Informed Consent and Privacy Laws

University of Calgary Faculty of Medicine

in collaboration with

National Privacy Services Inc.

& Clin Coach

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Conference Report by

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Executive Summary

This day conference was offered to Research Coordinators and Principal Investigators in the Faculty of Medicine at the University of Calgary. The conference presented two converging topics relevant to health professionals in the context of research and practice: informed consent and privacy laws. The former was presented as the focus of the morning session while the latter constituted the afternoon session.

According to Paula Jones-Wright of ClinCoach, presenter of the first session, the purpose of informed consent is to "provide assurances to the public, patients, and providers that personal health information will continue to be managed and shared confidentially and securely". Points raised included the minimal impact of the process of informed consent on the therapeutic/patient relationship, and the need for flexibility of the process to include changes as they are required in light of new information. It was stressed that informed consent is a process that should be revisited and does not end with obtaining a signature. Not only should it be an iterative process, but it must also be documented as such, throughout the process, including all discussions, questions raised, and even non-verbal language and expressions. This session presented situations pertinent to the research context, but also offered a practical stance on several issues related to informed consent.

The afternoon session was led by David T.S. Fraser from National Privacy Services Inc. This session provided a basic introduction about the applicable legislations and policies that shape the process of informed consent and that protect the rights of the individuals involved in research in Alberta. This presentation offered essential elements of privacy protection, as well as an overview of the established best practices based on the Good Clinical Practice and Health Information Act standards.

Informed Consent

Presentation #1 – Morning Session

Clinical Research and Informed Consent

This first section reviewed, in the context of research with human subjects, the history of informed consent, guidelines from section 2 of the Canada Tri-Council Policy Statement and the International Conference on Harmonization's Tripartite Guideline E6 (Good Clinical Practice). Finally, issues pertaining to informed consent were raised for discussion among class participants. Issues raised and associated discussions are described.

Informed Consent Issues

(Information from slides, p. 7, Appendix A)

Informed Consent Issue	Discussion
1. How can we tell when a patient, subject, research participant is truly informed?	Participants discussed the use of checklists to ensure that all aspects of consent were covered. A major concern that was voiced is the lack of documentation of the "process" of informed consent. This documentation provides the basis for others to review the consent process.
2. Is 100% informed consent possible?	The discussion initially revolved around defining reasonable consent, and what is realistic to achieve. Consensus was that 100% consent was likely never achievable as the research process is one of discovery even for the researcher with the research findings being unknown to both researcher and participants until at least the finalization of the project.
3. What does the participant's signature on the document mean?	The issue was raised that, interestingly, a signature is taken when informed consent is initially sought, yet the informed consent process is considered fluid and should be revisited throughout the research project to ensure that consent is still given. The discussion did not go into how to reconcile this discrepancy.
4. How can Research Ethics Boards truly validate the process of informed consent?	REBs can only validate the research process to a certain extent. They review and validate the process based on documentation, however they are limited in that they are not physically involved in the actual process of obtaining consent.
5. Should the investigator be involved in the process of informed consent?	There is a trend towards having the investigator present at the time of the informed consent process in order to give potential participants a sense of who they will be working with, and ultimately to provide

Informed Consent Issue	Discussion
	confidence in the research. However, concerns were raised about the possibility for coercion simply from the power differential present between researcher and participants.
6. Should the coordinator be involved in the process of informed consent?	Following the above discussion, general consensus was that the coordinator should definitely be present, and in fact, should be the representative for the actual researcher to minimize the potential for coercion.
7. What is ample time for the consent process?	The literature suggests that families take the consent forms to review them at home and think of their response for a day (24h). However, it was recognized that many types of research (e.g. ICU) were not conducive to a prolonged period for consent, and in those cases, it was recommended to have a 2 phase consent with the initial phase being a matter of minutes, and subsequently, when patients are able to, the process should be repeated in its full format.
8. Can there be any conflicts of interest during the informed consent process?	Several examples of conflicts of interest were discussed, including competitive enrollment and consent with vulnerable populations.
9. How long should the informed consent document be?	Class participants noted that some forms currently in use include often 10 and up to 18 pages. It was recommended that the consent form be no longer than 2 pages in length.

Consent Related to Privacy Laws

A brief introduction to the Personal Information Protection and Electronic Documents Act (PIPEDA) led to a more in depth discussion about how privacy laws shape the process informed consent. Mainly, the focus of the presentation revolved around the development of a sound informed consent process (consent forms, obtaining consent, documentation of process, etc.) based on ten general privacy principles. The information contained in this presentation provided a good foundation for making a checklist which included elements that should be a part of a well designed informed consent form.

