

ELECTRONIC CONSENT TO HEALTH RESEARCH IN CANADA

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Consent has long been considered as the crystallization of the researcher's duty to inform research participants. Indeed, providing consent is based on the right of participants to exercise full autonomy in decisions affecting their personal privacy. That being said, as the number of participants recruited in large-scale longitudinal studies – for example – grows, obtaining and maintaining consents will become increasingly onerous and complex. Hence, research studies are gradually using interactive, electronic media for consent procedures – which are seen as more accurate, dynamic and cost-effective. It is unclear, however, how and under what conditions such an approach will satisfy the legal and ethical requirements related to consent to health research in Canada. This article explores how the notion of written consent could be broadened to allow for an electronic consent approach – an approach which holds promise of new efficiency for health research, but that may raise a novel set of ethical, legal and social considerations.

Le consentement est considéré depuis longtemps comme étant le fondement du devoir du chercheur d'informer ses participants à la recherche. En effet, le consentement est fondé sur le droit des participants de se prévaloir d'une entière autonomie quant aux décisions ayant des répercussions sur leur vie privée. Ceci dit, vu l'augmentation du nombre de participants recrutés dans des études longitudinales à grande échelle, l'obtention et la tenue à jour des consentements devient onéreux et complexe. En conséquence, lors de l'obtention des consentements, les chercheurs ont de plus en plus recours à des outils électroniques interactifs. Ces outils sont considérés comme étant plus précis, dynamiques et rentables. On ignore, cependant, comment et sous quelles conditions une telle manière de procéder répond aux exigences juridiques

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et éthiques liées au consentement à la recherche médicale. Cet article examine comment le consentement par écrit pourrait être élargi afin de permettre l'utilisation d'un consentement donné sous forme électronique. Une telle approche, si elle promet une efficacité renouvelée pour la recherche médicale, peut, en revanche, également soulever de nouveaux enjeux éthiques, juridiques et sociaux.

1. Introduction

Consent to research participation is considered the core expression of a participant's autonomy in the decision-making process. Typically, the process is a formal session whereby the participant is provided with a form, given the opportunity to ask questions and then asked to sign the consent form in the presence of the research team. While the concept of signed consent form continues to be a pillar of the field of health research, the advent of new information technologies is steadily eroding the need for a "written" medium in many spheres of research.

Over the past decade, a number of important population studies have collected biological samples and associated data to elucidate gene-environment contributions to disease risk.¹ These research infrastructures are built as resources for present and future research, due to the large sample sizes they provide. An increasing number of participants are being recruited into these biobanking projects that range from disease-specific to large population studies.² In this context, the research community is striving to streamline and simplify the data collection process by using electronic data capture (a task for which the rate-limiting step can often be the consent process), but much of the effort to obtain consent is still centered on obtaining paper-based signatures from participants.³ Given the burden that comes with administering, obtaining and recording consent in such studies, many researchers have questioned whether the use of novel methods, such as electronic consent options, would be more appropriate in certain health research contexts.⁴

¹ See Bartha Maria Knoppers, Ma'n Zawati and Emily Kirby, "Sampling Populations of Humans Across the World: ELSI Issues" (2012) 13 *Ann Rev Gen Hum Genet* 395; Bartha Maria Knoppers and MH Abdul-Rahman (Zawati), "Health Privacy in Genetic Research" (2009) 28 *Politics Life Sci* 99; Helen Swede, Carol Stone and Alyssa R Norwood, "National Population-Based Biobanks for Genetic Research" (2007) 9 *Genet Med* 141.

² Knoppers, Zawati and Kirby, *supra* note 1.

³ See Jane Kaye *et al.*, "From Patients to Partners: Participant-centric Initiatives in Biomedical Research" (2012) 13 *Nat Rev Genet* 371.

⁴ See Mike Mitka, "Strategies Sought for Reducing Cost, Improving Efficiency of Clinical Research" (2011) 306 *JAMA* 364.

For the purpose of this discussion, we define electronic consent (“e-consent” – also known as digital consent, on-line consent, and informatics consent) as a method of obtaining and recording participant consent by any electronic means. For medical research, such consent could be obtained in one of two ways, “in-centre” and “at-home.” The first method involves research staff members meeting with the participant and collecting consent as well as information via a technological platform. When feasible, electronic consent can also be obtained “at-home” or from another remote location; in this model, the participant provides information and consent from a home/remote computer.⁵ In brief, electronic consent can be facilitated by an on-line medium, or through the use of a touch-screen device or computer. In biobanking particularly, it is anticipated that the use of electronic means to obtain consent could lead to increased flexibility for the entire data trajectory from consent, to collection, to access.

