

**Table of Concordance**  
***Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans***

**TCPS2 (2014) - TCPS2 (2010)**

This table is intended to facilitate a comparison between the latest edition (TCPS2 2014) of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, released in December 2014, and the previous edition (TCPS2 2010) of the Policy.

In this table, excerpts are presented that highlight the changes made to the latest edition.

| TCPS2 2010                                    | TCPS2 2014                                    | Excerpt  |
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| Chapter 2, Article 2.1, Application (page 15) | Chapter 2, Article 2.1, Application (page 13) | <b>TCPS2 2014 Addition of the following to define disciplined inquiry.</b> “The term “disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community. For example, a study seeking to explore the narratives of teens coping with mental illness would be evaluated by the established standards of studies employing similar methods, technologies and/or theoretical frameworks.”  |
| Chapter 2, Article 2.1, Application (page 16) | Chapter 2, Article 2.1, Application (page 14) | <b>TCPS2 2014 Addition of the following to clarify factors that determine whether an activity is research requiring REB review.</b> “In some cases it can be difficult to make this distinction, underscoring the need to have reviewers or ad hoc advisors (see <a href="#">Article 6.4</a> and <a href="#">Article 6.5</a> ) who can assist with this determination. It is important to note that choice of methodology and/or intent or ability to publish findings are not factors that determine whether or not an activity is research requiring ethics review.” |
| Chapter 2, Article 2.1,                       | Chapter 2, Article 2.1,                       | <b>TCPS2 2014 Rephrased Paragraph.</b> “Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to   |

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| Application (page 16)                            | Application (page 15)                             | determine whether the information or data proposed in research may reasonably be expected to identify an individual. For the purposes of this Policy, researchers and REBs shall consider whether information is identifiable or non-identifiable. Information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available information. Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information. The term “personal information” generally denotes identifiable information about an individual. The assessment of whether information is identifiable is made in the context of a specific research project. Guidance on the assessment of the potential for information to identify an individual is addressed in this Policy in <a href="#">Chapter 5, Section A.</a> “   |
| Chapter 3 Introduction (page 27)                 | Chapter 3 Introduction (page 25)                  | <b>TCPS2 2014 Rephrased Paragraph included more information about alterations of consent process.</b> “Certain types of research require alternate processes for seeking consent. These are also described in this chapter. Researchers may request an alteration to consent requirements if they can meet the criteria of <a href="#">Article 3.7A</a> . These include a requirement to satisfy the REB that it is impossible, impracticable or inappropriate (see <a href="#">Glossary</a> ) to address the research question without the requested alteration. Where elements of the consent process may need to be adapted to the requirements of a particular research project, the research ethics board (REB) can play an educational and consultative role in determining the appropriate process for seeking and maintaining consent. REBs must consider whether the requested alterations are justified or whether another approach would make it possible, practicable and appropriate to follow the normal consent requirements.” |
| Chapter 3, Article 3.1 Application (c) (page 30) | Chapter 3, Article 3.1, Application (c) (page 28) | <b>TCPS2 2014 Rephrased Paragraph to clarify that the option to withdraw information is required unless adequate justification for limiting or removing this option is provided.</b> “The consent process should set out any circumstances that do not allow withdrawal of data or human biological materials once collected. In some research projects, the withdrawal of data or human biological materials may not be feasible (e.g., when personal information has been anonymized and added to a data pool). Researchers must provide a rationale to the REB for using collection methods that do not permit subsequent withdrawal of data or human  |

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|   |   | biological materials. Where the terms of the research do not allow for withdrawal of their data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion. Participants shall also be informed that it is difficult, if not impossible, to withdraw results once they have been published or otherwise disseminated.”   |
| Chapter 3, Article 3.2, Application – paragraph (d) (page 32) | Chapter 3, Article 3.2, Application – paragraph (d) (page 30) | <b>TCPS2 2014 Rephrased Paragraph.</b> “Paragraph (d) helps to ensure the effectiveness of <a href="#">Article 3.1</a> – that a prospective participant’s choice to participate is voluntary. Paragraph (d) also supports the requirement that the consent process continue throughout the research. The consent process should set out any circumstances that do not allow withdrawal of data or human biological materials once collected (see <a href="#">Article 3.1(c)</a> ).”   |
| Chapter 3, Article 3.3, Application (page 34)                 | Chapter 3, Article 3.3 Application (page 32)                  | <b>TCPS2 2014 Replaced last paragraph in Application with the following to clarify that consent is based on decision-making capacity and not chronological age.</b> “Rather than an age-based approach to consent, TCPS2 advocates an approach based on decision-making capacity as long as it does not conflict with any laws governing research participation. Some children begin participation in a project on the basis of consent from an authorized third party (due to the determination that they lacked capacity to decide on their own behalf) and on the basis of their own assent (see <a href="#">Article 3.10</a> ). In these cases, if the children mature sufficiently to decide on their own behalf (subject to legal requirements), the researcher must seek the children's autonomous consent in order for their participation to continue. Similarly, in the case of children who are unable to assent to research participation (e.g., infants) at the beginning of a project, the researcher must seek their assent to continue their participation once they are able to understand the purpose of the research as well as its risks and benefits.” |
| Chapter 3, Article 3.4 (page 34)                              | Chapter 3, Article 3.4 (page 32)                              | <b>TCPS2 2014 Rephrased this section and Application discussion to introduce exceptions to the obligation to disclose material incidental finding.</b><br><br><b>Incidental Findings</b><br>“Incidental findings” is a term that describes unanticipated discoveries made in the course of  |

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|  | <p>research but that are outside the scope of the research. Incidental findings are considered to be material incidental findings if they have been interpreted as having significant welfare implications for the participant. Material incidental findings may appear at any stage of the research. This may include, for example, while screening for eligibility for inclusion in a study or while collecting baseline information, both of which may involve the prospective participants' consent.</p> <p>If researchers are unsure of how to interpret findings or are uncertain whether findings are material, they should consult with their colleagues and/or refer to standards in the discipline. Researchers should exercise caution in disclosing incidental findings that may cause needless concern to participants such as participant anxiety, unnecessary costs and burdens of follow-up; or may affect eligibility for employment or insurance.</p> <p><b>Article 3.4</b><br/> Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.</p> <p><b>Application</b><br/> In some areas of research, such as medical and genetic research, there is a greater likelihood of material incidental findings. When material incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants, and submit this plan to the REB. If there is uncertainty as to whether a research project warrants such a plan, researchers and REBs can make this determination on a case-by-case basis. When necessary, researchers should direct participants to a qualified professional to discuss the possible implications of the incidental findings for their welfare. In some cases, incidental findings may trigger legal reporting obligations and researchers should be aware of these obligations (see <a href="#">Article 5.1</a>).</p> <p>A researcher may request an exception to the obligation to disclose material incidental findings, based on the impracticability or impossibility of disclosing such findings to the</p> |
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|                                  |                                  | <p>participant. “Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Disclosure may be impossible or impracticable (see <a href="#">Glossary</a>) when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. The onus is on the researcher to justify to the REB the need for the exception. REBs should decide whether exceptions apply on a case-by-case basis.”</p>  |
| Chapter 3, Article 3.6 (page 35) | Chapter 3, Article 3.6 (page 33) | <p><b>TCPS2 2014</b> specifies that <b>critical inquiry</b> does not require permission from an institution, organization or other group in order to conduct research on them</p>   |
| Chapter 3, Part B (page 37)      | Chapter 3, Part B (page 35)      | <p><b>TCPS2 2014 Addition of the following.</b> “<a href="#">Articles 3.1 to 3.5</a> set out the default requirements for seeking the consent of individuals to participate in research. However, there are some research questions that cannot be answered without an alteration to these consent requirements. For example, the question of what factors influence whether people will choose to return a wallet dropped by someone on the street could not be answered if the prospective participants were alerted to the presence of the researcher observing them and to the presence of the confederate dropping the wallet in front of them. Alterations to consent requirements may include providing prospective participants with only partial disclosure about the purpose of the study, deceiving prospective participants entirely about the purpose of the study, and not informing participants that they (or their data or biological materials) are involved in a study.</p> <p><a href="#">Article 3.7A</a> sets out the conditions which a researcher must satisfy in order for an REB to approve research involving any alteration to consent requirements. The lack of prior consent, or of fully informed consent, may be addressed through debriefing conducted as soon as possible following participants’ involvement in the research, and within a timeframe that allows participants to withdraw their data or human biological materials (where possible, practicable and appropriate [see <a href="#">Glossary</a>]). <a href="#">Article 3.7B</a> provides guidance with respect to debriefing in the context of an alteration to consent requirements.”</p> |