Consent Form Checklist

(Developed based on information provided at the presentation, see Appendix B)

Important Components of Informed Consent Forms	**Included (✓)**
1. States how the organization will be accountable for the protection of personal health information when in its control.	
2. States the nature of the information that will be collected *(What)*, for what purpose *(Why?)*, and how it will be collected and used *(How?)*.	
3. Adequately defines any terms, such as "personal information", that lead to the understanding of what they are consenting to.	
4. States that the collection of information will be limited to that of the identified study purposes and will be collected by fair and lawful means.	
5. States that the information can only be used and disclosed for the purpose for which it was collected and will be retained only as long as it is necessary to fulfill its purpose.	
6. States all third parties to whom the information collected will be or may be disclosed to.	
6. States that the information collected and used must be as accurate, complete, and up-to-date as possible.	
7. States that the information will be protected using adequate safeguards, and details the safeguards and how this will be accomplished.	
8. States that the organization will have information about its privacy policies and practices readily available, and provides information on how to obtain these.	
9. States that all information will be available for review and correction by the individual whose personal information it is.	
10. States that the organization will provide the means to an individual to challenge an organization's compliance to the 10 general principles of privacy.	
12. States that there is no obligation to provide consent, and that the participant can withdraw at any time in the research process without consequence.	
13. For clinical applications, states the consequences for not providing or for withdrawing consent and how this will be dealt with by the providers in accordance to their professional standards.	

*** See sample consent form provided by the speaker – Appendix C**

Issues Related to Informed Consent

Patient Concerns about Privacy

It is important to address all concerns that patients may have about privacy and answer all their questions. Information about how to obtain an organization's privacy policy and practice documents should be made readily available. All complaints should be promptly addressed and investigated, and patients should be notified of their right to complain to the Office of the Privacy Commissioner of Canada.

Refusal to Give/Withdrawal of Consent

Patients should be informed of the consequences for refusing treatment of withdrawing from treatment that has been initiated. Patient records for these patients that did not consent or withdrew should reflect their decision and should not be destroyed. They should be kept for regulatory or audit purposes.

Emergency Care Situations & Consent

It was mentioned that there are exceptions to privacy consent where it is impossible to obtain due to the patient's condition (unconsciousness, not lucid, etc.) but these were not discussed in detail.

Language Barriers

It is often the case that consent materials are not available in several languages. Efforts should be made to communicate adequately (interpretation, translated documents, etc.) in order to obtain consent.

Access to One's Personal Information

Privacy laws require that patients be allowed access to their personal information. While protecting the rights of participants, this can be problematic in the context of blinded studies where patients may want to find out which treatment group they have been randomized to. Although this poses a threat to the validity of the study, patients cannot be denied access to this information. Those cases should be resolved in discussion with the patient about the purpose of keeping this information unknown for the duration of the study.

Practical Approach to Paediatric Consent and Assent

Obtaining consent from a child can be a complex task, especially if the child is very young. Most often, consent is usually obtained from parents who make decisions on behalf of their children with the child's best interest in mind, sometimes without considering the child's strong feelings about a proposed medical intervention. It can be daunting to decide how much emphasis should be given to a child's feelings when making such important decisions.

This presentation addressed issues of competency, informed permission and assent, and also provided suggestions for developing an age appropriate informed consent process for dealing with children.

Competency

Appelbaum & Grisso (Assessing Competence to Consent to Treatment, 1998) describe 4 related skills that are prerequisites for establishing competency to consent or assent to treat children:

1) A child's ability to make choices
2) A child's ability to understand relevant information
3) A child's ability to accept the current situation and its consequences
4) A child's ability to rationally manipulate information

According to the American Academy of Pediatrics (AAP), rather than consent, the investigator or person delegated should seek informed permission from the parents and should seek the assent of the child wherever possible. *(PowerPoint Slides, p.6 – Appendix D)*

Four Elements in Assent (AAP)

1) A conversation with the child and family should develop an appropriate awareness of the present illness.
2) Informing the child of what can be expected from the interventions.
3) Assessing the child's understanding of his or her medical condition and the factors influencing the child to accept the proposed therapy.
4) Soliciting the child's assent.

The AAP promotes the child's participation in the decision-making process, although it does not mean that the child is considered as an autonomous and rational decision maker. They should simply be considered as relevant contributors to the decisions that will affect them. The AAP also recognizes that different parenting styles can impact the informed consent process, and propose a flexible approach to soliciting consent.

Tips for Obtaining Assent in Children

1) Arrange a “special” room that is not intimidating or scary and located away from the action in the clinic to provide a safe zone without distractions.
2) Spend time with the family and child and arrange to introduce staff who will be involved in the treatment or research.
3) Give the child a summary that is easy to understand and age appropriate using flash cards and many pictures to explain concepts.
4) Note in your source documents the entire process of informed consent in detail, including the questions the child may have asked.

Informed Consent with Vulnerable Populations

(See slides, Appendix E)

This final section of the morning presentation provided a risk management perspective and conveyed the importance to obtain consent in the most careful way when working with vulnerable individuals. Vulnerable individuals can include people who are physically vulnerable (blind, deaf, pregnant and in labour, newborns, patients in a coma, etc.) or socially vulnerable (elderly, mentally challenged, prisoners, members of ethnic minorities, etc).