Today, industry is piloting the use of electronic consent models in clinical trials. For instance, the Food and Drug Administration (FDA)-approved Research on Electronic Monitoring of OAB Treatment Experience (REMOTE) trial, sponsored by Pfizer Inc, is currently recruiting 600 US participants through the Internet, and shipping study drugs directly to their homes.⁶ In addition, many biobanks have begun to rethink consent options in view of streamlining the data gathering process and administrative processing of consent forms. For example, the UK Biobank, which has used touch-screens to obtain consent, explains in its pilot-phase report that “[o]btaining consent electronically allows more cost-effective and secure long-term storage of consent forms compared with traditional paper forms, and is likely to facilitate retrieval of specific forms in the future if that is needed (e.g. to confirm the original consent).”⁷ The OBiBa software suite used by the Public Population Project in Genomics and Society (P³G) is another example of an initiative which integrates e-consent in its data management trajectory. Indeed, the Onyx software, part of the OBiBa project, is a web-based application used to manage participant baseline interviews by assessment centers and clinics that are collecting data for research.⁸ Onyx contains an electronic consent module, which essentially allows the participant to read the consent form on the workstation screen, and then sign on an electronic signature pad (the

⁵ *Ibid.*

⁶ *Ibid.*

⁷ United Kingdom, UK Biobank, *UK Biobank: Report of the Integrated Pilot Phase* (2006) at s 4.3.2.

⁸ Yannick Marcon, “Onyx User Guide” (23 October 2012), online: OBiBa <<http://wiki.obiba.org>>.

electronic signature is stored on the electronic consent form).⁹ Another important initiative in this field is the portable legal consent project, which seeks to allow participants to voluntarily contribute their genomic data for multiple future uses and for which they must complete a detailed informed consent process exclusively online.¹⁰

The main challenges of electronic consent are reflected by the conditions of the laws discussed below. Indeed, there is concern over ensuring the integrity of electronic consent, adequate linking of electronic consents to participants through a valid electronic signature, and ensuring records of electronic consents are properly retained and accessible. Shifting to electronic consent may also have an impact on ethics, by impacting the interaction between researchers and participants, and may also present challenges to maintaining participant privacy.

Overall, even though the use of electronic consent remains limited, many hope that this concept can evolve and begin to be included in health research. Indeed, electronic consent could become a cornerstone of some research projects such as biobanks; allowing for increased participant autonomy and participation, while also streamlining the data collection and data access.¹¹

In view of the anticipated future uses of electronic consent, this article explores how the notion of written consent could be broadened to allow for an electronic consent approach – an approach which holds promise of new efficiency for the health research community, but that may yet raise a novel set of ethical, legal and social considerations. In this article, we propose first to examine how the international normative context for research involving human participants accounts for this new consent method; next, to consider under what conditions the Canadian legal context allows for electronic consent in medical research; and finally, to briefly anticipate the ethical, legal and social issues (ELSI) that may emerge as research moves from a strictly paper-based consent format to incorporating electronic forms of consent.

⁹ Yannick Marcon, “Obtaining Participant Consent” (23 October 2012), online: OBiBA <<http://wiki.obiba.org>>.

¹⁰ “Discontent with Consent,” Editorial Comment, (2012) 30 Nat Biotech 469.

¹¹ See Jane Kaye, “From Single Biobanks to International Networks: Developing E-Governance” (2011) 130 Hum Genet 377; Kaye *et al*, *supra* note 3.

2. International Legislation and Guidelines for Use of E-Consent in Research

While there are few standards specific to e-consent in a health research context, the international standard governing many aspects of electronic transactions is the *Model Law on Electronic Commerce*,¹² which was adopted by the United Nations Commission on International Trade Law (UNCITRAL) in 1996. This standard was developed to facilitate the use of modern means of communication and storage of information, seeking to establish a functional equivalent in electronic media for paper-based concepts such as “writing,” “signature” and “original.” The instrument also provides standards by which the legal value of electronic messages can be assessed.¹³ The *Model Law on Electronic Commerce* was adopted by the Uniform Law Conference of Canada,¹⁴ and many Canadian provinces have incorporated principles of this model in their own legislation.¹⁵ As its name suggests, however, the *Model Law on Electronic Commerce* principally affects the domain of electronic commerce; it was not designed with research involving human participants in mind.

