

## **Electronic Consent Processes for Rheumatology Research**

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**Objective:** Informed consent is based on the right of research participants to be fully informed in order to exercise full autonomy in health decision-making. Traditionally, consent to research has been expressed in writing. Technological advances and increasingly complex research questions have created a potential environment where consent may be collected and managed electronically. Participants have begun to expect the same online functionality currently existing in other areas including banking and social media. There is an emerging need to evaluate ethical and legal challenges that will be created by using technologies to obtain consent. In collaboration with ethics and legal researchers, the Canadian Consortium of Rheumatology Cohort, analyzed international policy and Canadian legislation regarding consent and using electronic consent (e-consent) for rheumatology research.

**Methods:** A systematic review of international published and grey legal literature was conducted using established methods. We examined the Model Law on Electronic Commerce (United Nations Commission on International Trade Law), the Electronic Commerce Directive and European Union Signature Directive and the Food and Drug Administration regulations (US), which clarify the legal framework surrounding electronic transactions including electronic signatures and contracts. Subsequently, an evaluation of the Canadian legislation was performed to determine the conditions that permit e-consent in medical research nationally and in select provinces. Finally, we examined perceived impacts of the Ethical, Legal and Social Issues (ELSI) that may emerge as consent moves from a paper-based format to electronic.

**Results:** An international review revealed that there are few governing standards specific to e-consent in health research. Conditions examined within Canadian legislation for research consent included. 1) Integrity: ensuring an electronic document has not been altered. 2) Electronic signature: verifying the identity of a person and creating a connection with their document. 3) Accessibility: requiring that electronic documents remain accessible for subsequent reference. 4) Retention: requiring that electronic documents be protected and retained for subsequent reference. ELSI considerations identified potential benefits and challenges in the use of e-consent. Challenges include lack of guidance regarding interactions with and feedback to participants, and creating appropriate mechanisms for participants that do not use e-consent. Finally, potential electronic privacy and confidentiality issues were identified.

**Conclusion:** The Canadian legal framework currently allows the consent process to be completed electronically, if certain conditions are met. However, this legal framework was developed for e-consent in e-commerce and does not address the requirements of consent in the context of health research. Consequently, we will develop a Canadian consensus based guidance framework.