General statement

Voluntary and informed consent from legally competent individuals or authorized third parties is a fundamental principle in research involving humans (TCPS 2 Chapter 3). However, there are some research questions that cannot be answered without an alteration to these consent requirements. Under specified circumstances, given a satisfactory rationale by the researcher, an REB may approve the waiver of a consent requirement, or a partial waiver of some elements of a consent requirement.

This guidance document discusses:

- Alteration or Waivers of Consent
- Alteration or Waivers of Consent for the Use of Identifiable Secondary Information

Alteration or Waiver of Consent - Criteria

The REB may approve research that involves an alteration to the requirements for consent set out in TCPS 2 Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply:

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) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with TCPS 2 Article 3.7B.

Alteration or Waiver of Consent - Factors to Consider Within Each Criteria

Alteration or waiver of consent - factors to consider:
a. the research involves no more than minimal risk to the participants;

The research should present minimal risk of harm to individuals and, if appropriate, particular groups or communities. Harm is anything that has a negative effect on the welfare of the participants.

The level of risk is dependent on the participants, their capacity to provide free and informed consent and the nature of the intervention or activity being studied and the information to be collected.

Assessment of Risk

Alteration or waiver of consent - factors to consider:

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

Minimal risk research
Minimal risk research is research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Types of risk include (not an inclusive list):

- Physical risk: Risk of harm through bodily contact or administration of any substance, device or other intervention
- Psychological or emotional harm: Risks of harm due to feeling embarrassed, uncomfortable, anxious or upset
- Social Risk: Risk of harm due to loss of status, privacy, or reputation, and includes legal, financial or employment risk.

Vulnerability
In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (see Article 4.7). Vulnerability exists along a continuum and is influenced by many factors. The presence of these factors (including but not limited to those listed below) in combination with the research design can influence the level of risk and ultimately the designation of risk for the research study:

- Participant capacity (mental, emotional, cognitive)
- Age
- Wellness or health status
- Institutionalization
- Power relationships
- Gender and gender identity
- Setting and recruitment
- Dependency
- Socio-economic status

Assessment of Harm

Risk of harm is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties. A proper ethical analysis of research should consider both the foreseeable risk of harm and the available methods of eliminating or mitigating it. The magnitude or seriousness of the harm

- Potential harms in research may span the spectrum from minimal (e.g., inconvenience of participation in research) to substantial (e.g., a major physical injury or an emotional

Alteration or waiver of consent - factors to consider:

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

trauma). Harms may be transient, such as a temporary emotional reaction to a survey question, while other types of harm may be longer lasting, such as the loss of reputation following a breach of confidentiality, or a traumatic experience. The perspective of the participants regarding harm may vary from that of researchers. Participants themselves may vary in their reaction to the research. Researchers and REBs should attempt to assess the harm from the perspective of the participants to the extent possible. Research in certain disciplines, such as epidemiology, genetics, sociology or cultural anthropology, may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.

The probability of occurrence of the harm

- This refers to the likelihood of participants actually suffering the relevant harms. An assessment of such probability may be based on the researcher's past experience conducting such studies, the review of existing publications that provide rates of the relevant harms in similar issues, or on other empirical evidence. And while researchers should attempt to estimate the occurrence of the relevant harms, this may be more difficult, or not possible, for new or emerging areas of research where no prior experience, comparable research or publications exist.

The analysis, balance, and distribution of risks and potential benefits are critical to the ethics of research involving humans. In their review, REBs should be concerned with an assessment that the potential research outcomes and potential benefits merit the risks. In assessing risks and potential benefits for specific populations, researchers and REBs should understand the role of the culture, values and beliefs of the populations to be studied.

Examples of minimal risk studies:

- Studies using previously collected / existing clinical data, medical records
- Studies that involve only questionnaires or surveys (non-clinical, not a vulnerable population, not collecting sensitive information)
- Low risk exercise studies using healthy volunteers
- Studies that involve clinical data collected prospectively as part of standard clinical care

Alteration or waiver of consent - factors to consider:

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

The alteration to the consent requirements must be unlikely to adversely affect participants'

Alteration or waiver of consent - factors to consider:

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

welfare.

