GUIDANCE NOTES ON THE CONSENT PROCESS

INTRODUCTION

Free, informed, and ongoing consent is a fundamental principle of ethical research. These guidance notes provide an overview of the consent process and the submission requirements for REB review.

GUIDANCE NOTE #1: CONSENT REQUIREMENTS

Consent to participate in research must be given voluntarily and can be withdrawn at any point. Consent should be understood as a process, rather than an event. As such, consideration should be given to how initial consent will be obtained and how it will be ensured throughout the study.

The purpose of the consent process is to ensure prospective participants have full disclosure of the information necessary for making an informed decision whether to participate in the project. Researchers should be mindful of the need to balance the disclosure of necessary information about the study with the need to convey this information in a clear, comprehensible way.

Any consent materials should be written with the intended audience in mind. Informed consent documents should avoid confusing jargon, and should be written at a Grade 7 reading level. If the participant population includes individuals who require special assistance (e.g., translation for participants who do not speak English), the measures taken to provide this assistance should be detailed in the protocol/proposal.

Participants should be provided with a copy of all consent forms and/or other consent materials as applicable.

1.1 Who Can Obtain Consent?

Researchers are responsible for ensuring potential participants have sufficient information to decide whether to participate, and that the consent process is free from any coercion or undue influence. As such, the person obtaining consent should be sufficiently knowledgeable about the study to answer any questions the potential participant might have about the research.

1.2 Undue Influence

Undue influence may occur when participants are recruited and/or consented by a person in a position of authority over them, e.g., direct care provider and patient, employer and employee, etc.

Researchers should give consideration to elements of trust and dependency in the relationships and potential impacts on the voluntariness of participant from the perspective of the potential participant.

Any potential undue influence in the consent process should be addressed by the researcher, including a justification for why it is unavoidable and how it will be mitigated.

1.3 Time to Consent

Sufficient time must be given for the participant to decide whether or not to consent to the study. If participants cannot be provided with at minimum twenty-four hours to decide, a justification for a shorter decision period should be provided.

1.4 When Should Consent Be Obtained?

Generally, initial consent must be obtained prior to the initiation of study procedures or collection of data (refer to Guidance Note #7 Waivers of Consent for exceptions to this requirement).

Consideration should be given to the circumstances and location of the consent process. For instance, will potential participants be consented in a private location? Will they be approached at a time when they may be emotionally vulnerable, such as immediately after a major diagnosis?

In most studies, consent should be obtained after a face-to-face discussion with the Principal Investigator or designate, in which the potential participant has the opportunity to ask questions. If a face-to-face conversation is not feasible, this should be justified in the submission.

GUIDANCE NOTE #2: REQUIRED INFORMATION FOR REB REVIEW

Protocols/proposals submitted to the REB should include a detailed description of how free and informed consent will be ensured and documented throughout the study, including who will explain the consent process to the participant.

All documents related to the consent process should be submitted to the FHREB for review, including (as applicable):

1. Consent forms
2. Assent forms
3. Scripts for verbal consent/assent
4. Translated versions of consent/assent forms (these may be submitted to the REB as an acknowledgment request along with the translator's certificate of authenticity following the initial REB approval)

All documents must be clearly labelled with a version number and date. For specific guidance on the required content of consent and assent forms, please refer to the consent form templates on the FHREB website.

GUIDANCE NOTE #3: DOCUMENTATION OF CONSENT

Article 3.12 of the TCPS 2 requires that evidence of consent be documented either in a written signed consent form or by other means. In some instances, such as Health Canada regulated clinical trials, written consent may mandatory. In other situations, a written and signed consent process may be inappropriate. Researchers should be aware of cultural preferences, power relationships, and other circumstances that may impact the appropriateness of how consent is obtained and documented.

Where appropriate, researchers may use a range of consent procedures, such as oral consent, field notes, or other strategies. In these instances, the researcher should provide the REB with a detailed description of and rationale for the process. The verbal script that will be used to convey the required information as well as any handouts or other consent documents should also be submitted for review.