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| <p>Chapter 3<br/>Article 3.7 &amp;<br/>Application<br/>(page 37-39)</p> | <p>Chapter 3,<br/>Article 3.7A<br/>and Article<br/>3.7 B &amp; their<br/>Applications<br/>(page 36-40)</p> | <p><b>TCPS2 2014 Divided into two articles and clarifications were made to the range of alterations to consent and guidance regarding debriefing in the context of alterations.</b></p> <p><b>Article 3.7A</b><br/>The REB may approve research that involves an alteration to the requirements for consent set out in <a href="#">Articles 3.1</a> to <a href="#">3.5</a> if the REB is satisfied, and documents, that all of the following apply:</p> <ul style="list-style-type: none"> <li>a the research involves no more than minimal risk to the participants;</li> <li>b the alteration to consent requirements is unlikely to adversely affect the welfare of participants;</li> <li>c it is impossible or impracticable (see <a href="#">Glossary</a>) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;</li> <li>d in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and</li> <li>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 <a href="#">Article 3.7B</a>.</li> </ul> <p><b>Application</b><br/>In the circumstances described under <a href="#">Article 3.7A</a>, the nature of the research may justify some alteration(s) to consent requirements if the potential benefits outweigh the foreseeable risks. As stated in paragraphs (a) and (b), the risks to participants must fall within the definition of no more than minimal risk (<a href="#">Chapter 2, Section B</a>) and the alteration to the requirements must be unlikely to adversely affect participants' welfare. The potential benefits to be considered include benefits to the participants themselves, to the group they represent and/or to society more generally. Note that in paragraph (c) "impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience (see <a href="#">Glossary</a>). Researchers must clearly describe the nature and extent of the proposed alteration(s) (paragraph d) and their plans with respect to debriefing participants, in accordance with <a href="#">Article 3.7B (paragraph e)</a>. It is the responsibility of researchers to justify</p> |
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|  | <p>the need for any alteration to consent requirements to the satisfaction of their REB(s).</p> <p>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 (in accordance with <a href="#">Articles 3.1 to 3.5</a>), then that design must be adopted. It is the responsibility of REBs, however, to understand that certain research methods necessitate a different approach to consent, and to exercise judgment on whether the need for the research justifies any alterations to consent requirements. In determining whether to allow any alterations to consent requirements, REBs must consider both the proposed alterations and the proposed plan for debriefing or justification for not debriefing. In other words, the guidance in <a href="#">Articles 3.7A and 3.7B</a> must be considered together in determining whether an alteration to consent requirements is ethically acceptable.</p> <p>It should be noted that in some cases of randomization and blinding in clinical trials, neither the participants nor the researchers know which treatment the participant will be receiving. As long as participants are informed of the probability of their assignment to each arm of the trial, this random and blind assignment does not constitute an alteration to consent requirements.</p> <p><i>Research Involving Partial Disclosure or Deception</i></p> <p>Some social science research, particularly in psychology, seeks to learn about human responses to situations that have been created experimentally. Some types of research can be carried out only if the participants do not know the true purpose of the research in advance. For example, some social science research that critically probes the inner workings of publicly accountable institutions might never be conducted without the limited use of partial disclosure. In some research that uses partial disclosure or deception, participants may be asked to perform a task and informed about only one of several elements the researchers are observing. Research employing deception can involve a number of techniques, such as giving participants false information about themselves, events, social conditions and/or the purpose of the research. For such techniques to fall within the exception to the general requirement of</p> |
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|  | <p>full disclosure for consent, the research must meet all of the requirements of <a href="#">Article 3.7A</a>.</p> <p><i>Exception to the Requirement to Seek Prior Consent</i></p> <p>In the circumstances described under <a href="#">Article 3.7A</a>, an REB may allow an exception to the requirement that researchers seek consent from participants prior to collection of data and/or human biological materials. Researchers must demonstrate that this alteration to consent requirements is necessary to address the research question and that the lack of prior consent will not have an adverse impact on the welfare of participants. They must also demonstrate that the benefits of the research, whether direct, indirect or societal, justify any risks associated with no prior consent. For example, a study of the effect of environmental toxins on the members of nearby communities may involve the analysis of the level of toxins present in discarded hair clippings from the barber shops of these communities. The researchers may make the case that the collection and analysis of the hair clippings pose no risks to participants, that seeking prior consent for the use of the hair clippings could lead to a general panic about environmental toxins among the members of these communities, and that the possible benefits of identifying environmental toxins so that they can be removed, justify this approach to the research question.</p> <p>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 (see <a href="#">Article 3.7B</a>). 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 [see Glossary]). In light of these issues, the REB should apply greater scrutiny (see <a href="#">Article 2.9</a>) to the justification for an exception to the requirement to seek prior consent and an exception to the requirement to debrief (see <a href="#">Article 3.7B</a>).</p> <p>Note that <a href="#">Article 3.7A</a> does not address the exception to the requirement to seek consent for</p> |
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|  | <p>secondary use of identifiable information; this topic is addressed in <a href="#">Article 5.5A</a>.</p> <p><i>Participants in Vulnerable Circumstances</i><br/> In considering the need for an alteration to consent requirements, researchers and REBs should also consider whether the prospective participants (as individuals, groups, or populations) are in vulnerable circumstances (see Article 4.7). The existence of vulnerable circumstances may require greater effort to minimize risks to participants and/or maximize potential benefits (see Chapter 2, Section B).</p> <p><i>Population and Public Health Research</i><br/> Due to the nature of the research question and the need to test interventions that operate at the population level, some population and public health studies cannot be done with prior informed consent. For example, a cluster-randomized trial comparing the efficacy of two different stop smoking campaigns in two or more communities would not be able to answer the research question if community members were alerted, through a consent process, to the presence of the campaign and the existence of other campaigns in different communities as this knowledge could affect the group response to the campaigns. Similarly, in a study comparing the effectiveness of different types of water treatment facilities, it would not be possible to obtain individual informed consent for the type of water treatment each individual in a community is to receive. Researchers should, however, seek community engagement prior to data collection (see <a href="#">Chapter 9</a>).</p> <p>It is up to researchers to adequately explain why their research question cannot be answered without an exception to the requirement to seek prior consent. REBs are advised to have population and public health expertise involved in reviews of this type of research (see <a href="#">Articles 6.4</a> and <a href="#">6.5</a>).</p> <p><b>Debriefing in the Context of Alterations to Consent Requirements</b><br/> <b>Article 3.7B</b><br/> 1 Debriefing must be a part of all research involving an alteration to consent</p> |
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- requirements (see [Article 3.7A](#)) whenever it is possible, practicable and appropriate.
- 2 Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate (see [Article 3.1](#)).