According to TCPS 2 Chapter 3, Respect for Persons implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible. The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.

Alterations to consent should be permitted only to the extent necessary. If the aims of the research can be achieved with a design that allows for full – or fuller – prior disclosure, then that design must be adopted.

REBs must consider whether it is in the participants' best interests to be informed of the research (and to what extent) if not before, then afterwards. Debriefing must be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate.

If the research design calls for no prior consent and no debriefing, then the participants may never know of their involvement. This raises ethical issues that differ somewhat from other alterations to consent requirements as these participants will have no opportunity to ask questions about the nature and purpose of the study or to request the withdrawal of their data and/or human biological materials (where possible, practicable and appropriate). In light of these issues, the REB should apply greater scrutiny to the justification for an exception to the requirement to seek prior consent and an exception to the requirement to debrief once the research is complete.

Examples of when an alteration or waiver of consent is unlikely to affect the welfare of participants:

- A study of the effect of environmental toxins on the members of nearby communities that involves the analysis of the level of toxins present in discarded hair clippings from the barber shops of these communities.
- Studies involving the administration of online or mailed surveys, telephone interviews (can use implied consent)
- Retrospective chart review for the development of a de-identified database where every effort is made to assure privacy and confidentiality are protected.

Alteration or waiver of consent - factors to consider:

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

An example of when it may be **impossible** to carry out the research if the prior consent of participants is required is Emergency research. This is because it is simply impossible to ask (temporarily) incapacitated patients for informed consent. Please see TCPS 2 Chapter 3 Article 3.8 for more information about Research in Individual Medical Emergencies.

Seeking consent from individuals for the use of their personal data may be considered **impracticable** when there are difficulties in contacting or notifying individuals for reasons such as:

- the size of the population being researched;
- the proportion of prospective participants likely to have relocated or died since the time the personal information was originally collected; or
- the lack of an existing or continuing relationship between prospective participants and the data holder who would need to contact them (e.g. a patient database that does not have a regular follow-up program to maintain a complete and accurate record of changes in registrants' contact information over time);

such that:

- there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent, thereby affecting the validity of results and/or defeating the purpose of the study; or
- the additional financial, material, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done.

Alteration or waiver of consent - factors to consider:

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

The nature and extent of how the consent process will be altered must be clearly explained in enough detail to allow the REB to evaluate and make an informed decision as per TCPS 2 Chapter 3 Article 3.7A (Alterations to Consent Requirements) and Chapter 3 Article 3.7B (Debriefing in the Context of Alterations to Consent Requirements).

Alteration or waiver of consent - factors to consider:

e. the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with TCPS 2 Article 3.7B

Debriefing must be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate (TCPS 2 Chapter 3 Article 3.7B).

In studies in which a waiver of prior consent has been allowed, it may still be possible for participants to express their consent or refusal at the conclusion of the study, following debriefing. In cases where a participant expresses concerns about participation in a study, the researcher may give the participant the option of removing his or her data from the project. Researchers should be required, as part of their research proposal, to set out the conditions under which they would not be able to remove a participant's data from the study even if the participant requested such a withdrawal, and justify why these conditions are essential for conducting the research. Where under the terms of the research proposal the participants are not permitted to withdraw their data, the identity of the participant shall be protected. Participants who express concern about the conduct of the study at the time of debriefing or who contest the limits imposed on withdrawing their data should be given contact information for the REB that approved the research.

There may be circumstances in which debriefing is impossible, impracticable or inappropriate in research involving alterations to consent requirements. When considering whether to grant an exception to the requirement to debrief, REBs should consider the level of potential harm to the participant which the debriefing itself may cause and the impact of the debriefing on the feasibility of the research. When seeking an exception to the requirement to debrief, researchers must also provide a plan to disseminate information about the study to participants and/or their communities (e.g., through local media, direct mail). This plan is of particular importance when the findings may affect participant welfare.