Similarly, in Europe, national legislation governing electronic transactions has been primarily influenced by the Directives issued by the European Union.¹⁶ Indeed, the *Electronic Commerce Directive*¹⁷ aims to eliminate legal obstacles to the formation of contracts by electronic means, while the *EU Signature Directive*¹⁸ sets out a legal framework for electronic signatures to be implemented by member states. While the EU directives aim to clarify the legal framework surrounding electronic transactions, however, little clarification of what constitutes electronic

¹² United Nations Commission on International Trade Law, *UNCITRAL Model Law on Electronic Commerce with Guide to Enactment 1996*, 1996, 85th Plen Mtg, UN Doc. 51/162, (1996).

¹³*Ibid* at 16-17.

¹⁴ Uniform Electronic Commerce Act, [1999] *Proceedings of the Uniform Law Conference of Canada*, online: <<http://www.ulcc.ca/en/poam2/index.cfm?sec=1999&sub=1999ia>>.

¹⁵ Uniform Law Conference of Canada, *Status of E-Commerce Legislation of Canada*, online: <<http://www.ulcc.ca/en/cls/index.cfm?sec=4&sub=4b>>.

¹⁶ United Nations Commission on International Trade Law, *Promoting Confidence in Electronic Commerce: Legal Issues on International Use of Electronic Authentication and Signature Methods* (Vienna, 2009) at 37.

¹⁷ EC, *Commission Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market*, [2000] OJ, L 178/1.

¹⁸ EC, *Commission Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures*, [1999] OJ L13/12.

consent is provided by these texts, and no guidance is provided on electronic consent in the context of health research.

In 2011, to revise the 1999 *EU Signature Directive*, the European Commission launched a public consultation entitled “*Digital Agenda for Europe: Electronic identification, authentication and signatures in the European digital single market*.”¹⁹ Questions addressed by the European Commission included whether “electronic consent” should be recognized by future EU legislation and whether it should be considered equivalent to electronic signatures. Following this public consultation, the European Commission released a draft regulation on June 4, 2012, addressing electronic identification and trusted services for electronic transactions in the internal market.²⁰ While little is said about electronic consent generally, the draft regulations mention the use of electronic signatures with respect to medical data (primarily for healthcare purposes),²¹ and therefore begin to address the problem of online identification in health-related domains.

Finally, in the United States, *Title 21: Food and Drugs* of the *Federal Code of Regulations* defines an electronic signature as “a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual’s handwritten signature.”²² Therefore, an electronic signature is deemed equivalent to its handwritten counterpart for the purpose of FDA regulations, such as the regulations governing clinical trials. In addition, although the Department of Health and Human Services regulations do not address electronic signature requirements, the Office of Human Research Protection’s (OHRP) informed consent information sheet indicates that it allows electronic signatures to be used to document consent, provided jurisdictional laws allow for it.²³ Indeed, according to the information sheet, the “OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits [Institutional Review Boards] to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature

¹⁹ EC, *Report from the stakeholder workshop DAE: electronic identification, authentication and signatures in the European digital single market* (Brussels: 10 March 2011).

²⁰ EC, *Draft Regulation on electronic identification and trusted services for electronic transactions in the internal market*, COM(2012) 238/2.

²¹ *Ibid* (however, this may yet play an important role where linkage of healthcare data to research data is involved in the future use of interoperable European eHealth initiatives, at 11).

²² 21 § 11.3(b)(7).

²³ US Department of Health and Human Services, *Informed Consent FAQs*, online: <answers.hhs.gov/ohrp/categories/1566>.

can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject.”²⁴

3. Framework for E-Consent in Canada

As emphasized by several authors, the first challenge in designing and implementing an electronic consent mechanism for research is to “make sure that the translation of legal rules designed to regulate human activity does not have unexpected consequences when implemented in an electronic environment.”²⁵

A) Canadian Legal Framework

In Canada, consent to health research, as well as the use of electronic media to do so, is governed primarily by provincial legislation. In the context of biobanking, the participant’s consent may be sought for a variety of uses, including the collection of biological samples and data, the linking of data to administrative databases and the consent to future re-contact. Given the potentially broad range of this consent, our legislative review of these provinces included legislation (applicable to public bodies – including hospitals in most cases) addressing the following aspects of health research:

- Consent to participate in research;
- Consent to the collection of health information; and,
- Consent to disclosure of health information.

The table below lists the applicable legislation surveyed.

With regard to consent in a research setting, the fundamental question is: When legislation requires consent to be given “in writing,” is an electronic document sufficient to meet these requirements? In all five provinces studied, electronic consent was found to be a legally acceptable mechanism. This conclusion results from an interplay between legislation on consent (where provincial legislation requires consent to be in writing), privacy legislation, and electronic commerce legislation. The reason for this legislative framework stems in part from the fact that questions relating to e-consent have mainly been addressed in the context of contract law, as this is where “on-line” consent is most frequently encountered – as with electronic transactions, electronic exchange of documents and so on.

