



Ontario Best Practices Research Initiative (OBRI)

University Health Network

**Theoretical Framework for: Electronic Consent,
Governance and the Design and Evaluation of
Research Study Protocols**

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Executive Summary

Canadian rheumatology researchers are beginning to explore the issues of online data collection where data can potentially be shared across several investigators and studies. To address these issues, this report was developed as an internal discussion paper to aid our team in consolidating our work to date and planning of future work.

This report discusses an emerging recognition that both consent and governance are contingent on the study protocol. This follows from the notion that consent does not exist independent of the protocol, and that the governance framework put into place to ensure compliance is only meaningful in reference to the protocol.

This report reviews:

1. Operational objectives (productivity, efficiency)
 - This can include electronic forms, databases, import of data from other electronic sources, as well as patient communications and notifications (reminders/prompts).
2. Compliance
 - Can be tracked using electronic auditing techniques.
3. Governance
 - Can be enhanced by building in rules and permissions, and separation of data as recommended by "Privacy by Design".
4. Research Study Participant Control
 - Decisions that would previously have been made on the participant's behalf by REB's can now revert to the participant by implementing direct and dynamic consent.
5. Study Protocol Evaluation Methodology
6. Information and Communication Technology (ICT) Impact Guidelines

Further work is required:

- To investigate impact of ICT on research
- To create protocol evaluation methodology (identification of compliance, operational, participant, and governance issues)
- To develop impact guidelines
- To develop options and recommendations to address the identified issues
- To create example scenarios of common protocols implemented on the Consent and Data Management (CDM) system as an aid to researchers designing their own studies using ICT research platforms.

Impact of Information and Communication Technologies on Research

This research team at UHN has been developing an online research platform, and has direct experience in how Information and Communication Technology (ICT) can be used to achieve a number of objectives within a research study, some examples include:

Operational objectives (productivity, efficiency) can be met with electronic forms, databases, import of data from other electronic sources, as well as patient communications and notifications (reminders/prompts).

Compliance can be tracked using electronic auditing techniques.

Governance can be enhanced by building in rules and permissions, along with the separation of data as recommended by "Privacy by Design".

Participant control of their research experience can be increased. Decisions that would previously have been made on the participant's behalf by REB's and others can now revert to the participant by implementing direct and dynamic consent.

With respect to e-consent documents relative to paper-based consent documents, ICT can bring changes to consent content, presentation, structure and functionality. Some examples are:

ICT is able to transform consent **content** through the use of multi-media in addition to static text, and allow for finer grained consent questions. When coupled with changes in structure and functionality it is possible to formulate consent questions that permit consent revision rather than forcing outright withdrawal from a study.

Consent **presentation** can be responsive to the participants' needs, e.g. adaptive formatting for desktop monitor, tablets and smartphones. User Interface elements (buttons, font sizes, text to speech, etc.) can be adapted for people with various disabilities or user requirements.

Consent **structure** may be tiered: via a system level consent, a program consent, and a study specific consent. The consent documents need no longer be a linear text document but may have hyperlinks, outline views, and navigation aids.

ICT will give the consent process **functionality** through direct and dynamic consent, digital signatures, and when coupled with tiered consent, the ability for the participant to have fine grained control over the research experience.

The literature and world events have demonstrated that end users are increasingly demanding direct and dynamic control over their data. This approach is moving into the field of healthcare and will have major impacts on how we do research. Much of the functionality outlined above is available in consumer software, and study participants will rightly expect to have as much functionality or control when participating in a research study.

With ICT's ability to transform research in so many ways, the challenge is how to ensure that the needs of the researcher and the participant are reflected in the protocol and governance framework so that compliance and operational requirements are met. It must also be recognized that implementing ICT in a piece wise manner without considering its overall impact is likely to lead to unintended consequences. To address these challenges, a three step process is proposed in the next section.

Protocol Evaluation Methodology

This section outlines a methodology that a researcher can follow once they have a preliminary protocol in place. Briefly, the method has the following three steps:

1. Evaluate the protocol on the four dimensions detailed below. This evaluation will lead to the identification of compliance, operational, participant, and governance issues.
2. Review the identified issues singly, and in conjunction with each other since interaction is common.
3. Review the options and recommendations for potential solutions to address the identified issues.

Complex interventions require iterative feedback, therefore it may be necessary to revise the protocol and governance and go through the process again to ensure that no unaddressed issues remain.

