

UWO - HSREB	GUIDELINE	2-G-017	Page 1 of 1
Effective date: July 1, 2001	STUDY DOCUMENTS: CONFIDENTIALITY, ACCESS & OWNERSHIP		

In general the HSREB requires that unique coded study numbers be used instead of participant initials, chart numbers and/or birth date, especially when the data will be sent off-site. With the rapid advances in linkage technology the use of a person's initials and/or hospital chart numbers, especially when date of birth is known, no longer provides an adequate level of confidentiality.

Local Investigators should use unique coded study numbers and if linkage back to the subject or records is necessary, maintain a master list linking the study participant and the code number. The master list should be retained locally. Once the data collection or need for linkage has ended and/or the data cleaned and verified, the master list should be destroyed. Clinical trial sites are the exception and should maintain the master list indefinitely in the event the sponsor needs to notify participants of an adverse event or clinical outcome as a result of their participation in the trial that may affect their health.

In a clinical trial, the sponsor is obliged to verify that consent has been obtained and is entitled to do so; but typically, no documents (questionnaires, data collection forms etc) are permitted to leave an institution unless the patient to whom the document refers is not identifiable or the participant has explicitly agreed to allow such disclosure. Study monitors are entitled to view the medical records and to document that the protocol has been followed etc. The host institution is responsible for maintaining the records, and consent forms usually become part of the medical record or a special project file. The sponsor has an interest in the consent form but it is not an "ownership interest". The patient has an ongoing interest in his or her medical record and in most instances has a right to see the information contained therein.

Patients should be made aware in the Information/Consent documentation that their records may be viewed by the sponsor, representatives of the REB and by regulatory authorities (as appropriate) but that no identifying information will be provided to the sponsor company.

Please note that this is a general guideline only. Privacy legislation and institutional policies may dictate more precise and restrictive procedures.

Links:

Office of the Privacy Commissioner of Canada
http://www.privcom.gc.ca/index_e.asp

Information & Privacy Commissioner of Ontario
<http://www.ipc.on.ca/>

CIHR
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/index_e.shtml

See also:
 HSREB Guideline 2-G-018 – HIPAA (US)