²⁴ *Ibid.*

²⁵ Enrico Coiera and Roger Clarke, “e-Consent: The Design and Implementation of Consumer Consent Mechanisms in an Electronic Environment” (2004) 11 *J Am Med Inform Assoc* 129 at 130.

| Jurisdiction | Applicable Legislation |
|------------------|---|
| Quebec | An Act to establish a legal framework for information technology, RSQ, c C-1.1 (<i>AELEFIT</i>), 2001. Civil Code of Québec, LRQ c C-1991 (CCQ) |
| Ontario | Personal Health Information Protection Act, 2004, RSO 2004, c 3, Sch A (<i>PHIPA</i>) Electronic Commerce Act, 2000, RSO 2000, c 17 (<i>ECA</i> (ON)) |
| British Columbia | Freedom of Information and Protection of Privacy Act, RSBC 1996, c 165 (<i>FIPPA</i>) Freedom of Information and Protection of Privacy Regulation, RSBCReg 323/93 (<i>FIPPA Reg</i>) Electronic Transaction Act, RSBC 2001, c 10 (<i>ETA</i> (BC)) |
| Alberta | Health Information Act, RSA 2000, c H-5 (<i>HIA</i>) Health Information Regulation, Alta Reg 70/2001 (<i>HIA Reg</i>) Electronic Transaction Act, RSA 2001, c E-5.5 (<i>ETA</i> (AB)) |
| Nova Scotia | Freedom of Information and Protection of Privacy Act, SNS 1993, c 5 (<i>FIPPA</i>) Freedom of Information and Protection of Privacy Regulations, NS Reg 105/94 (<i>FIPPA Reg</i>) Electronic Commerce Act, SNS 2000, c 26 (<i>ECA</i> (NS)) |
| Federal | Personal Information Protection and Electronic Documents Act, SC 2000, c 5 (<i>PIPEDA</i>) Food and Drug Regulations, CRC, c 870. |

For instance, section 24 of the *Civil Code of Quebec*²⁶ prescribes that consent to research must be given in writing. However, the *Act to establish a legal framework for information technology*²⁷ establishes that the requirement that a document be “in writing” can be met by an electronic document in Quebec, if further conditions are fulfilled.²⁸ Therefore, in Quebec, there is a functional equivalence between paper and electronic media, meaning that consent captured electronically would not be in violation of the *Civil Code*’s requirements with respect to research.

In the common law provinces examined, however, we found no specific legislative requirements to obtain consent to research. In some provinces, such a requirement only exists for the collection or disclosure of health information.²⁹ Biomedical research involves health information

²⁶ *Civil Code of Québec*, SQ 1991, c 64 [CCQ].

²⁷ RSQ, c C-1.1, s 2 [*AELEFIT*].

²⁸ See also Vincent Gautrais, “The Colour of E-consent” (2003) 1 *Univ Ottawa Law & Tech Journ* 189.

²⁹ See e.g. *Personal Health Information Protection Act*, SO, 2004, c 3 Schedule A, s 18(1) [*PHIPA* (ON)] (for consent to the collection of health information); *Freedom of Information and Protection of Privacy Act*, SBC 1996, c 165, ss 32(b), 33.1(1)(b) (for consent (in writing) to the disclosure by a public body of an individual’s personal information); *Health Information Act*, SA 2000 c H-5, ss 22 and 34(2) [*HIA*] (for consent to collection and disclosure of health information); *Freedom of Information and Protection of Privacy Act*, SNS 1993, c 5, ss 26(b), 27(b) and 29(d) (for the general

and may seemingly be subsumed under this requirement. Moreover, even though no specific provisions require “in writing” consent for research, consent forms have typically been designed for a paper-based approach to collecting consent. Yet, as in Quebec, legislation in these common law provinces – often a mix of privacy as well as electronic commerce legislation – generally considers paper-based documents to be equivalent to their electronic counterparts provided requirements are met.³⁰ Interestingly, in Alberta, electronic consent is specifically permitted for the disclosure of health information in its *Health Information Act*.³¹

Under provincial laws, in order for an electronic consent to be valid, several conditions and standards must be met. Generally across provinces examined, we found four main requirements to achieve functional equivalence between a paper and an electronic document, namely:

- 1) Ensuring the *integrity* of the electronic documents;
- 2) Establishing a link between the participant and the electronic documents via an *electronic signature*;
- 3) Ensuring *accessibility* of the documents for subsequent reference; and,
- 4) Ensuring their *retention*.

