

<b>UWO – HSREB &amp; NMREB</b>	<b>GUIDELINE</b>	<b>4-G-002</b>	<b>Page 1 of 1</b>
Effective date: September 1, 2002 Revised: February 21, 2005	<b>RETENTION OF REB RECORDS</b>		

### **Health Sciences Research Ethics Board (HSREB) & Non-Medical Research Ethics Board (NMREB)**

The Office of Research Ethics maintains a data base of all HSREB and NMREB Full Board and Expedited decisions. This data base will be maintained indefinitely.

A hard copy of REB Full Board Minutes will be retained for a **minimum of 25 years**.

All relevant Research Ethics Board (REB) hard copy files for a closed study will be retained by The University of Western Ontario for a **minimum of 10 years** after the study has been formally closed by the Office of Research Ethics. Any requests to extend this period must be made in writing to the Office of Research Ethics *prior to* or *at the time of* the closing of the study.

### **HSREB – Clinical Trials Documentation**

In the case of Clinical Trials approved by Health Canada, all relevant Research Ethics Board (REB) hard copy files for a closed study will be retained by The University of Western Ontario for a **minimum of 25 years** after the study has been formally closed by the Office of Research Ethics.

**Adverse Event Reports:** For non-local adverse events reported to the REB, only the summary listing of the adverse events will be retained in the archived file. Any supporting adverse event documentation remaining in the file will be destroyed when the file is archived.

**Sponsor Documents:** Only the most recent documents (e.g. Investigator Brochures, Company Protocols) will be retained and all previous versions will be destroyed when the file is archived.

### **References**

- ICH Good Clinical Practice: Consolidated Guideline Section 3.4 – 3 years for REB records
- US Food and Drug Administration Section 46.115 – 3 years for REB records
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – silent
- UWO Conduct of Research MAPP 7.0 Section 6.04 – 5 years for research data