Western Research

Office of Human Research Ethics
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Document	Integrated Consent Guidance
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What is Integrated Consent?

An integrated consent model seeks to implement an abbreviated research informed consent process. Instead of relying on research staff, a consent discussion is performed by circle of care during the course of usual clinical care. Verbal consent is then documented in clinical notes with a brief handout/letter of information provided to participants for their future reference.

TCPS2 outlines the requirements for obtaining and documenting ongoing informed consent (Articles 3.1-3.5). It also outlines criteria that must be met for alterations to these requirements (Article 3.7A). Integrated consent is an approach that operates within the confines of TCPS2 to introduce, inform, and document informed consent in an abbreviated manner. It is critical to note that the type of research, risk, and context are important considerations to when integrated consent is appropriate. The burden is on researchers seeking REB approval to provide the rationale for integrated consent.

Why Integrated Consent?

Obtaining consent for research participation in certain circumstances can pose a potential barrier with resourcing, timing, and considerations related to the population.

Obtaining written consent by someone with no relationship to the participant remains best practice. However, when researchers may wish to seek a waiver or deferral of consent, but all of the requirements in TCPS2 Article 3.7A for an alteration to informed consent are ***not*** sufficiently met, integrated consent can serve as a compromise.

The REB will consider alternative methods of approach and documentation in a hierarchy (for example, verbal consent, remote consent, eConsent, implied consent, deferred consent, or a waiver of consent) placing integrated consent at the appropriate location in the continuum given the nature of the research under review. Some research may benefit from multiple models of consent that can be implemented based on pre-defined criteria such as participant or SDM capacity, availability, timelines, and context of initial approach.

When is Integrated Consent Appropriate?

Each research protocol proposing integrated consent is assessed on an individual basis. Currently, trials that include or compare only current and local standard of care interventions where there is clinical equipoise will be considered for integrated consent.

What needs to be submitted to the REB for review of Integrated Consent?

Much like a traditional consent model requires review of recruitment materials and the letter of information and consent, the REB must also review the verbal consent script circle of care will use to introduce the study and the handout that participants will be provided. Protocols should also outline training provided to clinicians who are recruiting in terms of documenting informed consent in the clinical record. Templates can be found below.

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STUDY TITLE – Information for Research Participants

PI Name, Institution, Contact Information

If SDM is involved, insert: Please note, throughout this document "you" refers to the patient.

Please note that often more information can be fit on one page if you use two columns. Please be concise and precise using plain language as much as possible.

What is the study about?

Inclusion/Exclusion Criteria/Why the person has been approached to participate

What will happen to you and what information are we collecting?

What would happen if you weren't in the study? Delineate any differences in care and assure that standard of care would still be provided.

How long will the study last? Describe the study as a whole and the participant's time commitment/duration of individual data collection.

What are the risks and benefits?

Questions?

- **If you have any questions about your participation you can contact the Research Coordinator: xxx– pager #### or office #### or Dr. xxxx (Principal Investigator – office ####)**
- **If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at [institution/contact #]/OHRE [contact#]**
- **If you have any questions at any time your 24 hour contact person is your [bedside nurse]**

Important Information

- **Research is VOLUNTARY. No legal rights are waived by consenting to participate.**
- **You can WITHDRAW CONSENT at ANY time by talking to your [nurse]. If you withdraw you can also request withdrawal of your data, if applicable/if able.**
- **Your data will be DE-IDENTIFIED and CONFIDENTIALLY maintained per Institution guidelines**
- **To ensure proper study conduct representatives of Western University and its Health Sciences Research Ethics Board and/or the Quality Assurance and Education Officers from the hospital's Office of Research Services may review your identifiable study information**
- ***A statement around data leaving the institution/technology in use as applicable***

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Verbal Script for circle of care (i.e. bedside nurse)

We are currently conducting a study on [study indication]. As you/(your child) has been admitted to the [department] with [study indication] we are hoping to collect information about your/(your child's) [condition/device/stay etc.]. As part of the study [explain how this is standard of care/pragmatic]. We will record information about [information you will collect]. All information collected will be de-identified. Please read the information form and please let me know if you agree to let us collect the information or not. Please let me know if you have any questions.