How Does Privacy Legislation Influence Screening, Recruitment, Follow-Up, and Event Documentation?

Background

- As Director of NCIC CTG, as a physician coordinator for a large international breast cancer trial, and, later, as the manager of NCIC CTG's ethics and regulatory office, I had substantial personal experience in dealing with privacy or confidentiality issues
- When I was asked to speak on the topics mentioned in the title of this lecture, I wondered what I would say as we had managed to deal with the US privacy legislation (with some help from NCI) and the parallel Canadian legislation without much difficulty
  - Major issue was obtaining bio-specimens from Europe and I though I might focus my talk on this area

Background

- However, my involvement with privacy concerns in the research arena ended in 2008, so I decided the best way to approach this topic was to update my knowledge by finding out how the issues we faced five years ago are being dealt with now
  - Spoke with current manager of NCIC CTG's ethics/regulatory office (Alison Urton) and two individuals (Alison van Nie and Keitha McMurray) who have institutional privacy protection roles and also sit on the central ethics board for oncology trials in Ontario (OCREB)
  - Reviewed relevant public documents

Perspective

- Things have evolved since 2008
- Legislation has had an impact, but not because of specific statements about the use of personal health information (PHI) in research
- Rather, because of legislation and because of broader societal concerns about privacy, institutional custodians of PHI have become more and more determined to protect against potential breaches of confidentiality
- This is reflected in how ethics boards deal with confidentiality when they review trial proposals

Perspective

- Thus, what I'm really going to talk about is how, currently, privacy issues are handled in the interchange between institutions and trial organizers
- My focus will be on a few key areas where privacy concerns are typically raised
- Will finish with a few observations on the extent to which there are real impediments to conducting trials

Specific Topics

- *Screening*
- *Recruitment*
- Identifiers
- Specification of data to be collected for trial and its use
- Provision of data to third parties; location of third parties
- Biologic and genetic materials
- Right of access for monitoring
- Future research

Intra-institutional Issues

- Screening
  - Separate talk on this topic
  - Will mention that this one area where privacy concerns have had a major impact on trial conduct, but there is variability among institutions
- Recruitment
  - Again will be addressed separately
  - One problematic area is potential need for consent to obtain additional information to assess eligibility

Main Topics

Identifiers

- Fundamental issue is potential conflict between the desire of the trial organizers to be sure they are dealing with the data from the correct participant and the institution's desire to protect privacy by de-identification
  - Although in the past and, in some cases, currently, trial organizers were provided with highly specific identifiers (including hospital number), balance is shifting substantially
    - Some institutions will only allow a unique study code as identifier
    - Other identifiers such as initials, full date of birth may be problematic
    - There is substantial variability among institutions
    - Explicit justification for collection of identifying information is important

Identifiers

- Even when institutions and trial organizers agree on identifiers to be used, issues arise when supporting documentation (X-ray reports) or pathology materials (blocks may have identifiers) are provided

- Trial organizers have to be trustworthy no matter how carefully the data they receive are de-indentified
  - Ethics boards may want evidence of this
  - NCIC CTG includes a statement regarding confidentiality in its centre agreements

Trial Data

- The current expectation is that trial subjects will be aware of and consent to the following:
  - The type of data to be collected during the trial
    - For example, "test results, reports of operations, xray and other reports, reports about treatment and side effects"
  - The fact that the information sent might identify them
  - The parties who will receive data
    - Their location
  - How identifying information will be protected
  - The fact that data will be published but they won't be identified

Right of Access for Monitoring

- On site monitoring is a component of many trials and consent to access patients' records for this purpose must clearly be obtained in advance
- In addition to the trial organizers, other agencies that may want to access records must also be identified

Biologic and Genetic Materials

- The collection, storage and analysis of blood and tissue samples raise issues that go beyond privacy concerns, for example:
  - Whether patient will be informed of results
  - Potential for commercialization
- Otherwise, privacy concerns are similar to those with other data, except for the possibility that the patient can ask that specimens can be returned or destroyed and the fact that some jurisdictions will not permit the transport of these materials

Future Research

- By consenting to participate in a trial, patients are obviously consenting to the use of their data and, in some cases the results of studies of their biologic specimens, for the specific purposes of the trial
- However, trial data and specimen analysis may be useful for future projects, which gives rise to several issues:
  - The description of the future research
    - Separate consent form for non-intrinsic research may be useful
    - May help to provide graded consent for future research that ranges from the specific to the general

Future Research

- The need for ethics review of future projects
- The provision of trial data to future researchers other than the trial organizers
- Consideration of whether the patient can or cannot be contacted as part of the research
- Whether there is any limit to the duration of consent

Observations/conclusions

- Privacy concerns undoubtedly require more consideration by trial organizers than they used too
- Once a patient has been recruited to join a trial, almost all privacy/confidentiality issues can be dealt with by:
  - Designing consent forms to address privacy issues
    - This contributes to further complicating the consent process
    - Agreed upon templates can help
  - Understanding and accepting limitations on obtaining identifying information
  - Developing appropriate organizational policies and procedures for protecting privacy

Observations/conclusions

- Institutional variability substantially complicates the process of developing approaches to protecting privacy in the setting of multi-centre studies
  - Central ethics review can help in this regard
- The major impact of privacy concerns is in situations where consent is not possible or has not yet been obtained
  - That will be the theme of a later talk