We examine these four conditions as they apply in the context of consent to research.

1) Integrity

Ensuring the integrity of an electronic document entails that the document or information contained therein, has not been altered and has been maintained in its entirety. Some provincial legislation indicates that this requirement may be assessed in light of all the circumstances in which the document was created³² and in view of the purposes for which the record was created.³³

disclosure and disclosure for research purposes, use of information held by a public body).

³⁰ See e.g. *PHIPA* (ON), *supra* note 29, s 2 “record;” *Electronic Commerce Act*, SO 2000, c 17 [*ECA* (ON)]; *Electronic Transaction Act*, SBC 2001, c 10 s 5 [*ETA* (BC)]; *Electronic Transaction Act*, SA 2001, c E-5.5 [*ETA* (AB)]; *Electronic Commerce Act*, SNS 2000, c 26 s 8 [*ECA* (NS)].

³¹ *HIA*, *supra* note 29.

³² *ECA* (ON), *supra* note 30 ss 8(1-2), 16.

³³ *ETA* (BC) s 8(1)(a), *supra* note 30; *ETA* (AB), *supra* note 30 s 14, 20; *ECA* (NS), *supra* note 30 s 12.

In addition, in Quebec, the integrity of the electronic document must be ensured throughout the document's lifecycle – creation, transmission, retention and until destruction. Not only should security measures be set to protect this integrity, but the medium used to create the document should provide stability and perennity to the information it contains.³⁴

In terms of consent forms, ensuring the criteria of “integrity” will generally require evidence that technological security mechanisms were applied to the document, such that it can be demonstrated that the content of the consent form was not altered during its entire lifecycle. Examples of such mechanisms include the use of encryption mechanisms, or notarization (for example, where a publicly recognized third party is entrusted with the storage of data to ensure integrity).³⁵

2) *Establishing a Link between a Person and an Electronic Document*

Establishing a link between the participant and the electronic documents aims to verify the identity of the person. Provincial laws examined indicate that this link is established via the use of an electronic signature.³⁶ This concept relates to the reliability of the document signed: indeed, one needs to be able to on the one hand identify the signatory of a document, and on the other, to allow the document to be identified so as to trace its origins.

In Quebec, a signature is defined as the affixing of a person's name or the distinctive mark regularly used by this person to signify his intention. In other provinces, however, legislation does not define an electronic signature, and therefore, it is not always clear as to what may be sufficient for an electronic document to be ‘signed.’³⁷

The specific requirements relating to an electronic signature can vary widely across jurisdictions both within³⁸ and outside of Canada. Many different technical norms can, however, be used to satisfy these legislative requirements.

³⁴ *AELFIT*, *supra* note 27 ss 6, 19.

³⁵ See Vincent Gautrais, *Afin d'y voir clair – Guide relatif à la gestion des documents technologiques* (Montréal: Fondation du Barreau du Québec, 2005).

³⁶ *AELFIT*, *supra* note 27 ss 38, 39; CCQ, *supra* note 26, art 2827.

³⁷ Also, in all provinces surveyed, there were no regulations adopted to describe any required technology standards. Therefore, it remains unclear as to how such legislation will apply in terms of the signature of electronic consent forms.

³⁸ Personal information protection legislation may provide useful guidance for electronic consent to health research. For example, s 48 of the federal *PIPEDA* discusses the determination of technologies and processes required for the purpose of a “secure electronic signature” for electronic documents.

3) Accessibility

Legislation also requires that an electronic document remain accessible for subsequent reference.³⁹ In terms of e-consent, this calls for the mechanisms of information technology (IT) used to collect and record consent to be able to record it in such a way as to make the consent “document” subsequently accessible. Generally, requests for access will be sent to the custodian of the electronic document. The system used to store the electronic consent forms must therefore allow for accessibility and retrieval of individual forms.

4) Retention

Finally, the last criterion to ensure functional equivalency between a written document and its electronic counterpart requires that electronic documents be retained for subsequent reference.⁴⁰ Essentially, the electronic document must be stored in a way that will protect it from being destroyed or damaged over time.⁴¹ In some provinces, however, additional conditions must also be met. For instance, in Alberta and Nova Scotia, a legal requirement to retain a record that is originally created, sent or received electronically is satisfied if it is retained in the same format in which it was created or in a format that accurately represents the information in the record. In Nova Scotia, this requirement is satisfied if the document is saved in a format that does not materially change the information contained in the document originally made. Additionally, the record must be accessible for subsequent reference and, if the electronic record was sent or received, information regarding its origin and destination, date and time must also be retained.