Waiver of Consent and the Use of Identifiable Secondary Information Criteria

The TCPS 2, Chapter 5, Section D, Article 5.5A, sets out the criteria that must be met in order for a researcher to be approved to use secondary data without obtaining consent from the participants.

Secondary use refers to when researchers use information originally collected for a purpose other than the current research purpose (e.g. program evaluation, health care chart). TCPS 2 Chapter 5 Article 5.5 states that researchers are not required to seek consent from individuals for the secondary use of non-identifiable information. However, researchers who seek a waiver of consent for secondary use of identifiable information in research shall satisfy the REB that:

a. identifiable information is essential to the research;
b. the waiver 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 uses of their information;
e. it is impossible or impracticable to seek consent from individuals to whom the information relates;
f. the researchers have obtained any other necessary (e.g. legal) permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

Waiver of Consent and the Use of Identifiable Secondary Information Factors to Consider Within Each criteria

Waiver of Consent: Identifiable Secondary Information – factors to consider **a. identifiable information is essential to the research;**
Researchers must provide a detailed rationale explaining how personal data, in the proposed amount and at the proposed level of identifiability and sensitivity, are necessary to fulfill the research objectives

Waiver of Consent: Identifiable Secondary Information – factors to consider **b. the waiver is unlikely to adversely affect the welfare of individuals to whom the information relates;**
In assessing potential harm, REBs should consider: • the probability of harm (related to the identifiability of data and the adequacy of security measures), and

- the magnitude of potential harm (related to the sensitivity of data), including potential:
  - physical injury;
  - emotional or psychological harm;
  - social harm (e.g. stigmatization);
  - financial harm (e.g. insurability, employability);
  - loss of trust;
  - harm from a perceived invasion of privacy, such as when a researcher has made secondary use of existing records with an REB waiver of the consent requirement, and then proposes to contact individuals for additional data collection; or
  - negative impact of the findings of the research.

For more information see previous section *Alteration or Waiver of Consent:* (a) related to Risk

Waiver of Consent: Identifiable Secondary Information – factors to consider

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

Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal (see TCPS 2 Chapter 5)

Waiver of Consent: Identifiable Secondary Information – factors to consider

d. the researchers will comply with any known preferences previously expressed by individuals about uses of their information

For example, stated in an advanced careplan, expressly indicated to the treating physician by the patient, research team is contacted by a patient, refusal by research participant to be part of optional or add-on study, etc.

Waiver of Consent: Identifiable Secondary Information – factors to consider

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

“Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

For more information see previous section *Alteration or Waiver of Consent* c) related to impossibility and impracticability of consent

Waiver of Consent: Identifiable Secondary Information – factors to consider

f. the researchers have obtained any other necessary (e.g. legal) permission for secondary use of information for research purposes

In addition to REB approval, access to personal data for research without consent may be subject to specific legal requirements in relevant jurisdictions.

For example, some jurisdictions require some or all of the following:

- a data-sharing agreement between the data holder and the researcher;
- notification and/or approval by other relevant oversight bodies; and/or
- agreement that personal data will not be used to contact individuals.

Secondary Use of Anonymous Data is Exempt from REB Review

- TCPS2 article 2.4 specifies that "REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information."
- TCPS2 chapter 5 clarifies that anonymous information "never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low."
- **Anonymized, coded, or de-identified information is not anonymous.**

Types of Information (TCPS 2 Chapter 5)

- Identifying information: The information identifies a specific research participant through direct identifiers (e.g., name, address, social insurance number or personal health number).
- Identifiable information: The information could be used to re-identify a participant through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic) using reasonably foreseeable means.
- De-identified/coded information: Identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific research participants (e.g., participants are assigned a code name and the principal investigator retains a list that links the code name with the participant's actual name so data can be re-linked if necessary.) Researchers who have access to the code and the data have identifiable information.
- Anonymized information: Information is irrevocably stripped of identifiers, and a code is not kept to allow future re-linkage.
- Anonymous information: Information never had identifiers associated with it (e.g., anonymous surveys).

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