3.1 Implied Consent for Anonymous Questionnaires

Studies exclusively using questionnaires completed anonymously by participants do not require signed consent forms, as the act of completing and returning the questionnaires to the researcher can be taken as implied consent. However, the introductory letter to the questionnaire must include wording that explains the implied consent procedure.

3.2 Electronic Consent

Electronic informed consent, sometimes referred to as “e-consent” involves the use of electronic or technological systems and processes instead of, or in supplement to, traditional paper informed consent forms. E-consent can include the use of electronic media such as videos to convey key information as well as the use of electronic signatures like DocuSign in lieu of wet ink signatures. The e-consent must include all the required elements of informed consent as required by the TCPS 2 and other applicable regulations.

Researchers should carefully consider the equity issues specific to their study population when adopting e-consent procedures. E-consent may potentially increase accessibility and comprehension for participants through user-friendly and interactive features. However, it can potentially lead to exclusion when certain participants do not have access to the modalities for e-consent or have low e-literacy. Where possible, researchers should offer prospective participants the option of paper-based or electronic informed consent forms.

When using e-consent procedures researchers must provide the REB with a copy of the consent document and include the following information in the application:

- The technology and platforms that will be used,
- Will the consent process be in person or remote?
- How will capacity to consent/assent be determined?

- How will the participant receive a copy of their consent form (i.e. electronic or paper?) and will the consent include their signature?
- An explanation of how the privacy and confidentiality of participants will be protected, and whether any personal information (e.g., email or IP addresses) will be collected,
- How the consent documents will be stored?
- Where e-signatures are used, how they will be validated and ensured to be legitimate?

3.2.1 Regulated Clinical Trials:
The use of e-consent in regulated clinical trials is subject to more stringent requirements. E-consent procedures should have the following:

- Contain an audit trail,
- Feature a validated signature authentication component,
- Control for access and passwords,
- Be remotely or directly accessible for audit, monitoring, and inspection.

3.3 Witness Signature Requirements

Witness signatures on consent forms are generally not required except in circumstances where the participant is unable to read the informed consent form and/or where the information in the informed consent form is orally conveyed to the participant. In such cases, an impartial witness is also required to sign the consent form to attest the information was accurately explained to the participant.

GUIDANCE NOTE #4: FORMATTING GUIDELINES

Consent documents should be double-spaced and written in minimum 12 point font. All consent documents should include the following:

1. The Fraser Health logo
2. Version number and date
3. Page numbers

Signature pages should begin after a page break and include the study titles. The signature lines for the participant and PI/designate should be on a single page.

For longer consent forms, section sub-headers are strongly encouraged.

For specific content and formatting requirements, refer to the consent form templates.

GUIDANCE NOTE #5: NEGATIVE CONSENT/CHECK BOXES

The use of Yes/No check boxes for consent to participate in a study is not permitted. The lack of a signature on consent form must be taken of evidence of dissent. Check boxes may be permitted in instances where there are multiple optional sub-components to a study in which the participant can indicate a desire to participate.

GUIDANCE NOTE #6: ONGOING CONSENT

While signed consent forms provide documentation of initial consent, the researcher is responsible for ensuring ongoing consent throughout the study, through both tacit and formal mechanisms.

When new study procedures are introduced via amendment, researchers should consider how they will re-consent participants. If re-consent will not be sought, a justification should be provided to the REB.

GUIDANCE NOTE #7: ALTERATIONS/WAIVERS OF CONSENT

In some circumstances, an alteration of the standard consent procedures (i.e., partial disclosure/deception or an exception to requirement to seek prior consent) may be permissible. Studies requesting an alteration of consent must meet a rigorous set of criteria outlined in the TCPS 2, including providing a debriefing plan for participants. Alterations to consent will only be approved to the extent necessary.