For the first step, it is proposed that the protocol be evaluated on four dimensions, two from the researcher perspective and two from the participant perspective. The proposed dimensions are:

1. **Responsibility:** Ultimately, the researcher (PI) is responsible for the implementation and conduct of a study. In the standard case of a single PI/single study, this responsibility is clear. In the case where there is a research platform capable of hosting multiple studies, for multiple researchers, responsibility is no longer clear without added technology and governance. Factors that impact responsibility are number of PI's, number of studies, number of centres, and number of jurisdictions.
2. **Researcher Relationship:** characterizes the relationship of the researcher to the study and to the platform. For example, is the researcher accessing data from one study that is changing over time, or accessing data from multiple studies?
3. **Participant Relationship:** Is the participant's experience with the study, or platform a single event or do they have an ongoing relationship with either a study or the platform? Is the study population only assembled for one study (single encounter), or might the users of the platform be in a cohort that could be in multiple parallel or serial studies (ongoing relationship)?
4. **Participant interaction:** Does the participant enter their own data directly (in whole or in part)? If the participant is able to interact directly with the research platform, then in addition to providing information they will be able to change their own information and receive information. As will be discussed later, there is also the potential for the participant to control aspects of the study.

Impact Guidelines

The discussion of each dimension will highlight the impact of that dimension on operational, compliance, governance and participant issues. As an example of how this can be used in step 2 to address specific scenarios, consider two examples: 1) the case of a study collecting specimens for bio-banking which uses ICT for cataloging specimens, and 2) another study using Electronic Medical Records (EMR) to collect research data. In both cases the consent documents would have questions pertaining to the capture and use of research data. With respect to consent questions, it could be asked "What are the salient differences between a study involving bio-banking of a specimen and one using EMRs that would impact the questions asked of a study participant in the consent process, and what would the differences in those questions be?" Using the process outlined, it will be seen that on the dimension of participant relationship that the two studies differ significantly. The difference is that typically the collection of a specimen to be banked is a one-time event, whereas an EMR may generate multiple data points over a series of visits by the patient. Therefore the

participant relationship in the bio-banking case is termed a single encounter, and in the EMR case, an ongoing relationship.

For the second step, a set of impact guidelines is required. In the case of bio-banking, with the consent procedure being a one-time event, the patient could be asked to give permission for all future uses of the donated specimen at that time. If on the other hand, the patient has an ongoing relationship with the study (data collected from the EMR over a series of encounters), and is therefore relatively easy to contact, it may be more appropriate to only ask for the use of data as the need arises, i.e. for a specific study rather than seeking blanket permissions for all future use of data. Patients may also choose to not be 'poked' when research opportunities arise, and should be able to indicate their level of engagement, meaning that a specific question pertaining to contact and communication is required.

For the purposes of this example, the analysis was performed on only one dimension (participant relationship) and only highlighted how the consent questions pertaining to data use and communication would be affected. The impact guidelines would also provide guidance for the impact on protocol, compliance and governance as well as contexts where there is an interaction between dimensions, such as participant relationship and participant interaction.

Given the issues identified in step 2, options and recommendations are required to remove or mitigate the impact of those issues. The discussion of governance options would include both procedural (policies and procedures) and technical solutions so that the researcher can choose those most appropriate for their protocol. This section would recognize that blanket recommendations are not possible, since any protocol must seek a balance of the needs of the researcher, the participant, and the public good.

Example Scenarios

As is apparent, it is not possible to provide a template for consent, protocol or governance since they are all study specific. In place of a template, examples of common protocols and ICT implementations will be presented and discussed as an aid to researchers designing their own studies.

The above examples will be implemented in the CDM system developed at UHN to demonstrate feasibility and actual operation of the research process. A related project of this research team, the Ontario Best Practices Research Initiative (OBRI), will serve

as an additional example of a more complex study design OBRI has multiple points of responsibility, ongoing researcher and participant relationships, and a high level of participant interaction.

Summary

In summary, further work is required to develop the final deliverables in the form of a single report which will be disseminated in a future document. Elements to be addressed include:

- Impact of ICT on research
- Protocol evaluation dimensions
- Impact guidelines
- Options and Recommendations
- Example scenarios implemented on CDM

Glossary of Terms

Digital signature: verifies the identity of a person and creating a authentic connection with their electronic document.

Direct and Dynamic Consent: is informed consent given directly by a participant to manage their study related activities including study participation, permission for the use of their data, and contact with researchers.

Electronic Data Collection (EDC) System: is a computerized system designed for the collection of clinical data in electronic format.

Governance: technology driven governance, the system of rules, practices and processes by which research protocol and activities are directed and controlled. Includes continuous monitoring for proper implementation.

Information and Communications Technology (ICT): refers to technologies that provide access to information through telecommunications. It is similar to Information Technology (IT), but focuses primarily on communication technologies. This includes the Internet, wireless networks, cell phones, and other communication mediums. instant messaging, voice over IP (VoIP), and video-conferencing. Social networking websites

Ontario Best Practices Research Initiative (OBRI): the OBRI includes a clinical registry of RA patients (OBRI-RA registry) followed in routine care in Ontario, Canada.

Privacy By Design: is an approach to protecting privacy by embedding it into the design specifications of technologies, business practices, and physical infrastructures. That means building in privacy up front – right into the design specifications and architecture of new systems and processes.

Research Platform / Application: is software designed for internet based data collection of clinical and self-reported research data for longitudinal cohort/population based studies.

Research Practice: research frameworks, paradigms within applied research and research ethics.

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