### **Application**

#### *Debriefing*

Where alterations to consent have been used, debriefing is an important mechanism in maintaining the participant's trust in the research community. Often, debriefing in this context can be a simple and straightforward candid disclosure as described in [Article 3.2](#). To allow for the possibility that participants may wish to withdraw their data or biological materials once they know the details of the study (see *Post-debriefing option to withdraw data and/or human biological materials* in this application), debriefing should take place while it is still possible to give participants this option (e.g., prior to merging or de-identification).

Researchers must explain why participants were temporarily led to believe that the research, or some aspect of it, had a different purpose, or why participants received less than full disclosure. In cases where participants were not asked for their consent prior to collection of data and/or human biological materials, researchers must explain why this exception to consent requirements was necessary. Researchers must give details about the importance of the research, the necessity of having to use alterations to consent requirements, and address any concerns raised by participants. In order to address any misconceptions that may have arisen, researchers must explain why these research procedures were necessary to obtain scientifically valid findings. When debriefing, researchers should be alert and sensitive to participants' needs, feelings, reactions and concerns. REBs should assess the risks and benefits of the debriefing itself and whether the proposed plan is appropriate for participants – particularly those who are in vulnerable circumstances and/or who lack the capacity to make a consent decision.

When it is not appropriate to provide complete details of the research in a debriefing, the level of detail should be determined by considering the impact of the information on the participant in terms of foreseeable risks and potential benefits. It should also be proportionate to the

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|  | <p>sensitivity of the issue and tailored to the decision-making capacity of participants. For example, in research involving children who do not have the capacity to make a consent decision on their own behalf it may be more appropriate to debrief the parents, guardians or authorized third parties as well as the participants themselves. The debriefing process should be based upon the participants' capacity to understand the information provided. Note that in some cases, excluding children from a debriefing may be justified (e.g., when debriefing is focused on findings of a sensitive nature that relate to the child, such as intellectual capacity). In other cases, it may be more appropriate to debrief the entire family or community. Immediate, full debriefing of all individuals who have contributed data may not be feasible in all cases. In studies with data collection over a longer term, debriefing may have to be deferred until the end of the project.</p> <p><i>Post-debriefing option to withdraw data and/or human biological materials</i><br/> At the time of debriefing, participants should, whenever possible, practicable and appropriate, be able to indicate their consent/assent or their refusal for the continued use of their data or human biological materials. In cases where participants express concerns about their participation in a project, the researcher must address their concerns (e.g., by explaining the rationale for the research design, answering questions about data usage or privacy). Regardless of whether any concerns are raised, the researcher must give participants the option of removing their data and/or human biological materials unless this option is impossible, impracticable or inappropriate (see <a href="#">Glossary</a>).</p> <p>In determining whether it is ethically acceptable not to permit the withdrawal of data and/or human biological materials, REBs must consider whether withdrawal of data is possible or practicable. If researchers intend to collect data or human biological materials without identifying information, or if all identifying information will be removed, it may not be possible for researchers to withdraw the data associated with specific individuals. Researchers must provide a rationale for using collection methods that do not permit subsequent withdrawal of data or human biological materials. REBs must also consider whether the option to withdraw data is appropriate. In some types of research, permitting the</p> |
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|  | <p>withdrawal of data and/or human biological materials could skew the results of the research, invalidating the study and denying potential benefits to society. The invalidation of study findings may also demonstrate a lack of respect of the contributions made by other participants. The onus is on researchers, however, to satisfy the REB that the withdrawal of data or biological materials by individual participants would threaten the validity of their research.</p> <p>Where the terms of the research proposal do not permit the participants to withdraw their data, in the absence of the consent of the participant, the identity of the participants shall be protected at all times during and following completion of the project. Participants who express concern about the conduct of the project at the time of debriefing, or who contest the limits imposed on withdrawing their data, should be given the contact information for the REB that approved the research. Researchers must report to the REB concerns about the conduct of the project raised by participants at the time of debriefing.</p> <p><i>Exception to the requirement to debrief</i><br/> There may be circumstances in which debriefing is impossible, impracticable or inappropriate in research involving alterations to consent requirements. Note that “impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience. The onus is on researchers to satisfy the REB that their research involves circumstances that make it impossible, impracticable or inappropriate to offer a debriefing.</p> <p>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.”</p> |
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| Chapter 3<br>Part C (page<br>40)                      | Chapter 3<br>Part C (page<br>42)                      | <b>TCPS2 2014 Use of the term Decision Making Capacity rather than Capacity</b>  |
| Chapter 3<br>Research<br>Directives<br>(page 42)      | Chapter 3<br>Research<br>Directives<br>(page 44)      | <b>TCPS2 2014 – Removal of First Paragraph from TCPS2 2010.</b>  |
| Chapter 5<br>Identifiable<br>Information<br>(page 56) | Chapter 5<br>Identifiable<br>Information<br>(page 58) | <b>TCPS2 2014 – Rephrasing of Paragraph to clarify that the assessment of identifiability is context-specific.</b> “Where researchers seek to collect, use, share and access different types of information or data about participants, they are expected to determine whether the information or data proposed in research may reasonably be expected to identify an individual. For the purposes of this Policy, researchers and REBs shall consider whether information is identifiable or non-identifiable. Information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available information. Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information. The term “personal information” generally denotes identifiable information about an individual. The assessment of whether information is identifiable is made in the context of a specific research project.” |
| Chapter 5,<br>Article 5.5<br>(page 62-64)             | Chapter 5,<br>Article 5.5A<br>and 5.5 B<br>(page 66)  | <b>TCPS2 – Split Article 5.5 into 5.5A and 5.5B to distinguish between secondary use of identifiable information and secondary use of non-identifiable information. In addition Article 5.5B now makes it explicit that consent is not required for research that relies exclusively on secondary use of non-identifiable information.</b><br><br><b>Article 5.5A</b> Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that:<br>a identifiable information is essential to the research;  |