B) Canadian Guidelines on Research and Consent

In addition to this Canadian legal framework, guidelines also frame the context of research involving humans. In Canada, the primary guideline for research ethics, the second edition of the *Tri-Council Policy Statement*:

³⁹ See *AELFIT*, *supra* note 27, ss 23-26; *ECA* (ON), *supra* note 30, ss 5, 8(1)(b); *ETA* (BC), *supra* note 30, ss 5, 8(1)(b); *ETA* (AB), *supra* note 30, s 11(b); *ECA* (NS), *supra* note 30, ss 8, 12(1)(b).

⁴⁰ *AELFIT*, *supra* note 27, ss 20 and 21; *ECA* (ON), *supra* note 30, ss 6(1), 9; *ETA* (BC), *supra* note 30, ss 7(b-c), 9, 10; *ETA* (AB), *supra* note 30, ss 12(a-b), 15, 17; *ECA* (NS), *supra* note 30, ss 13, 14.

⁴¹ For clinical trials, the *Food and Drugs Regulations*, CRC, c 870 require records to be kept in respect of each study subject, “a copy of their signed consent form and sufficient information ...” (s C.03.315(3)(d)).

*Ethical Conduct for Research Involving Humans*⁴² (TCPS), does not explicitly address e-consent. Indeed, while the TCPS indicates that “[e]vidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent,”⁴³ nothing is said of the acceptability of using electronic means to do so. Explanatory notes describe that there “are other means of providing consent that are equally ethically acceptable. [...] In [some] cases, oral consent, a verbal agreement or a handshake may be required, rather than signing a consent form.”⁴⁴ Other aspects of the TCPS may also be relevant to electronic consent. For example, the retention of electronic consent may pose potential privacy and security risks that will have to be identified and assessed by both researchers and Research Ethics Boards.⁴⁵

Although not reflected in the current version of the TCPS, the Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC) was commissioned both in 2004 and again in 2008 to address ethical issues associated with research conducted over the Internet (including both web-based and online research). While recommendations to update the TCPS made in the 2008 Report⁴⁶ were not included in the subsequent revision of the TCPS, comments were made with respect to online research that provide a basis for the examination of ELSI matters to consider in this domain. In particular, for online research, the SSHWC recommended that researchers be required to explain strategies used to obtain informed consent and that there be verification mechanisms for research involving minors. Furthermore, it was also suggested that the TCPS indicate that sending research data over the Internet requires the use of encryption and denormalization software to prevent any interception of data and to protect anonymity and confidentiality. Although these recommendations were never adopted, they provide some insight into what factors in the realm of research ethics are important to consider when interpreting the applicable legal framework.

Although legal clarifications on these concepts, or at the very least, guidance on how to apply provincial legislation, could facilitate the

⁴² Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans” (December 2010), online: <<http://www.pre.ethics.gc.ca>>.

⁴³ *Ibid* at 3.12.

⁴⁴ *Ibid* at 44.

⁴⁵ *Ibid* at 5.3.

⁴⁶ Social Sciences and Humanities Research Ethics Special Working Committee: A Working Committee of the Interagency Advisory Panel on Research Ethics, “Extending the Spectrum: The TCPS and Ethical Issues in Internet-based Research” (February 2008), online: <<http://www.pre.ethics.gc.ca>>.

implementation of electronic consent mechanisms for medical research, another important component of the current challenge lies in the revisiting and re-evaluation of ELSI in an electronic context.

4. ELSI Considerations: Anticipating the Potential Benefits and Challenges in the Use of an E-Consent System

The anticipated ELSI hurdles impeding a widespread implementation of electronic consent to medical research may lie not in legislative and regulatory requirements, but rather in the perceived impact of the shift from a paper-based to an electronic medium. As of yet, the issue of the ethical and legal acceptability of electronic consent has rarely been discussed. In the following paragraphs, we examine elements that may be affected by such a shift. Our analysis focuses on three themes, examining both problems and potential benefits of the following: (a) the use of an electronic medium; (b) the process of obtaining informed consent and interaction with the participant; and, (c) privacy and confidentiality issues.

A) Shifting the Medium of Consent and Sampling of Populations

Shifting from a paper-based medium to an electronic one may in itself be considered an ethical issue. In a scenario where consent is collected at the research site, this may not be problematic as research staff can assist in the understanding of the contents of the form. Some authors suggest, however, that consent that is given remotely could lead to selection bias, as those who lack online access would be less likely to use electronic consent via the Internet.⁴⁷ For example, recent statistics in Canada appear to indicate that older individuals, those with less education, or those with a lower family income use the Internet less than their counterparts.⁴⁸ The same trend can be seen in the use of the Internet for transactional purposes. There are very few empirical studies examining this issue in the context of health research – and therefore as electronic consent systems are increasingly used, data should be collected to investigate whether the range of users differ from that of paper-based consent.