Tips for Obtaining Informed Consent from Vulnerable Individuals

1) Pay close attention to details that may have to be modified for the incapable adult and approach the sponsor about this modification.
2) Have staff experienced in working with the incapable adult group.
3) Allow sufficient time for the process and time to answer all questions.
4) Be aware of cultural differences.
5) Be aware of attention spans in vulnerable populations (e.g. Alzheimer’s)

The final part of this presentation was used to review and discuss a case study. See Appendix E for information about this case.

Privacy – A Practical Approach

Presentation #2 – Afternoon Session

Background – Individual Privacy, Privacy Best Practices & the Health Information Act

According to the speaker, David Fraser from National Privacy Services Inc, privacy denotes the control that one has over their own personal information, as expressed by the choice to disclose this information, to whom, and how it will be used.

Personal information can then be considered as any information about an identifiable individual including opinions about this individual or any information that can be traced back to this individual. According to this definition, "virtually any information in an individual's medical file is their personal information". According to the Personal Information Protection and Electronic Documents Act (PIPEDA), it does not include the name title or business address or telephone number of an employee of an organization.

Privacy Laws Relevant to Alberta

(Information from Slide 3, p. 3 – see Appendix F)

Health Information Act (HIA)

- Governs custodians and their agents for health information that is related to publicly funded health care.
- "Custodians" and "affiliates" in connection with "health services" which are "direct or indirect" and "fully or partially" paid for by Alberta Health and Wellness.

Personal Information Protection Act (PIPA)

- Applies to all organizations in Alberta, other than public bodies, but **does not apply to personal health information collected, used or disclosed for research purposes**.
- Probably applies to other information – sponsors, CROs, etc. in Alberta.

Personal Information Protection and Electronic Documents Act (PIPEDA)

- Applies to the collection, use and disclosure of personal information in the course of commercial activities, except in a province that has substantially similar legislation
- HIA is not substantially similar; PIPA does not apply to health information, so PIPEDA applies
- Applies to sponsored clinical research in Alberta

In Alberta, HIA and PIPEDA overlap, however, there are significant gaps between the two laws, particularly in the coverage between private and public health care. Contrary to some opinions, the speaker stated that HIA and PIPEDA are not substantially similar, but that PIPA is in fact largely similar to PIPEDA. Within clinical health research in Alberta, both HIA and PIPEDA may be applicable. "In some cases, HIA will apply if there is any connection to Medicare-funded services", while "PIPEDA only exempts activities and personal information to which PIPA applies. As "PIPA does not apply to health research, PIPEDA applies".

According to the speaker, complying with both laws is simpler than it may seem at first glance. With minor modifications, following good information practices will achieve this purpose. These "10 principles of the CSA Model Code for the Protection of Personal Information are recognized to be the basis for good information practices in Canada":
(See slides p. 5 – 9, Appendix F)

1. Accountability *(see slides p. 22 – 28 for additional details, Appendix F)*
    a. Having a privacy officer within the organization ensure accountability and ownership pf responsibility towards implementing the ten principles.
2. Identifying purposes
    a. It should not be assumed that research participants know what their information will be used for and who it will be disclosed to. All efforts should be taken to convey this knowledge to the participants.
3. Consent *(see slides p. 17 – 22 for additional details, Appendix F)*
    a. Medical or health information is considered amongst the most sensitive, so it is recommended to "have a higher threshold of consent".
    b. Implied consent within the circle of care – does not apply to research.
4. Limiting Collection
    a. Organizations are responsible for collecting only the information that is necessary for the purpose of the research that was communicated to the participant at the time of consent.
5. Limiting use, disclosure and retention
    a. It is advisable to obtain consent for all purposes and to foresee all possible uses in advance.
6. Accuracy
    a. "If information is going to be used to make a decision about an individual, the decision maker has the obligation to use current, accurate information".
7. Safeguards *(see slides p. 29 – 33 for additional details, Appendix F)*
    a. Appropriate measures should be applied to protect against the accidental disclosure, alteration, deletion, etc of personal information. Obligations begin with collection and end with safe disposal, and must also be followed while being processed by a third party.
8. Openness
    a. Organizations should have a privacy policy in place that is designed for clear understanding. If conducting research however, these policies generally cannot apply to all situations in all projects. It is thus advisable to have a special handout or pamphlet to distribute to participants that answers any potential questions.
9. Access
    a. Individuals have a right to have access to their information within 30 days of requesting it. This information should be understandable to them, and for this purpose, any means should be applied to fulfill this goal, including transcription of handwriting, translations to other languages or Braille, etc.
10. Challenging compliance
    a. Organizations should have an established, easy, and accessible process for receiving, investigating, and promptly addressing complaints from individuals that relate to the handling of their personal information.

Appendices

Appendix A

Appendix B

Appendix C

Appendix D

Appendix E

Appendix F