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|  | <p>b the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;</p> <p>c the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;</p> <p>d the researchers will comply with any known preferences previously expressed by individuals about any use of their information;</p> <p>e it is impossible or impracticable (see <a href="#">Glossary</a>) to seek consent from individuals to whom the information relates; and</p> <p>f the researchers have obtained any other necessary permission for secondary use of information for research purposes.</p> <p>If a researcher satisfies all the conditions in <a href="#">Article 5.5(a) to (f)</a>, the REB may approve the research without requiring consent from the individuals to whom the information relates.</p> <p><b>Application</b> In the case of secondary use of identifiable information, researchers must obtain consent unless the researcher satisfies all the requirements in <a href="#">Article 5.5A</a>. The exception to the requirement to seek consent in this article is specific to secondary use of identifiable information. The terms of <a href="#">Article 3.7</a> address alteration of consent in other circumstances and do not apply here.</p> <p>Secondary use of information identifiable as originating from a specific Aboriginal community, or a segment of the Aboriginal community at large, is addressed in <a href="#">Articles 9.20 to 9.22</a>.<sup>3</sup> "Impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience (see <a href="#">Glossary</a>). Consent may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to track and contact members of the group may raise additional privacy concerns. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship on the researcher. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information.<sup>4</sup></p> |
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|  | <p>The researcher must respect relevant privacy laws, regulations and institutional policies and may be required to consult with or obtain approval from appropriate data stewards. Privacy laws may impose specific rules regarding disclosure of information for secondary use in research. These laws may require the individual or organization that has custody or control of requested personal information to obtain approval from a privacy commissioner or other body before disclosing information to researchers. They may also impose additional requirements such as information-sharing agreements that describe disclosure conditions. These requirements may include the stipulation that the researcher not publish identifiable information or contact individuals to whom the information relates.</p> <p>At the time of initial collection, individuals may have had an opportunity to express preferences about future uses of information, including research uses (see paragraph <a href="#">[d]</a> in the Application of <a href="#">Article 3.2</a>). Data stewards have an obligation to respect the individual's expressed preferences. For example, where an individual does not want information used for future research, data stewards shall remove this information from any datasets used or made available for research.</p> <p>In cases where the proposed research involves information of greater sensitivity (e.g., genetic information, information about individuals who seek help through domestic violence shelters, information about sexual practices), the REB may require that researchers engage in discussion with people whose perspectives can help identify the ethical implications of the research, and suggest ways to minimize any associated risks. Discussion is not intended to serve as proxy consent. Rather, a goal of discussion is to seek input regarding the proposed research, such as the design of the research, measures for privacy protection, and potential uses of findings. Discussion may also be useful to determine whether or not the research will adversely affect the welfare of individuals to whom the information relates. Researchers shall advise the REB of the outcome of such discussions. The REB may require modifications to the research proposal based on these discussions.</p> <p><b>Article 5.5B</b> Researchers shall seek REB review, but are not required to seek participant</p> |
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|   |   | <p>consent, for research that relies exclusively on the secondary use of non-identifiable information.</p> <p><b>Application</b> The onus will be on the researcher to establish to the satisfaction of the REB that, in the context of the proposed research, the information to be used can be considered non-identifiable for all practical purposes. For example, the secondary use of coded information may identify individuals in research projects where the researcher has access to the key that links the participants' codes with their names. Consent would be required in this situation. However, the same coded information may be assessed as non-identifiable in research projects where the researcher does not have access to the key. Consent would not be required in this situation.</p>                      |
| Chapter 6, Article 6.2 Application (page 68)  | Chapter 6, Article 6.2 Application (page 70)  | <p><b>TCPS2 2014 Changes to Application paragraph to add considerations for determining the highest body of an institution for the purposes of establishing an REB.</b></p> <p><b>Application</b> The highest body of the institution that establishes the REB or REBs could be an individual, such as the president, rector or chief executive officer, or an equivalent body, such as a governing council, board of directors, or council of administration. Institutions determine the highest body based on their individual governance structures and taking into consideration whether other responsibilities of those bodies may conflict with the responsibility for establishing an REB. Institutions shall have in place written procedures for the appointment, renewal and removal of REB members, including Chairs.</p> |
| Chapter 6, Article 6.12 Application (page 78) | Chapter 6, Article 6.12 Application (page 80) | <p><b>TCPS2 2014 Changes to one paragraph in the Application to clarify that student research projects that are used for their own research program (e.g. thesis or equivalent) require REB Review.</b> “An institution may decide that ethics review of course-based research activities intended solely for pedagogical purposes can be delegated to non-REB members at the institution’s department, faculty or equivalent level. Such pedagogical activities are normally required of students (at all levels) with the objective of providing them with exposure to research methods in their field of study (e.g., interviewing techniques). If these activities are used for the purposes of research (e.g., as part of a researcher’s own</p>  |

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|  |   | <p>research program), they should be reviewed by the regular institutional REB procedures. Theses or equivalent research projects involving human participants typically meet this Policy’s definition of research (see Application of <a href="#">Article 2.1</a>), and should be reviewed by the REB following a proportionate approach (see <a href="#">Article 6.12</a>). The REB should establish written procedures and set out criteria for determining which categories of research proposal may be eligible for this type of review, and specify who is responsible for implementing and overseeing the approval mechanisms.”</p>  |
| <p>Chapter 6, Article 6.12 Application (page 78)</p> | <p>Chapter 6, Article 6.12 Application (page 80-81)</p> | <p><b>TCPS 2 2014 Changes to the list of categories that may be delegated for research ethics review to clarify when annual renewal of more than minimal risk research may be delegated.</b></p> <p>“Examples of categories that may be delegated for research ethics review include:</p> <ul style="list-style-type: none"> <li>• research that is confidently expected to involve minimal risk;</li> <li>• minimal-risk changes to approved research;</li> <li>• annual renewals of approved minimal risk research;</li> <li>• annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal e.g., the research will no longer involve new interventions to current participants and no additional participants will be enrolled in the study;</li> <li>• annual renewals of more than minimal risk research in which there has been: <ul style="list-style-type: none"> <li>○ no significant changes to the research,</li> <li>○ no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB, and</li> <li>○ the REB Chair has determined that the delegated review process is appropriate.</li> </ul> </li> </ul> <p>Note that other applicable guidelines or policies (such as ICH-GCP) may require a full REB review of the annual renewal for specific types of research.”</p> |
| <p>Chapter 6, Article 6.14,</p>                      | <p>Chapter 6, Article 6.14,</p>                         | <p><b>TCPS2 2014 Addition to Application to add requirement for institutions to develop criteria for determining when REB involvement is no longer required.</b> “Institutional</p>   |

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| Application (page 80)                        | Application (page 82)                        | ethics policies should include provisions that assist REBs, researchers and institutions to determine when continuing research ethics review is no longer required. Such provisions should consider different types of research designs (e.g., short-term project, longitudinal research, research with reporting back requirements). They should also consider issues such as the extent of any remaining risk to participants, the nature of plans (if any) for future interaction with participants; the status of any commitments or agreements made to participants, for example, with respect to reporting findings; and/or the relative likelihood of future unanticipated events, material incidental findings, or new information.”  |
| Chapter 10, Observational Studies (page 141) | Chapter 10, Observational Studies (page 145) | <b>TCPS2 2014 Changed the examples for publically accessible spaces in first paragraph.</b><br>“In qualitative research, observation is used to study behaviour in a natural environment. It often takes place in living, natural and complex communities or settings, in physical environments, or in virtual settings. Observational studies may be undertaken in publicly accessible spaces (e.g., a stadium, library, museum, planetarium, beach, park), in virtual settings (e.g., Internet chat rooms), or in private or controlled spaces (e.g., private clubs or organizations).”   |
| Chapter 11 Introduction (page 147)           | Chapter 11 Introduction (page 151)           | <b>TCPS2 2014 Changed 2<sup>nd</sup> paragraph of introduction to address concerns that parenthetical phrase is inaccurate as not all clinical trials involve patient populations.</b><br>“For the purposes of this Policy, a clinical trial (a form of clinical research) is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, manual therapies and psychotherapies. Clinical trials may also include questions that are not directly related to therapeutic goals – for example, drug metabolism – in addition to those that directly evaluate the treatment of participants.” |
| Chapter 11 Part A (page                      | Chapter 11 Part A (page                      | <b>TCPS2 2014 Addition of description and responsibility of Principal Investigator.</b>   |

