Proposed Changes to TCPS 2

#	Reason for proposed change Reference in TCPS 2	Current Text	Proposed Text (*New/added text is in italics and bold)*
	Chapter 2		
1	Define disciplined inquiry. *Insert new text in Article 2.1, Application, end of 2nd paragraph, (p.15); Glossary (p. 191)*	No current text in TCPS 2.	***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.***
	Chapter 3		
2	Clarify TCPS 2's advocacy of a capacity-based approach to consent. *Article 3.3, Application, last paragraph (p. 34)*	In the case of children who begin participation in a project on the basis of consent from an authorized third party, the researcher must seek their autonomous consent if they reach the age of majority during the research, in order for their participation to continue.	In the case of children who begin participation in a project on the basis of consent from an authorized third party ***(because it was determined that they lacked capacity to consent on their own behalf),*** the researcher must seek their autonomous consent if***, during the research: (1) their cognitive capacity matures sufficiently to allow them to consent on their own behalf; or; (2)*** they reach the age of majority ~~during the research, in order for their participation to continue.~~ ***(a legal division between childhood and adulthood that varies by province and territory).***
3	Restructure Article 3.4. Introduce a preamble to the Article based on existing text in current application. Clarify that material incidental findings can appear at any stage of the research. *New preamble to Article 3.4. Moved text from 1st and 3rd paragraphs of current Application. (p. 34)*	**Incidental Findings** **Article 3.4 …** **Application** "Incidental findings" is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. If, in the course of research, material incidental findings are	**Incidental Findings** "Incidental findings" is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. ~~Material~~ Incidental findings are ***considered to be material incidental*** findings ~~that~~ ***if they*** have been interpreted as having significant welfare implications for the participant ~~whether health-related, psychological or social. . If, in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participant.~~ ***Material incidental findings may appear at any stage of the research including, for example, screening for eligibility***

		discovered, researchers have an obligation to inform the participant. … If researchers are unsure of how to interpret findings or uncertain whether findings are material, they should consult with colleagues or refer to standards in the discipline. If researchers are unsure of the most appropriate method for disclosing material incidental findings to participants, they should consult with their REB or with colleagues. Researchers should exercise caution in disclosing incidental findings that may cause needless concern to participants.	***of inclusion in a study population or in collecting baseline information, both of which may involve the participants' consent.*** 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. ~~If researchers are unsure of the most appropriate method for disclosing material incidental findings to participants, they should consult with their REB or with colleagues.~~ Researchers should exercise caution in disclosing incidental findings ~~that~~ ***without verifying that they are material,*** as this 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.***
4	Introduce conditions for the researchers' obligation to disclose material incidental findings to participants. Signal that exceptions to this obligation are possible. *Article 3.4 (p. 34)*	**Article 3.4** Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.	**Article 3.4** Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research ***if:*** ***(a) the disclosure is deemed advisable by the REB, and*** ***(b) the participant consents to the disclosure.*** ***The REB may grant researchers an exception to this obligation if researchers satisfy the REB that the disclosure is deemed impossible or impracticable.***
5	Clarify the first step in the decision-making process for the obligation to disclose material incidental findings: researchers report the findings to their REB. Provide criteria for the REB to decide whether incidental findings are material and whether the researcher's disclosure of the findings to the participant is advisable.	No current text in TCPS 2.	**Application** ***If, in the course of research, material incidental findings are discovered, researchers shall report them to the REB in accordance with Article 6.15. The researcher should provide enough information to enable the REB to determine whether the incidental findings are material, and to assess the risks and benefits of disclosing the findings to the participant. In confirming whether incidental findings are material, REBs should consider the significance and immediacy of the harm, and the strength of the evidence provided. REBs should assess the harm from the perspective of the participant to the extent***