This sampling bias may become an issue in population studies where cross-sectional samples of entire populations are required. Therefore, in these studies, special care must be taken to ensure that technologically vulnerable populations are properly accounted for when implementing electronic consent mechanisms.

⁴⁷ James Paul, Rachael Seib and Todd Prescott, “The Internet and Clinical Trials: Background, Online Resources, Examples and Issues” (2005) 7 *J Med Internet Res* e5.

⁴⁸ Statistics Canada, “Internet use by individuals, by selected characteristics” (Table of latest data available) (2009), online: <<http://www.statcan.gc.ca/>>.

B) *Interactions with the Participant*

1) *Informing Consent*

The implementation of health information technologies such as e-consent may require a reframing of the manner in which we view the process of giving consent. Indeed, in the field of biomedical research consent is traditionally viewed as a “face-to-face” process between the researcher and the participant, ending with the signature of a paper-based consent form.⁴⁹ Reframing this image will likely result in a shift of perception and practices in the administrative and institutional procedures currently in place.

For example, one author argues that while technologies such as electronic consent may place a physical barrier between the physician and patients or research participants, electronic tools could also increase access to information, shifting focus away from a one-time, signature-based consent form to a more dynamic process of information exchange.⁵⁰ Consent can be understood as an “autonomous authorization,” as in the case of a participant who “with substantial understanding and in substantial absence of control by others, intentionally authorizes a professional to perform an intervention.” On the other hand, consent can be viewed as “effective consent” – a process which “does not require autonomous authorization but instead focuses on consent that has been obtained according to the rules and requirements that satisfy a specific institution’s practice in health care.”⁵¹ Indeed, some anticipate that electronic media may provide an impetus to move beyond the “effective consent” towards an “autonomous authorization” by increasingly allowing the use of dynamic tools such as videos, comprehension questionnaires, adapted consent forms, photographs or glossaries.⁵²

Finally, while an entirely electronic informed consent may appeal to some researchers wishing to diminish the administrative overhead required to obtain consent, there appears to be at least some consensus that the involvement of a study representative remains imperative⁵³ in order to

⁴⁹ See Kaye *et al*, *supra* note 3.

⁵⁰ Melissa M Goldstein, “Health Information Technology and the Idea of Informed Consent” (2010) 38 J Law Med & Ethics 27.

⁵¹ *Ibid* at 28.

⁵² See Daniel Purcaru *et al*, “e-Informed Consent in Clinical Trials: Ethical Considerations” (Paper published in Proceedings of the 11th WSEAS International Conference on Applied Informatics, 66, 2011); Sarah A McGraw *et al*, “Clarity and Appeal of a Multimedia Informed Consent Tool for Biobanking” (2012) 34 IRB 9.

⁵³ See Paul, Seib and Prescott, *supra* note 47.

answer questions and provide clarifications, and in some cases, to help with the verification of baseline data collection.

2) *Interactions with and Feedback to the Research Participant*

Beyond changing the way consent is typically provided, stakeholders are optimistic about the potential increased use of electronic media with research participants. Researchers proposing this option have suggested that use of electronic media might provide a solution to the reluctance and unease surrounding the use of broad consent, especially in biobanking research.⁵⁴ It is hoped that the use of electronic media may empower the participant and allow for more active choices.

Several electronic consent models taking into account increased involvement of the participant in the consent process have been proposed. For example, the proposed model of “Participant-centric initiatives” (PCIs),⁵⁵ uses interactive IT interfaces to engage and communicate with actors involved. While these platforms typically provide tools beyond the initial consent process, it is recognized that they also call for a re-examination of the current consent methods in that PCIs may ease the obtaining of consent and ensure compliance with e-consent legislation in different jurisdictions.

Another key initiative in the use of electronic consent in health research is the Portable Consent project. This project proposes to create a standardized online informed consent agreement that will enable participants to upload genomic data about themselves. Although this initiative does not yet replace standard consent, it moves research into an increasingly online environment and aims to streamline the consent process to make data more available to researchers.⁵⁶

In addition, the EnCoRe Dynamic Consent project ultimately proposes to “provide an easy-to-use piece of technology that will allow biobanking patients to achieve some levels of ‘control’ over how information and data relating to them are used by researchers and clinicians.”⁵⁷ This control is to be exercised as giving and revoking consent. The project aims to rethink consent through the use of new technologies. Rather than making consent

⁵⁴ Kaye *et al*, *supra* note 3.