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| 149)  | 153-154)  | <p><b>Principal Investigator</b><br/>In studies involving more than one researcher, particularly multi-site studies, the researcher who has overall responsibility for the ethical conduct of the study, and for the actions of any member of the research team, is known as the principal investigator (PI). The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site researchers, who must then inform their local REBs.</p>  |
| Chapter 11<br>Article 11.3<br>(page 156)                | Chapter 11<br>Article 11.3<br>(page 161)                | <p><b>TCPS2 2014 Changes to Article 11.3 to clarify requirements associated with registering clinical trials.</b> “All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE).”</p>  |
| Chapter 11<br>Article 11.3<br>Application<br>(page 157) | Chapter 11<br>Article 11.3<br>Application<br>(page 161) | <p><b>TCPS2 2014 Changes to 2<sup>nd</sup> paragraph of Application to clarify requirements associated with registering clinical trials.</b> “Clinical trials shall be registered in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE). All fields outlined in the WHO Trial Registration Data Set (TRDS) must be completed in order for a trial to be considered fully registered. A registration with missing information or uninformative fields in the TRDS is unacceptable. Researchers shall provide the REB with the number assigned to the trial upon registration.”</p> |
| Chapter 11<br>Article 11.8<br>(page 161)                | Chapter 11<br>Article 11.8<br>(page 165)                | <p><b>TCPS2 2014 Changes to Article 11.8 to clarify requirements associated with updating clinical trial registries.</b></p> <p><b>Article 11.8</b> Researchers shall promptly report new information that may affect the welfare or consent of participants, to the REB, and to other appropriate regulatory or advisory bodies. New information must be submitted to the publicly accessible trial registry along with reports of findings once the trial is completed. Where possible, this information can be reported earlier to the registry in descriptions of study design, intervention, or an equivalent data field.</p>  |

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|   |   | When new information is relevant to participants' welfare, researchers shall promptly inform all participants to whom the information applies (including former participants). Researchers shall work with their REB to determine which participants must be informed, and how the information should be conveyed.   |
| Chapter 11<br>Article 11.8<br>Application<br>(page 161) | Chapter 11<br>Article 11.8<br>Application<br>(page 165) | <b>TCPS2 2014 Changes to 1<sup>st</sup> paragraph of Application to clarify requirements associated with updating clinical trial registries.</b> "In the course of any type of clinical trial, new information may arise that is relevant to participants' welfare and/or their ongoing consent to participate (see <a href="#">Article 2.8</a> , <a href="#">Article 3.3</a> , <a href="#">Articles 6.15</a> and <a href="#">6.16</a> , and <a href="#">Article 11.8</a> ). This new information may arise from unanticipated issues (e.g., adverse reactions to interventions) or from routine evaluations of participant health that occur in the context of the trial. It may pertain to all participants, or only to those in one arm of a trial, or only to one participant with a particular health issue. It may be information that arises from other related research that has repercussions for ongoing trials. To understand the particular relevance of new information, it should be considered from the perspective of the participant. <a href="#">Article 11.8</a> outlines the continuing duty of researchers to share new and relevant information regarding clinical trials with the REB, the publicly accessible registry where the trial is registered, other relevant bodies, and with participants and their primary care clinicians, as indicated by the nature of the information. The more relevant, serious and urgent the information, the more promptly it should be disclosed." |
| Chapter 11<br>Article 11.8<br>Application<br>(page 162) | Chapter 11<br>Article 11.8<br>Application<br>(page 167) | <b>TCPS2 2014 Changes to 2<sup>nd</sup> last paragraph of Application to clarify requirements associated with updating clinical trial registries.</b> "The welfare of participants must also be considered when a trial is unexpectedly discontinued. When a researcher, a sponsor or other body (institution, funding agency, regulatory body) stops or unblinds a clinical trial, or a part of a clinical trial, the principal investigator has an ethical and a regulatory responsibility to inform both clinical trial participants and the REB of the discontinuance or unblinding and the reasons for it. Researchers must update the publicly accessible trial registry with any changes to the trial that require REB review and approval, adverse events that occur during a trial, and decisions taken to end a trial early. In the case of a trial that has stopped early, an explanation   |

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|  |  | <p>must be provided as part of the update to the registry. Where no specific field for this information exists, this update can be added to descriptions of study design and/or intervention (or an equivalent data field). Any risks to participants that may arise from the closing of the trial must be communicated in writing to the REB and the participants, and the researcher shall indicate any measures that will be taken to mitigate these risks. “</p>  |
| <p>Chapter 11<br/>Article 11.9<br/>Application<br/>(page 163)</p>  | <p>Chapter 11<br/>Article 11.9<br/>Application<br/>(page 167)</p>  | <p><b>TCPS2 2014 Changes to 1st paragraph of Application to that REBS must be aware that investigators are required to update clinical trial registries.</b> n accordance with <a href="#">Articles 11.7</a> and <a href="#">11.8</a> and <a href="#">Articles 6.15</a> and <a href="#">6.16</a>, REBs can expect to receive safety reports and new information, including, but not limited to, unanticipated issues, changes to the research design and newly discovered risks. The reports are usually submitted by the local site researcher, who may also be the principal investigator, or by an established safety monitoring body, such as a DSMB (see <a href="#">Article 11.7</a>). REBs should be aware that researchers are also required to update the publicly accessible trial registry where their trial is registered (see <a href="#">Article 11.8</a>).</p> |
| <p>Chapter 11<br/>Article 11.12<br/>(page 164)</p>                 | <p>Chapter 11<br/>Article 11.12<br/>(page 169)</p>                 | <p><b>TCPS 2 2014 Changes to Article 11.12 (a) changed to harmonize with the CIHR program guidelines regarding dissemination of clinical trial results.</b></p> <p><b>Article 11.12</b> With respect to research findings:<br/>(a) Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions publish or otherwise disseminate the analysis of data and interpretation of clinical trial results (i.e., the findings) in a timely manner without undue restriction.</p>  |
| <p>Chapter 11<br/>Article 11.12<br/>Application<br/>(page 165)</p> | <p>Chapter 11<br/>Article 11.12<br/>Application<br/>(page 169)</p> | <p><b>TCPS 2 2014 Changes to 1st paragraph of Application to harmonize with the CIHR program guidelines regarding dissemination of clinical trial results. IN addition to add a requirement that researchers disclose information affecting the welfare of participants at the end of the trial in subsequent publications.</b> “To justify the involvement of participants, and the risks and other burdens they are asked to bear, research must be valuable. That is, it must have a reasonable likelihood of promoting social good. If research</p>   |