7.1 Alterations of Consent for Minimal Risk Research

A waiver or alternation of consent may be granted for minimal risk research if the following criteria are satisfied:

a) the research involves no more than minimal risk to the participants;

b) the alteration to consent requirements is unlikely to adversely affect the welfare of participants;

c) it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;

d) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and

e) the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

Researchers are responsible for demonstrating to the REB how the study meets all of the above criteria. Particular attention should be paid to the TCPS 2 definition of impracticable: "Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience."

Debriefing following an alteration of normal consent procedures is important in maintaining the participant's trust in the research community. Debriefing plans should be tailored by the researcher to the specific participant population, and give details about the importance of the research, the reason for the alteration to consent requirements, and answer any questions or concerns raised by the participants. Debriefing should take place at a time when it is still possible for participants to withdraw their data or biological materials, should they choose to do so. The debriefing plan must be presented to the REB for review at the time of the request for a waiver or alteration to consent requirements.

Researchers seeking a waiver or alteration of consent for minimal risk research are strongly encouraged to review articles 3.7A and 3.7B of the TCPS 2.

7.2 Consent for Research in Individual Medical Emergencies

When individuals are unable to provide consent for research due to a medical emergency, a legally authorized substitute decision maker may provide consent on the participant's behalf. In some circumstances, it may not be possible to seek substitute decision maker consent prior to enrolling the participant in the study. In such circumstances, a waiver of consent may be approved if the following criteria are satisfied:

a) A serious threat to the prospective participant requires immediate intervention.

b) Either no standard efficacious care exists, or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care.

c) Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant.

d) The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project.

e) Third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so.

f) No relevant prior directive by the participant is known to exist.

Researchers are responsible for demonstrating to the REB how the study meets all of the above criteria. Researchers requesting a waiver of consent for individual medical emergencies are strongly encouraged to review article 3.8 of the TCPS 2.

Requests for waivers of consent for individual medical emergencies should also include a plan for obtaining consent from the participant once capacity is regained as well as from a substitute decision maker as soon as possible after enrollment.

GUIDANCE NOTE #8: CONSENT AND SECONDARY USE OF INFORMATION

As stated in the TCPS 2, secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. For example, chart review studies that access medical records.

While there are numerous reasons to conduct secondary analyses of existing data, such as avoiding duplication in primary collection and associated reduction of burdens on participant, or applications of new tests of hypotheses that were not available at the time of original data collection, the use of secondary identifiable information represents significant privacy and confidentiality concerns. Researchers who wish to use identifiable information without consent must satisfy the following criteria:

a) identifiable information is essential to the research;

b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;

d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;

e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and

f) the researchers have obtained any other necessary permission for secondary use of information for research purposes

Researchers are responsible for demonstrating to the REB how the study meets all of the above criteria. If the criteria are not satisfied, consent for the use of this information will be required. Researchers requesting the use of secondary identifiable information without consent are strongly encouraged to review article 5.5A of the TCPS 2.

In addition to the TCPS 2 requirements, relevant privacy laws and/or regulations must also be satisfied. The researcher is responsible for being aware of the privacy laws/regulations governing the release of the information for a research purpose.

Researchers should be aware that while the REB may ethically approve a study using secondary information, the data steward/custodian of that information may have other approval processes that must be satisfied before the information can be released. Researchers are responsible for being aware of these other approvals.

GUIDANCE NOTE #9: WITHDRAWAL OF CONSENT

The option of withdrawing consent at any time and without suffering any disadvantage or reprisal is a fundamental component of voluntary and ongoing consent. The consent process should explain to participants that they may with withdraw their consent at any time, and describe any circumstances that do not allow withdrawal or data or human biological materials once collected.

In some circumstances, such as clinical trials regulated by Health Canada or studies collecting data anonymously, the withdrawal of data may not be possible. Researchers must provide a rationale to the REB for using data collection methods that do not permit subsequent withdrawal of data.

