Memo

To:        The Research Community
From:      Michelle Storms, Manager Providence Health Care Research Ethics Board
Date:      May 24, 2013
Re:        FDA Wording in the ICF Template

There have been many concerns expressed by sponsors and researchers with respect to the use of the “FDA” language in the UBC Informed Consent Template for clinical studies.

The current required wording is:

Because this is a study that also falls under U.S. regulations, in some circumstances the U.S. Food and Drug Administration (US FDA) may seek to copy records that contain your personal information. If this occurs, you will be informed by the study doctor or study staff before the records are copied, but your consent may not be sought. You should be aware that privacy protections on personal information may differ in other countries.

To explain:

• Technically, U.S. law does not extend into Canada.
• If however, an Investigator has signed a US FDA Form 1572, they bring themselves and their institution under the jurisdiction of the US regulations. Accordingly, Investigators should be encouraged not to sign 1572’s as there are other available options for non US sites. This wording is ONLY applicable where a 1572 has been signed.
• If an Investigator has signed a U.S. FDA Form 1572, then technically, under the US regulations, US Federal Regulators do have the right to copy original study documents but only in very limited circumstances. These circumstances basically include situations where there are allegations of possible fraud, tampering with the data, etc.
• In such situations, the US FDA is required to provide prior notice to the document holders that they are making this request.
• Under BC law, personal information cannot be transferred out of the province, unless there is consent.
• UBC and its REBs, presumably want to cooperate with the US FDA in any investigation that impugns the credibility of a study.

Our current wording is intended to provide the requisite consent under BC law, but in point of fact it isn’t clear that that is what is intended. It is confusing because even with original consent, if this situation occurred, Investigators would be requested to notify participants of the specific situation and to attempt to obtain additional “specific” consent at that time. It might, however, not always be possible for them to do so, depending upon a participants particular circumstances after the passage of time and amount of notice etc.
The UBC Informed Consent Template will be modified slightly to the following wording:

Because this study also falls under U.S. regulations, in the event of an investigation of the study, the US Food and Drug Administration (US FDA) may need to copy and take away records that contain your personal information. By signing this consent form you are agreeing to this. If possible, the study doctor will inform you and confirm your consent at that time. You should be aware that privacy protections of personal information differ in other countries.

Laurel Evans, Associate Director, Research Director did contact the US FDA and ask them what would happen if a study site was unable (e.g. due to BC law) to cooperate and allow them to copy the documentation. She was advised that ultimately, what would happen is that the data from the specific site would be removed from consideration in the analysis of the results.

Accordingly if a Sponsor really does not want the language included, and is aware of this potential circumstance, the language may be omitted.

Hopefully this clarifies a confusing situation, and the proposed modified language will be more acceptable for use in these very limited circumstances.

Please contact REB Administration: (604) 806-8567 for further details.