	Article 3.4., Application. Insert new text as first paragraph (p. 34)		***possible. This assessment includes determining whether the disclosure of findings to the participant will allow the participant to take action to avoid or ameliorate a disease, condition or situation.***
6	Restructure existing text for flow. *Article 3.4, Application, 2nd paragraph (p. 34)*	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.	~~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~~ ***The report to the REB shall include the researchers'*** plan ~~indicating~~ ***for*** how they will disclose such findings to participants, ~~and submit this plan to the REB.~~ ***If researchers are unsure of the most appropriate method for disclosing material incidental findings to participants, they should consult their REB and/or their colleagues.*** 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.
7	Clarify the second step in the decision-making process for researchers to disclose material incidental findings to the participant: the researcher offers the choice of disclosure to the participant. *Article 3.4, Application, Insert new text as 3rd paragraph (p. 34)*	…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 Article 5.1).	***If the REB deems the disclosure to a participant advisable, the researcher shall offer a choice to the participant of whether or not to receive information about the individual material incidental findings. If the participant decides to receive the information about his/her individual material incidental findings (see Article 3.1) or an authorized third party exercises the authority in the best interest of the participant (see Article 3.9), the researcher shall disclose all known information about those findings to the participant/authorized third party (see Article 3.2).*** When necessary, researchers should ~~direct~~ ***offer to the*** participant***s options for support and referral*** to a qualified professional to discuss the possible implications of the ***material*** incidental findings for their welfare. In some cases, incidental findings may trigger legal reporting obligations ***(e.g. evidence of an infectious disease or child abuse)*** ~~and~~***. R***esearchers should be aware of these obligations ***(see Article 5.1).***
8	Elaborate on possible exceptions to the obligation of researchers to disclose material incidental findings to the participant.	No current text in TCPS 2.	***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 participant. "Impracticable" refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere***

	Article 3.4, Application, Insert new text as 4th paragraph (p. 34)		***inconvenience. 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. 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.***
9	To signal that the article pertains to critical inquiry, and for consistency of Article 3.6 and its application to broaden it beyond "organizations" *Article 3.6 (p. 35)*	Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.	***In critical inquiry, p***permission is not required from an ***institution****,* organization ***or other entity*** in order to conduct research on ~~that organization~~ ***them*****.** If a researcher engages the participation of members of **any such entity** without the ~~organization's~~ **entity's** permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.
10	Clarify advocacy of a capacity-based approach to consent *Article 3.7, Application, 2nd to last paragraph (p. 38)*	*Research Involving Partial Disclosure or Deception* … In some cases –for example, in research involving children – it may be more appropriate to debrief the parents, guardians or authorized third parties rather than the participants themselves.	*Research Involving Partial Disclosure or Deception* …In some cases – for example, in research involving children ***who do not have the capacity to consent on their own behalf –*** it may be more appropriate to debrief the parents, guardians or authorized third parties ~~rather than~~ ***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 a sensitive aspect of the child, such as intellectual capacity).***

11	Explain Article 3.7(d) when partial disclosure or deception may not be possible or appropriate. *Insert new text in Application, before the last paragraph (p. 38)*	No current text in TCPS 2.	***The intention of the phrase "whenever possible and appropriate" in Article 3.7 (d) is to acknowledge that there may be circumstances in which debriefing is not possible or would not be appropriate in research involving deception or partial disclosure. When identifying what types of research involving deception or partial disclosure justify no debriefing, REBs should consider the level of potential harm to the participant which the debrief itself may cause, the impact of the debriefing on the feasibility of the research, and whether a debriefing is even possible as a practical matter (e.g., an anonymous surveyor research conducted in a public space). The onus is on the researcher to provide justification to the REB where the researcher does not intend to debrief participants.***
12	Address the contradiction between Article 3.7, which states that debriefing may not always be possible or appropriate, and its Application that implies that debriefing is always required. *Article 3.7, Application, last paragraph (p.38)*	In studies involving partial disclosure or deception in which an alteration to the requirement for prior consent has been allowed, participants must nevertheless be able to indicate their consent or their refusal at the conclusion of the project, following debriefing.	In studies involving partial disclosure or deception in which an alteration to the requirement for prior consent has been allowed, participants ~~must nevertheless~~ ***should, whenever possible and appropriate,*** be able to indicate their consent or their refusal at the conclusion of the project, following debriefing.
13	Remove an unnecessary barrier to seeking waiver of, or an alteration to consent processes for research involving therapeutic, diagnostic or clinical interventions *Article 3.7 (p. 37)*	**Article 3.7** The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with Articles 3.1 to 3.5 where 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 lack of the participant's consent is unlikely to adversely affect the welfare of the participant; (c) it is impossible or impracticable to carry out the	**Article 3.7** The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with Articles 3.1 to 3.5 where 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 lack of the participant's consent is unlikely to adversely affect the welfare of the participant; (c) it is impossible or impracticable to carry out the research