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|  |  | findings and the research materials and research data they are based upon, are not disseminated (e.g., published in a peer-reviewed journal, added to a publicly available clinical trials database) within a reasonable time, their value may be diminished or lost, betraying the contributions and sacrifices of participants. For this reason, and based on respect for participant expectations and protection of the public good, researchers, research sponsors and institutions have an ethical responsibility to make reasonable efforts to publicly disseminate the findings of clinical trials in a timely manner by publications and by the inclusion of the findings (where possible), or information about where to access findings (e.g., lists of publications, links to publications or to the trial website) in the publicly accessible registry where the trial has been registered. In publications, researchers have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials <sup>4</sup> ). Furthermore, any new information that has an effect on the welfare of participants that comes to light at, or after, the end of the trial should be reported in subsequent publications.” |
| Chapter 11<br>Article 11.12<br>Application<br>(page 165)     | Chapter 11<br>Article 11.12<br>Application<br>(page 170)     | <b>TCPS 2 2014 Addition paragraph in Application to encourage researchers to make their data available for further analysis or verification by peers.</b> “Researchers are encouraged to make their data available for further analysis or verification by their peers. When sharing participant data with peers, researchers must be mindful of their responsibility to safeguard participant privacy and confidentiality (see <a href="#">Articles 3.2</a> , <a href="#">5.1</a> and <a href="#">5.5A</a> ) and may have to code or anonymize the data to do so.”   |
| Chapter 11<br>Article 11.12<br>Application<br>(page 165-167) | Chapter 11<br>Article 11.12<br>Application<br>(page 170-172) | <b>TCPS 2 Rewording and additions made to Application to eliminate potential conflict between TCPS2 and the Model Clinical Trials Agreement.</b><br><br><i>Confidentiality clauses and publication restrictions in research contracts</i><br><br>Institutions and REBs should require satisfactory amendment or removal of any confidentiality clauses or publication restrictions in research contracts that unduly limit either the content of the scientific information that may be disseminated or the timing of   |

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|  |  | <p>dissemination. Contracts should also ensure that principal investigators have the necessary access to original trial data and the opportunity to analyze them, to ensure that they can report trial findings fairly and accurately, particularly with respect to both efficacy and safety.</p> <p>Institutional and REB policies should ensure that sponsors' legitimate interests are reasonably balanced against the researcher's ethical and legal obligations to participants, and to the scientific and public good to disseminate data and research findings (see <a href="#">Chapter 7</a> with respect to Conflicts of Interest). It shall be understood that the welfare of participants takes precedence over the interests of both researchers and sponsors.</p> <p>Such policies should require that clinical trial research contracts be examined to ensure that contractual provisions comply with institutional policy standards. They should do all of the following:</p> <ol style="list-style-type: none"> <li>1) require that confidentiality and publication clauses be submitted to a responsible authority (e.g., the REB or research administration) for a determination of their consistency with the policy;</li> <li>2) require that any ethical concerns arising in the review be referred to the REB as an integral part of the research ethics review process;</li> <li>3) provide that any proposed restrictions on publication include an ethically acceptable justification;</li> <li>4) provide that all confidentiality and publication clauses: <ol style="list-style-type: none"> <li>a be consistent with the researcher's duty to share new information from clinical trials with REBs and trial participants in a timely manner (Section D);</li> <li>b be reasonable in terms of any limitations or restrictions on the publication or other dissemination or communication of information;</li> <li>c permit principal investigators to access all trial data;</li> <li>d permit researchers to access all trial data collected at their respective sites; and</li> </ol> </li> </ol> |
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|                                       |                                    | <p>e permit all researchers to access all trial data in cases where no principal investigator is named.</p> <p>In the interests of transparency and accountability, it is necessary for researchers to have access to trial data. Normally, it is the responsibility of the named PI to examine the entire trial data set and to ensure that data are not inappropriately excluded from analyses and disseminations of findings. If a PI is not named to avoid sharing the entire data set of a multi-site trial, this would be contrary to ethical clinical trial reporting in accordance with TCPS 2. To promote transparency and accountability, TCPS 2 requires that, in the absence of a named PI, all site researchers shall be entitled to access the entire data set.</p>   |
| Chapter 12 Part A (page 168-169)      | Chapter 12 Part A (page 175-176)   | <p><b>TCPS2 2014 Changes made to the beginning of this section to clearly specify what constitutes identifiable information. The list and description of the categories remains the same.</b></p> <p><b>Identifiable Human Biological Materials</b><br/> Human biological materials that may reasonably be expected to identify an individual, alone or in combination with other available information, are considered identifiable biological materials for the purposes of this Policy. Identifiability of human biological materials has to be assessed relative to the current state of science and the availability of other sources of identifying information about participants and increasingly sophisticated methods of re-identification. The assessment of whether human biological materials are identifiable is made in the context of a specific research project.<br/> Types of Human Biological Materials The following categories, similar to those found in <a href="#">Chapter 5</a>, provide guidance for assessing the extent to which human biological materials could be used to identify an individual:</p> |
| Chapter 12 Article 12.3 & Application | Chapter 12 Article 12.3A and 12.3B | <p><b>TCPS2 2014 Divided into two articles and clarifications were made to consent requirements. These changes are consistent with changes made to Chapter 5.</b></p>   |

