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Effective date: February 1, 2003	US HIPAA Authorization Forms & Consent		

With the implementation of the Health Insurance Portability and Accountability Act (HIPAA) in the United States, Investigators will get requests from US-based sponsors, to modify or add additional consent forms to the specification of the US HIPAA regulations. The HIPAA legislation establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Canadian entities (e.g. hospitals, health insurers etc) and research participants located in Canada are subject to Canadian federal and provincial legislation and do not fall under the jurisdiction of the US Federal government or the US HIPAA legislation. Canadian federal privacy legislation and pending Ontario privacy legislation should be consulted when a Canadian institution creates data release forms for their institution. Researchers should work together with their institution’s legal advisors to determine what, if any, documentation is required for release of information for research purposes.

Please note, Canadian participants should not be prevented from participating in a study if the only reason for their exclusion is that they do not sign the US HIPAA forms.

The UWO REBs will not approve the use of US HIPAA Authorization forms. However, if a local institution requires it, the HSREB will consider the inclusion of “information release” language in the Information and Consent documentation in so much that a) it does not contradict HSREB guidelines, Canadian or Ontario law; b) does not add to the complexity of the material to be read by participants; c) does not unduly add to the burden of research participants; and d) does not refer to HIPAA or US regulations.

New subjects:

The ‘information release’ statements should be incorporated into the study’s Letter of Information rather than be set out on a separate form. The exception to this would be if the institution releasing the data requires a consent to release information authorization in a different format.

Ongoing participants

For those studies where this requirement has been added after participants have already consented to participate, a separate information and consent form may be presented to the participants.

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/>

US Department of Health & Human Services
Office for Civil Rights - HIPAA
<http://www.hhs.gov/ocr/hipaa/>