		research and to answer the research question properly, given the research design, if the prior consent of the participant is required; (d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and (e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.	and to answer the research question properly, given the research design, if the prior consent of the participant is required; (d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and (e) ~~the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.~~
	Note: For all changes proposed for Article 3.7, see ***Proposed Revisions to Article 3.7 (December 2013)****.*		
	Chapter 5		
14	Clarify the assessment of identifiability is context-specific. *Add new text to definition of identifiable information in Chapter 5, Section A, Key Concepts, Identifiable Information (p. 56)*	Information that may reasonably be expected to identify an individual, alone or in combination with other available information, is considered identifiable information (or information that is identifiable) for the purposes of this Policy. Where the term "personal information" appears in this Policy, it refers to identifiable information.	Information that may reasonably be expected to identify an individual, alone or in combination with other available information, is considered identifiable information (or information that is identifiable) for the purposes of this Policy. Where the term "personal information" appears in this Policy, it refers to identifiable information. ***The assessment of whether information is identifiable is made in the context of a specific research project.***
15	Clarify that even anonymous information can present risks of re-identification *Insert new text to discussion in Chapter 5, Section A, Key Concepts, Types of Information (p. 57)*	Although these measures are effective ways to protect participants from identification, the use of indirectly identifying, coded or anonymized information for research may still present risks of re-identification.	Although these measures are effective ways to protect participants from identification, the use of indirectly identifying, coded, anonymized ***or anonymous*** information for research may still present risks of re-identification.

16	Create new article from first line of Article 5.5 Application and clarify the assessment of identifiability is context specific. *Add new text of Article 5.5A* *Delete first line of Article 5.5, Application (p. 63)*	This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable information.	***Article 5.5 A*** ***Researchers must seek REB review, but are not required to seek participant consent for research that relies exclusively on the secondary use of non-identifiable information.*** ***Application*** ***The onus will be on the researcher to establish to the satisfaction of the REB that, for the purposes of the proposed research, the information to be used is non-identifiable. For example, the secondary use of coded information may identify individuals in research projects where the researcher has access to the code. 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 code. Consent would not be required in this situation.*** Article 5.5, Application ~~This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable information.~~ In the case of secondary use of identifiable information, researchers must obtain consent in accordance with applicable laws, unless the researcher satisfies all the requirements in Article 5.5.
	Chapter 6		
17	Provide guidance when determining which is the "highest body" of the institution for the purposes of establishing the REB. *Article 6.2, Application, 1st paragraph (p. 68)*	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 shall have in place written procedures for the appointment, renewal and removal of REB members.	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 what is 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.
18	Clarify that thesis-based student research should be reviewed by the regular institutional REB procedures. *Article 6.12, Application 6th paragraph (p. 78)*	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. If these activities are used for the purposes of research (e.g., as part of a researcher's own research program), they should be reviewed by the regular institutional REB procedures. The REB…	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 research program), they should be reviewed by the regular institutional REB procedures. ***Theses or equivalent research projects involving human participants generally meet this Policy's definition of research (see Application of Article 2.1), and should be reviewed by the REB following a proportionate approach (see Article 6.12).*** The REB…
19	Clarify the circumstances in which annual renewals of more than minimal risk research may be done by delegated review. *Article 6.12, Application 8th paragraph (p. 78)*	Examples of categories that may be delegated for research ethics review include: ▪ … ▪ annual renewals of more than minimal risk research where the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis.	Examples of categories that may be delegated for research ethics review include: ▪ … ▪ annual renewals of more than minimal risk research where ***the phase or intervention that is more than minimal risk is complete, and the remaining phase(s) is only minimal risk*** −the research will no longer involve new interventions to current participants, renewal does not involve the recruitment of new participants, and the remaining research activities are limited to data analysis. ▪ ***annual renewals of more than minimal risk research as long as: (1) the REB Chair remains responsible for determining that the delegated review process is appropriate; and (2) there have been no significant changes to the research and no increase in risk to (or other ethical implications for) the participants since the initial review by the full REB.***

			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.
20	Provide guidance for institutions on how to determine the point after which REB review would no longer be required, while taking into account the different types of research designs. *Insert new text in Article 6.14, Application 3rd paragraph (p. 80)*	No current text in TCPS 2	***Institutions should develop policies that establish criteria to determine the point at which REB review would no longer be required. Such policies should take into consideration the different types of research designs (short-term project, longitudinal research, research with reporting back requirements, etc.). Such policies and associated procedures should guide the REB, researchers and the institution to determine at what point in the life-cycle of the project REB involvement is no longer required.***
	Chapter 9		
21	Flag that guidance in Chapter 9 or some aspects of it may also apply to other communities – where relevant. *Insert new text in Preamble 2nd to last paragraph (p. 106)*	No current text in TCPS 2	***While this chapter is designed to guide research involving First Nations, Inuit and Métis Peoples of Canada, its discussion of respectful relationships, collaboration and engagement between researchers and participants may also be an important source of guidance for research involving other distinct communities. The need to respect a community's cultural traditions, customs and codes of practice may extend beyond First Nations, Inuit and Métis communities. REBs and researchers may draw on articles of this chapter that are of relevance for the particular community involved in the research.***
	Chapter 10		
22	Provide appropriate examples of "public spaces" for the purposes of observational studies. *Article 10.2, Application (p.141)*	**Observational Studies** 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	**Observational Studies** 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