⁵⁵ *Ibid*.

⁵⁶ Editorial, “Your Data are not a Product” (2012) 44 *Nature Genetics* 357.

⁵⁷ Centre for Health, Law, and Emerging Technologies, EnCoRe/ORB Pilot Study, online: <<http://www.publichealth.ox.ac.uk>>.

a one-time event, the process is ongoing, dynamic and granular, allowing participants to change their minds.⁵⁸

Finally, another author corroborates the view that integrating electronic consent in the health care and research environment would likely translate into a system that allows multiple options regarding the sharing of participant information and linkage.⁵⁹ This approach resembles some aspects of the proposal for a dynamic consent process as well as the EnCoRe initiative. However, it will be interesting to examine whether these systems will ultimately be administratively burdensome and costly,⁶⁰ what socio-economic strata and age groups will avail themselves of e-consent and whether they can be readily implemented in health research.

B) Privacy in an Electronic Environment

Many researchers hope that electronic consent might provide a means to allow users to specifically indicate what information they want to share and with whom, becoming a means to streamline the consent and access to information processes without compromising privacy.⁶¹ Yet, although these potential advantages of an electronic system appear promising, some authors argue that providing highly interoperable electronic platforms may heighten ethical duties. Indeed, the degree of harm to privacy that may result from the structure of a highly interoperable electronic system may be greater than the unethical structuring of a stand-alone consent management database.⁶²

In addition, in the context of an electronic environment, research participants' privacy concerns (or inadequate comprehension of the risks) may hinder the implementation of electronic consent systems.⁶³ Studies have indicated that participants who "do not understand who is accessing

⁵⁸ Edgar A Whitley and Nadja Kanellopoulou, "Privacy and Informed Consent in Online Interactions: Evidence from Expert Focus Groups" (Paper published in ICIS 2010 Proceedings).

⁵⁹ Goldstein, *supra* note 50.

⁶⁰ See *ibid*; Tom Beauchamp and James F Childress, *Principles of Biomedical Ethics*, 7th ed (New York: Oxford University Press, 2012).

⁶¹ Robert H Shelton, "Electronic Consent Channels: Preserving Patient Privacy Without Handcuffing Researchers" (2011) 3 *Sci Transl Med* 1 at 2.

⁶² See Eike-Henner W Kluge, "Security and Privacy of EHR Systems – Ethical, Social and Legal Requirements" (2003) 96 *Stud Health Technol Inform* 121.

⁶³ Shelton, *supra* note 61.

their information and how their data might be used” could be more reluctant to participate in the study and share their private information.⁶⁴

Furthermore, there is an additional privacy concern that could present itself in an e-consent system: protecting the privacy of the participant during the transmission of the consent from the participant’s electronic interface to the research site. Therefore, mechanisms should be in place to ensure that the information communicated between the parties is secured.

5. Conclusion

The Canadian legal framework currently allows for the consent process to be completed electronically, if certain conditions are met. However, this legal framework was developed around electronic consent for electronic commerce and does not address the particularities of consent in the context of health applications (and even less so for health research). In addition to this little-adapted legal context, the ELSI community has not paid much attention to the topic of the ethical and legal conditions surrounding e-consent, yet many health researchers are increasingly interested in the potential applications of these new initiatives.

Therefore, there is a clear need to prepare specific guidelines to clarify the Canadian legislation as it applies to health research. Such guidelines should outline how electronic consent can be implemented in practice, how the requirements of integrity, authentic signing, accessibility, and reliability can be met. In addition, the broader impact of electronic consent on participant autonomy and privacy needs to be considered by the ELSI community. Indeed, encouraging this dialogue will help in establishing an ethical framework for electronic consent for biomedical research. It will undoubtedly make it easier for researchers to eventually use these tools and for REBs to accept such proposed uses. A first step in the understanding of the complex path of electronic consent, as well as the subsequent use of data provided by the participant, may well be examined through feasibility studies⁶⁵ and pilot projects. These projects could identify unforeseen consequences of electronic consent. They could also aim to determine what areas of health research could be streamlined by electronic consent, and how the researcher-participant dynamic may be affected. Finally, any such guidance should be both principled and practical with sufficient flexibility to incorporate and govern future IT developments.

⁶⁴ *Ibid* at 1; see also Beth A Tarini *et al*, “Not Without my Permission: Parents’ Willingness to Permit use of Newborn Screening Samples for Research” (2010) 13 Public Health Genomics 125.

⁶⁵ See e.g. Purcaru *et al*, *supra* note 52.