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| (page 173-174) | and their Applications (page 179-181) | <p><b>Article 12.3A</b> Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if they have satisfied the REB that:</p> <ul style="list-style-type: none"> <li>(a) identifiable human biological materials are essential to the research;</li> <li>(b) the use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;</li> <li>(c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;</li> <li>(d) the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;</li> <li>(e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and</li> <li>(f) the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.</li> </ul> <p>If a researcher satisfies all the conditions in <a href="#">Article 12.3(a) to (f)</a>, the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.</p> <p><b>Application</b> In the case of the secondary use of identifiable human biological materials, researchers must obtain consent unless the researcher satisfies all the requirements in <a href="#">Article 12.3A</a>.</p> <p>The exception to the requirement to seek consent in this article is specific to secondary use of identifiable human biological materials. The terms of <a href="#">Article 3.7</a> address alteration of consent in other circumstances and do not apply here.</p> <p>Secondary use of human biological materials identifiable as originating from a specific Aboriginal community, or a segment of the Aboriginal community at large, is addressed in <a href="#">Articles 9.20 to 9.22</a>.<sup>1</sup></p> |
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|  |  | <p>“Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.<sup>2</sup> Consent may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. Attempting to track and contact members of the group may raise additional privacy concerns. Financial, human and other resources required to contact individuals and seek consent may impose undue hardship on the researcher. In some jurisdictions, privacy laws may preclude researchers from using personal information to contact individuals to seek their consent for secondary use of information.</p> <p>At the time of initial collection, individuals may have had an opportunity to express preferences about future uses of their biological materials, including research uses (see paragraphs (d) and (i) in the Application of <a href="#">Article 3.2</a>). Custodians that hold human biological materials have an obligation to respect the individual’s expressed preferences. Where an individual does not want biological materials used for future research, custodians should remove these biological materials from any collections used or made available for research. Alternatively, individuals may have made an express donation of biological materials for research in accordance with human tissue gift legislation.</p> <p>In cases where the proposed research involves issues of greater sensitivity (e.g., research involving stigmatizing conditions), an REB may require that researchers engage in discussion with people whose perspectives can help identify the ethical implications of the research, and suggest ways to minimize any associated risks. Discussion is not intended to serve as proxy consent. Rather, a goal of discussion is to seek input regarding the proposed research, such as the design of the research, measures for privacy protection, and potential uses of findings. Discussion may also be useful to determine whether the research will adversely affect the welfare of individuals from whom the biological materials were collected. Researchers shall advise the REB of the outcome of such discussions. The REB may require modifications to the research proposal based on these discussions.</p> |
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|   |   | <p><b>Article 12.3B</b> Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable human biological materials.</p> <p><b>Application</b> The onus will be on the researcher to establish to the satisfaction of the REB that, in the context of the proposed research, the human biological materials to be used can be considered non-identifiable for all practical purposes. For example, the secondary use of coded human biological materials may identify individuals in research projects where the researcher has access to the key that links the participants’ codes with their names. Consent would be required in this situation. However, the same coded human biological materials may be assessed as non-identifiable in research projects where the researcher does not have access to the key. Consent would not be required in this situation.</p> |
| Chapter 12<br>Article 12.9<br>(page 178-179)            | Chapter 12<br>Article 12.9<br>(page 185)                | <p><b>TCPS2 2014 Changed wording of Article 12.9 (b) to strengthen and clarify conditions for research involving fetus or fetal tissue.</b></p> <p><b>Article 12.9</b> Research involving a fetus or fetal tissue:<br/>(a) requires the consent of the woman; and<br/>(b) shall not compromise the woman’s ability to make decisions regarding continuation of her pregnancy.</p>  |
| Chapter 12<br>Article 12.9<br>Application<br>(page 179) | Chapter 12<br>Article 12.9<br>Application<br>(page 185) | <p><b>TCPS2 2014 Additional paragraph added to Application to clarify consent where fetus has been born alive.</b></p> <p>Where the fetus has been born alive and viable, research involving human biological materials associated with the child must meet the conditions of <a href="#">Article 3.9.A</a> fetus that has been born alive and viable is a child with its own independent interests.</p>   |
| Chapter 12<br>Part F (page                              | Chapter 12<br>Part F (page                              | <p><b>TCPS2 2014 Additional text added to incorporate CIHR’s Guidelines for Human Pluripotent Stem Cell Research.</b> “Guidance regarding a proportionate approach to research</p>   |

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| 179)   | 185-186)   | <p>ethics review, consent, privacy, confidentiality, and research with human biological materials and other ethical guidance described in earlier chapters of this Policy apply equally to research involving human pluripotent stem cells. This section provides further guidance for research involving human pluripotent stem cells. In addition to following the guidance provided in this Policy, researchers are responsible for compliance with all applicable legal and regulatory requirements, e.g., the Assisted Human Reproduction Act and its Regulations and the Food and Drugs Act and its Regulations.</p> <p><b>Stem Cell Oversight Committee (SCOC)</b><br/> In recognition of the complex ethical issues associated with research involving pluripotent stem cells, a Stem Cell Oversight Committee (SCOC) was created by CIHR in 2003. SCOC reviews research involving human pluripotent stem cells that:</p> <ul style="list-style-type: none"> <li>a have been derived from an embryonic source; and/or</li> <li>b will be transferred into humans or non-human animals</li> </ul> <p>to ensure compliance with Chapter 12, Section F of this Policy. Applications that receive SCOC approval shall then be submitted to local REBs as part of the local research ethics review process.</p> <p>SCOC does not review research involving human pluripotent stem cells that come from somatic (non-embryonic) tissue and that are not going to be transferred into humans or non-human animals.”</p> |
| Chapter 12<br>Article 12.10<br>& Application<br>(page 179) | Chapter 12<br>Article 12.10<br>& Application<br>(page 186-188) | <p><b>TCPS2 2014 Article and Application have been completely rewritten to incorporate CIHR’s Guidelines for Human Pluripotent Stem Cell Research.</b></p> <p><b>Article 12.10</b> Research involving human pluripotent stem cells that have been derived from an embryonic source and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by SCOC and an REB. The researcher</p>   |

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|  |  | <p>shall provide evidence of SCOC approval to the REB.</p> <p><b>Application</b></p> <p>1. Research Conforming to this Policy and Requiring SCOC Review</p> <p>Types of stem cell research that conform to this Policy and require SCOC review include:</p> <p>a) Research for the purpose of deriving or studying human embryonic stem cell lines or other cell lines of a pluripotent nature from human embryos, provided that:</p> <ul style="list-style-type: none"> <li>I. the embryos used, whether fresh or frozen, were originally created for reproductive purposes and are no longer required for such purposes; and</li> <li>II. consent was provided by the persons for whom the embryos were originally created for reproductive purposes. Where third party donor gametes were used to create the embryo, the third party gamete donor(s) shall have given, at the time of donation, consent to the unrestricted research use of any embryos created, when these embryos are no longer required for reproductive purposes. Where the third party gamete donors referred to in this paragraph are anonymous, it is not possible to seek their consent for embryo use. In such cases, the responsibility of consent for embryo use has, in effect, been transferred to the persons for whom the embryos were created for reproductive purposes; and</li> <li>III. neither the ova nor the sperm from which the embryos were created, nor the embryos themselves, were obtained through commercial transactions (i.e., were acquired by payment of money in excess of costs actually incurred, or in exchange for services).</li> </ul> <p>b) Research on anonymized or coded human embryonic stem cell lines that have been created in Canada, or created elsewhere and imported for research purposes, provided that:</p> <ul style="list-style-type: none"> <li>I. those created in Canada were developed in compliance with this Policy or, prior to December 9, 2014, the Guidelines for Human Pluripotent Stem Cell Research. It is incumbent on the recipient of such cell lines to ensure that this is the case. The recipient shall provide satisfactory evidence to SCOC and the local REB that the cell lines fulfill the consent provisions before research can begin;</li> </ul> |
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|  |  | <p>II. the recipient of stem cell lines created in a country other than Canada provides SCOC with satisfactory evidence that the manner in which the stem cell lines were created in the country of origin, including the embryo donors' consent, satisfies the laws and policies of that country. Should SCOC find that the manner of creation of these stem cell lines and the consent provisions vary significantly from the principles of this Policy, or, prior to December 9, 2014, the Guidelines for Human Pluripotent Stem Cell Research, it may not approve the use of these cell lines in stem cell research in Canada.</p> <p>c) Research involving the grafting or any other form of transfer of human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, cells derived from those cells, or other human cells that are likely to be pluripotent into non-human animals, from birth to adulthood, provided that:</p> <p>I. the research is designed to reconstitute a specific tissue or organ to derive a pre-clinical model or to demonstrate that the cells are pluripotent (e.g., teratoma formation); and</p> <p>II. these non-human animals grafted with human stem cells will not be used for reproductive purposes.</p> <p>d) Research involving the grafting or any other form of transfer of human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, cells derived from those cells, or other human cells that are likely to be pluripotent into humans with legal capacity shall be in compliance with the Food and Drugs Act and its Regulations, including the Safety of Human Cells, Tissues and Organs for Transplantation Regulations.</p> <p>2. Research Not Conforming to this Policy</p> <p>The following types of stem cell research do not conform to this Policy:</p> <p>a. Research involving the creation of human embryos specifically to derive stem cell lines or other cell lines of a pluripotent nature;</p> <p>b. Research involving somatic cell nuclear transfer into human oocytes (cloning) or</p> |
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|                      |   | <p>involving stimulation of an unfertilized egg to produce a human embryo (parthenogenesis) for the purposes of developing human embryonic stem cell lines or other cell lines of a pluripotent nature;</p> <ul style="list-style-type: none"> <li>c. Research involving the directed donation of human embryos or human embryonic stem cell lines to particular individuals;</li> <li>d. Research in which human or non-human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, or other cells that are likely to be pluripotent are combined with a human embryo;</li> <li>e. Research in which human or non-human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, or other cells that are likely to be pluripotent are grafted or transferred in any other form to a human fetus;</li> <li>f. Research in which human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, or other cells that are likely to be pluripotent are combined with a non-human embryo; or</li> <li>g. Research in which human embryonic stem cells, embryonic germ cells, induced pluripotent stem cells, or other cells that are likely to be pluripotent are grafted or transferred in any other form to a non-human fetus.</li> </ul> |
| Nothing in TCPS 2010 | Chapter 12 Articles 12.11 – 12.20 and their applications (page 188-191) | <p><b>TCPS2 2014 Additions of Articles 12.11 to 12.20 to incorporate CIHR’s Guidelines for Human Pluripotent Stem Cell Research.</b></p> <p><b>Consent</b><br/>Chapter 3, especially <a href="#">Articles 3.1</a> to <a href="#">Articles 3.5</a>, provides detailed guidance on the need to seek consent for participation in research. The following articles provide additional guidance for situations that are unique to stem cell research.</p> <p><b>Article 12.11</b> Embryos no longer needed for reproductive purposes may be donated for use in research (including research to derive and study human embryonic stem cells). Embryo donors and gamete donors, if these are different individuals, shall be advised of all available options in respect of the use of the embryos and their consent sought prior to the use.</p>   |