		may be undertaken in publicly accessible spaces (e.g., classrooms, hospital emergency wards, locations where religious services or practices are held)…	publicly accessible spaces (e.g. ~~classrooms, hospital emergency wards~~ ***a stadium, library, museum, planetarium, beach, park***, locations where religious services or practices are held) …
	Chapter 11		
23	Address concerns that the parenthetical phrase is inaccurate and potentially confusing – not all clinical trials involve patient populations *Introduction, 2nd paragraph (p. 147)*	For the purposes of this Policy, a clinical trial, a form of clinical research (also known as patient-oriented research), is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes	For the purposes of this Policy, a clinical trial, a form of clinical research ~~(also known as patient-oriented research)~~, is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes
24	Specify what information is required for the registration of clinical trials. *Article 11.3, Application last paragraph (p.157)*	Clinical trials shall be registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE) as of November 2010. Researchers shall provide the REB with the number assigned to the trial upon registration.	Clinical trials shall be registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE) as of November 2010. ***All fields outlined in the WHO Trial Registration Data Set (TRDS) must be completed in order for a trial to be considered fully registered.*** Researchers shall provide the REB with the number assigned to the trial upon registration.
25	Require that any changes to the trial (e.g. new information, decisions to stop or unblind, unanticipated events, safety reports, etc.) are reported in the public trial registry. *Article 11.8 (p. 161)*	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.	Researchers shall promptly report new information that may affect the welfare or consent of participants to the REB, ***to the publicly accessible registry where the trial is registered,*** and to other appropriate regulatory or advisory bodies.
26	Require that any changes to the trial (e.g. new information, decisions to stop or unblind, unanticipated events, safety reports, etc.) are reported in the public trial registry.	Article 11.8 outlines the continuing duty of researchers to share new and relevant information regarding clinical trials with the REB and other relevant bodies, and with participants and their primary care clinicians, as indicated by the nature of the information.	Article 11.8 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,*** ~~and~~ other relevant bodies, and with participants and their primary care clinicians, as indicated by the nature of the information.

	Article 11.8, Application 1st paragraph (p. 161)		
27	Require that any changes to the trial (e.g. new information, decisions to stop or unblind, unanticipated events, safety reports, etc.) are reported in the public trial registry. *Article 11.8, Application 6th paragraph (p. 162)*	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, the REB of the discontinuance or unblinding and the reasons for it.	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, the REB***, and the publicly-accessible registry where the trial is registered*** of the discontinuance or unblinding and the reasons for it.
28	Require that any changes to the trial (e.g. new information, decisions to stop or unblind, unanticipated events, safety reports, etc.) are reported in the public trial registry. *Article 11.9, Application 1st paragraph (p. 163)*	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 Article 11.7).	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 Article 11.7). ***Researchers must also update the publicly accessible trial registry where their trial is registered.***
29	Clarify the responsibility of the REB regarding the review of potential conflicts of interest in clinical trial budgets. *Article 11.11, Application 1st paragraph (p. 164)*	REBs may delegate the review of clinical trial budgets to an appropriate institutional body. The body should ensure financial conflicts of interest are reported to the REB.	REBs ~~may delegate the review of clinical trial budgets to~~ ***should consider whether there is*** an appropriate institutional body ***to review conflicts of interest in clinical trial budgets***. The REB ***must ensure that this body*** ~~should ensure~~ ***reports all*** financial conflicts of interest ~~are reported~~ to the REB..
30	Resolve inconsistencies in terminology in the article re: findings and to harmonize this guidance with CIHR program	**Article 11.12** With respect to research findings: (a) Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions publish or	**Article 11.12** With respect to research findings: (a) Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions publish or

	guidelines regarding dissemination of clinical trial results. *Art.11.12(a), Application, 1st paragraph (p. 165)*	otherwise disseminate the analysis of data and interpretation of clinical trial results in a timely manner without undue restriction. **Application** …If research 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 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 raw data and results in appropriate databases. In publications, they have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials).	otherwise disseminate the analysis of data and interpretation of clinical trial results ***(i.e. the findings)*** in a timely manner without undue restriction. **Application** …If research 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 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 ~~raw data and results in appropriate databases~~ ***the findings***. In publications, they have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials). ***Researchers are encouraged to make their raw data available for further analysis or verification by their peers***.
31	Avoid the potential for broad or diverse misinterpretation by specifying the detailed requirement. Also, to add a requirement that researchers disclose any new information affecting the welfare of participants at the end of the trial in subsequent publications. *Article 11.12, Application 1st paragraph (p. 165)*	For this reason, and based on respect for participant expectations and protection of the public good, researchers 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. In publications, they have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials). Researchers are encouraged to make their raw data available for further analysis or verification by their peers.	For this reason, and based on respect for participant expectations and protection of the public good, researchers 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 ***in a publicly accessible registry where the trial will be registered***. In publications, they have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials). Researchers are encouraged to make their raw data available for further analysis or verification by their peers.

