THE UNIVERSITY OF BRITISH COLUMBIA

INTERIM GUIDANCE TO CLINICAL RESEARCHERS REGARDING COMPLIANCE WITH THE U.S. HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

2MAY03

FROM:
UBC Clinical Research Ethics Board
Providence Health Care Research Ethics Board

Health provision organizations in the United States are required to comply with the "HIPAA Privacy Rule" as of April 14th, 2003. The Privacy Rule sets standards for the use and disclosure of personally identifiable health information.

Since its implementation, there has been widespread speculation about how the Privacy Rule will affect research in Canada, particularly that sponsored by U.S. entities. A key component of HIPAA affecting researchers is the requirement for written authorization from subjects for use of their personal health information for research purposes. These statements are generally entitled **"Authorization for use and disclosure of protected health information"**, and according to HIPAA, may either be embedded in the main consent to participate in the research project or presented as a separate document. Either way, refusal to sign this authorization precludes subjects' participation in the research project. This originates from section 164.508(f) and 164.512(i) of the Privacy Rule (http://www.hhs.gov/ocr/regtext.html)

The following guidance is being offered to assist UBC-affiliated researchers in their interactions with sponsors related to the HIPAA Privacy Rule and consent issues. It is based on an emerging consensus in Canada and the U.S. among the pharmaceutical industry, research consortiums (e.g. NCIC, RTOG, NSABP), and unofficial advice from Health Canada. It is possible that as the numerous concerned organizations develop their own responses to HIPAA that the advice offered here will change.

The UBC Research Ethics Boards (REBs) provide the following advice to UBC-affiliated investigators doing research under the purview of the UBC REBs:

1. The privacy protections required by the UBC REBs, provincial, and federal legislation meet or exceed the HIPAA standards as they relate to research. For example, it is forbidden by the UBC REBs for investigators to release health information to anyone which contains identifiers beyond a unique study ID and, in some cases, subject initials. The relevant standard statement in all consent forms approved by the UBC REBs is:

   "Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of (name the sponsoring company if relevant), Health Canada, (the U.S. Food and Drug Administration, if relevant), and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices."

   As a result, it would be very unusual for personally identifiable health information to be

released to any U.S. entity in the course of research at UBC-affiliated institutions.

2. HIPAA governs the *release* of protected health information (PHI) by U.S. health-provision organizations and other "covered entities" (which does not include research sponsors). Collection of PHI or release of same by Canadian investigators *to* such organizations is therefore not covered by HIPAA.

   While a US-based covered entity may claim that because they may subsequently need to release that information to others it must have been originally obtained under a HIPAA-compliant authorization, in fact the information would in almost all cases have been obtained from a non-US citizen living outside the United States (i.e., in Canada). It is our view that HIPAA cannot apply extraterritorially to non-US citizens outside the US in this way.

3. Research sponsors may request that Canadian researchers add an **"Authorization for use and disclosure of protected health information"** to consent forms or require separate HIPAA authorizations from potential subjects of research as a condition of participation in the research.

   These statements are generally lengthy (approaching 3 pages in some cases), contain mostly information already required by the UBC REBs to be disclosed (e.g. types of information being collected, who has access to the information, ability to revoke consent for personal information to be collected), and contain other information which may not be applicable in Canada (e.g. required access to research records after study is finished, re-disclosure of information). As such, they are considered an additional inefficacious burden on subjects. The UBC REBs will not approve them for use.

4. The UBC REBs have always, and will continue to review and approve reasonable additions to the "Confidentiality" section of study consent forms. Whether these are motivated by HIPAA or not, such statements will continue to be judged according to their accuracy, legality, and applicability within the context of Canadian privacy legislation and the REBs' policies.

5. There is advice emanating from the U.S. Department of Health & Human Services and the FDA that REBs do not need to review or approve HIPAA-related authorizations. While this may apply in the U.S., the UBC REBs take the view (as per GCP-ICH) that all research-related documents encountered by subjects must be approved by the REB. Hence, UBC-affiliated investigators are dissuaded from implementing any HIPAA-related consent document without the REBs' knowledge.

Questions related to this guidance should be directed to the appropriate UBC Research Ethics Board:

- UBC Clinical Research Ethics Board: Susan Chunick, Manager, 604-875-4149
- Providence Health Care Research Ethics Board: Kathy Dunstan, Manager, 604-682-2344 loc 63199