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|  |  | <p><b>Article 12.12</b> At the time when the embryos are to be used for research to derive and study embryonic stem cells (and other human cells or cell lines of a pluripotent nature), consent of the embryo donors shall be sought again. Research shall not proceed unless consent is obtained.</p> <p><b>Application</b> This requirement affirms the right of the donors to withdraw consent and is necessary because of the possible lengthy delay between the time at which the original consent is given and the time at which the embryos are utilized for research purposes. Members of the health care team treating and/or counselling prospective participants should not be the persons to obtain consent from the embryo donors at the time of re-consent. A renewal of the consent provided by the gamete donors (if the gamete donors are not the same individuals as the embryo donors), is not required provided that appropriate consent for the unrestricted research use of the embryos was given at the time of gamete donation.</p> <p><b>Article 12.13</b> When seeking consent for human embryonic stem cell research, in addition to the information outlined in <a href="#">Article 3.2</a> researchers shall provide to prospective research participants the following:</p> <ol style="list-style-type: none"> <li>a. An explanation that the cell line(s) will be anonymized or coded;</li> <li>b. An assurance that prospective research participants are free to not participate and have the right to withdraw at any time before an anonymized or coded cell line is created;</li> <li>c. An explanation that the research could result in the production of a stem cell line that could be maintained for many years, distributed to other parts of the world, and used for various research purposes;</li> <li>d. An explanation that the research participants will not benefit directly financially from any future commercialization of cell lines; nor will there be any personal benefit in terms of dispositional authority over any embryonic cell lines created (i.e., there will be no directed donation of the cells or cell lines to particular individuals).</li> </ol> <p><b>Application</b></p> |
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|  |  | <p><a href="#">Article 12.13</a> (b) refers to the withdrawal of both consent and human biological materials. Once an anonymized or coded cell line is created, it may have a wide distribution, making withdrawal of materials almost impossible.</p> <p><b>Creation of Excess Embryos</b><br/> <b>Article 12.14</b> Researchers shall not ask, encourage, induce or coerce members of the health care team to generate more embryos than necessary for the optimum chance of reproductive success. This is tantamount to creating embryos for research, which is prohibited under the Assisted Human Reproduction Act.</p> <p><b>National Registry</b><br/> SCOC maintains an electronically accessible national registry of human pluripotent stem cell lines derived from an embryonic source, generated in Canada. Induced human pluripotent stem cell lines are not listed with the registry, as they are not derived from embryonic sources.</p> <p><b>Article 12.15</b> All human pluripotent stem cell lines derived directly from embryos under the auspices of an institution that is eligible to receive any Agency funds shall be listed with the national registry of human embryonic stem cell lines and made available by the researcher to other researchers, subject to reasonable cost-recovery charges.</p> <p><b>Privacy and Confidentiality</b> The secondary use of human biological materials for research purposes must meet the requirements of Articles 12.3A and 12.4 that provide detailed guidance on protecting personal information of participants. The following articles provide additional guidance for situations that are unique to stem cell research. In these cases, all human cells or cell lines should be delivered in an anonymized or coded form and, if coded, the key code should be accessible only to a custodian or trusted third party who is independent of the researcher who receives the cells (see Chapter 5, Section A, Types of Information).</p> |
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|  | <p><b>Article 12.16</b> All human pluripotent stem cell lines shall be anonymized or coded unless the research only involves the directed donation of induced pluripotent stem cells.</p> <p><b>Application</b><br/>While research involving the directed donation of human embryonic stem cell lines is not permitted under this Policy (Article 12.10.2 (c)), research involving the directed donation of induced pluripotent stem cells is permitted, as induced pluripotent stem cells are not derived from human embryos.</p> <p><b>Article 12.17</b> All researchers who make stem cell lines available to other academics shall ensure that the cell lines are anonymized or coded.</p> <p><b>Conflicts of Interest</b><br/>Chapter 7 (in particular <a href="#">Articles 7.2</a> and <a href="#">7.4</a>) provides guidance on conflicts of interest. The following articles provide additional guidance for situations that are unique to stem cell research.</p> <p><b>Article 12.18</b> Stem cell research teams shall not include members of the health care team treating and/or counselling prospective participants who could influence the prospective participants' decisions to donate their embryos.</p> <p><b>Application</b><br/>This article seeks to minimize the risk that, for the purposes of stem cell research, women will feel pressured to create more embryos than needed for reproductive purposes or be pressured to donate embryos no longer needed for reproductive purposes. There may be a risk of undue influence where health care team members are also members of the stem cell research team (see <a href="#">Article 3.1</a>).</p> <p><b>Article 12.19</b> When researchers or their institutions have, or acquire, financial interests in the outcome of the stem cell research including, but not limited to, income from commercial</p> |
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|  | <p>firms supporting their research, stock holdings in corporations supporting their research, or patents in products produced through their research, they shall disclose this information to SCOC, the REB and current and prospective research participants (see <a href="#">Articles 7.2</a> and <a href="#">7.4</a> regarding institution and researcher conflicts of interest). In some instances, disclosure may not be a sufficient response to concerns about actual, perceived or potential conflicts of interest. Researchers and/or their institutions may be asked to remedy any possible distortion of proper procedures attributable to such conflicts.</p> <p><b>Article 12.20</b> Copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information shall be provided to SCOC and the REB to examine and evaluate any potential or actual conflicts of interest and to ensure the right to publish in a timely manner without undue restriction.</p> |
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