		[This text presumes the changes in #20 have been accepted.]	***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.***
32	Eliminate potential conflict between TCPS 2 and the Model Clinical Trials Agreement. http://www.cihr-irsc.gc.ca/e/44186.html *Article 11.12, Application 6th paragraph, item 4 (c) (p. 166)*	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 Chapter 7 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. 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: … 4. provide that all confidentiality and publication clauses: (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); (b) be reasonable in terms of any limitations or restrictions on the publication or other dissemination or communication of information; and (c) permit researchers to access all trial data.	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 Chapter 7 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. 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: … 4. provide that all confidentiality and publication clauses: (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); (b) be reasonable in terms of any limitations or restrictions on the publication or other dissemination or communication of information; and (c) permit ~~researchers~~ ***principal investigators*** to access all trial data; ***(d) permit researchers to access all trial data collected at their respective sites;*** ***e) permit all researchers to access all trial data in cases where no principal investigator is named.***

	Chapter 12		
33	Create new article from first line of Article 12.3 Application and clarify the assessment of identifiability is context specific. *Add new text of Article 12.3A* *Delete first line of Article 12.3, Application (p. 173)*	This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable human biological materials.	***Article 12.3 A*** ***Researchers must 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.*** ***Application*** ***The onus will be on the researcher to establish to the satisfaction of the REB that, for the purposes of the proposed research, the human biological materials to be used are non-identifiable. For example, the secondary use of coded human biological materials may identify individuals in research projects where the researcher has access to the code. 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 code. Consent would not be required in this situation.*** Article 12.3, Application ~~This Policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable human biological materials.~~ In the case of the secondary use of identifiable human biological materials, researchers must obtain consent in accordance with applicable laws, unless the researcher satisfies all the requirements in Article 12.3.
34	Clarify definition of fetal tissue *Add text to definition of fetal tissue in Chapter 12, Section E (p. 177)*	Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.	Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus. ***Fetal tissue is regarded as part of the fetus prior to separation of the fetus from the woman.***

35	Strengthen and clarify condition for research involving fetus or fetal tissue. *Change and add text to Article 12.9 (b) (p. 178-179)*	Article 12.9 Research involving a fetus or fetal tissue: (a) requires the consent of the woman; and (b) should not compromise the woman's ability to decide whether to continue her pregnancy.	Article 12.9 Research involving a fetus or fetal tissue: (a) requires the consent of the woman; and (b) ***shall*** not compromise the woman's ability to decide whether ***or not*** to continue her pregnancy.
36	Clarify consent where fetus has been born alive. *Add text to Article 12.9, Application (p. 179)*	Article 12.9 Application Research may be undertaken on methods to treat, in utero, a fetus with genetic or congenital disorders. Because the fetus and the woman cannot be treated separately, any intervention to one involves an intervention to the other. Research involving a fetus or fetal tissue shall be guided by respect for the woman's autonomy and physical integrity. Guidance provided in other chapters of this Policy (e.g., consent, privacy and confidentiality, inclusion and exclusion) will also apply. Researchers should ensure that a clear distinction is made between consent to research and consent for any clinical procedures or testing. In practice, this may mean separate consent information and documents, but regardless of the process employed, the differences between research and clinical procedures must be clearly explained.	Article 12.9 Application Research may be undertaken on methods to treat, in utero, a fetus with genetic or congenital disorders. Because the fetus and the woman cannot be treated separately, any intervention to one involves an intervention to the other. Research involving a fetus or fetal tissue shall be guided by respect for the woman's autonomy and physical integrity. Guidance provided in other chapters of this Policy (e.g., consent, privacy and confidentiality, inclusion and exclusion) will also apply. Researchers should ensure that a clear distinction is made between consent to research and consent for any clinical procedures or testing. In practice, this may mean separate consent information and documents, but regardless of the process employed, the differences between research and clinical procedures must be clearly explained. ***Where the fetus has been born alive, research involving human biological materials associated with the child must meet the conditions of Article 3.9.***