In studies where there are multiple procedures or time points for data collection, researchers should ensure participants are aware they may request the withdrawal of data and/or biological materials already collected (if applicable). Mandatory retention of data after withdrawal is generally not permitted with the exception of regulated clinical trials. In circumstances where participants are choosing to withdraw from future participation in the study but are not requesting the destruction of data/biological materials collected until that point, researchers should have a plan to document the consent to retain such data/biological materials.

Participants cannot be required to submit a request for withdrawal in writing only. The option to withdraw verbally must be presented. For clinical trials, researchers must provide participants who withdraw an explanation of follow-up care options.

In studies where incentives or honoraria are provided to participants, such incentives or honoraria should not be withheld. If the study uses a lump-sum incentive for participation, the withdrawing participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation. Studies offer participants entry into a prize draw as a form of incentive must allow participants who have withdrawn to enter. Prize draws that use study completion as a qualifier for entry are considered lotteries and are illegal in British Columbia without a license.

GUIDANCE NOTE #10: OPTIONAL SUB-STUDIES

Optional sub-studies should only be embedded within the main study consent form if the risks and procedures are not substantively different from those in the main study. Otherwise, a separate consent form for optional consents should be used. Examples of optional sub-studies that are appropriate for inclusion in a main consent include additional questionnaires for optional

cost-effectiveness studies, or additional collection of blood (for purposes other than genetic testing or tissue banking) when blood samples are already being taken for the main study.

Separate consent forms should be used for sub-studies that include genetic and DNA testing, tissue and blood banking studies, pharmacokinetic studies, use of individual data, records, or personally identifying information in another study, and analysis of secondary data from linked databases.

The consent form must clearly indicate which procedures are optional and that participation in the main study is not contingent on participation in the optional studies. The section on withdrawal should also explain what will happen to the data collected in optional studies. All required information for free and informed consent, such as the confidentiality provisions and the right to withdraw, must be included in the optional consent form. It is not permitted to refer back to the main consent form.

10.1 OPEN LABEL EXTENSION STUDIES

If a study protocol includes a provision/plan for an open-label extension study, the main consent form should mention that the participant might be offered an opportunity to participate in another longer-term study after this initial study is finished.

An entirely separate informed consent process must be administered at the time of enrolment into the extension study, using a specific consent form dedicated to the extension study.

When necessary, the consent form for the open-label extension study may be submitted as an amendment.

10.2 MANDATORY TISSUE BANKING

Mandatory tissue banking for potentially therapeutic research trials where such banking of samples is not necessary to answer the primary research question is not permitted. Consent forms for optional tissue banking for future unspecified research or research unrelated to the study for which consent was obtained are permissible, but participation in the main trial cannot be contingent upon such banking.

GUIDANCE NOTE #11: REMOTE CONSENT

Remote consent refers to the process of obtaining informed consent in which the prospective participant and researcher are not physically located in the same space. This can include e-consent processes, and/or conducting the consent process over the phone, or virtual conferencing platforms like Zoom or Teams. It also applies to circumstances where the consent form is mailed or emailed to participants. Researchers should carefully consider the nature of

the study and the population when adopting remote consent procedures. The appropriateness of remote consent procedures varies across study types and populations.

Regardless of the method of remote consent, participants must have the opportunity to discuss the study and ask questions about their prospective participation with a knowledgeable member of the research team. Where possible, researchers should provide a copy of the consent form to the participant in advance Researchers should also ensure mechanisms are in place to enable ongoing consent and notify participants of any significant changes or new findings.

It is essential that the remote consent procedures include a method for verifying the identity of the individual and ensuring the person signing the consent is the participant (or legally authorized representative where appropriate). In cases where email will be used to send and received informed consent forms, researchers should ensure there is permission from the participant to contact them via email.

11.1 MAILED CONSENT FORMS

In cases where a signed consent form will be returned by the research participant to the study team via mail, the participants must be provided with a pre-addressed envelope with postage pre-paid.