setting**, the REB will also require assurances from investigators that quality control, transportation, security issues etc. will be dealt with satisfactorily and that local investigators are aware of their responsibilities.
- b) Specimens received by the researcher **retain identifiable information** or a code that may allow **the researcher to identify the donor and/or link to the donor's clinical or other records.** This does not include tissue specimens from the Pathology tissue bank or Anatomy that contain a departmental tracking number and no other identifiers. However, researchers from within the Pathology department who have access to patient records via the Pathology number must get REB approval for research on samples that are identified by the Pathology number.

**2) HSREB approval is not required in the following circumstances:**

- a) Use of de-identified archival specimens from the hospital Pathology Tissue Bank.
- b) Use of de-identified specimens from cadavers donated to the UWO Department of Anatomy Bequeathal Program.

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- c) Use of de-identified specimens from other legitimate, internal or external tissue or blood repositories provided that the donor has not specifically forbidden use of the specimen for secondary purposes.
- d) The preparation of Case Reports for cases that the clinician was involved with as either the primary caregiver or consultant. These generally are not considered to be research and therefore do not fall under the jurisdiction of the Research Ethics Board. Clinicians should consult with the hospital Privacy Office to determine if patient consent is required for the release of information.
- e) A search of the Pathology department database that is undertaken to determine the number of potential cases which meet the criteria of a proposed research study. No information/specimen collection pertaining to the patients or specimens can be gathered beyond assessment of the number of potential cases available. The reports cannot be printed or examined other than to determine the number of cases that are available and meet the criteria of the project.

**Note that HSREB approval must be obtained before the research can commence. The HSREB will not give retroactive approval for research that has already been started.**

References:

- Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans Article 1.1 and Section 3 C Article 3.3
- UWO HSREB Guideline 1-G-002 Secondary Use of Data