



30 June 2009

Susan Zimmerman, Executive Director
Interagency Secretariat on Research Ethics
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Dear Ms. Zimmerman:

RE: Written comments on the Draft 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)

We are writing as members of the Canadian Subcommittee of the IRB/REB Workgroup on Community-Engaged Research, convened and supported by Community-Campus Partnerships for Health.¹ We are a group of individuals from across Canada with expertise in collaborative approaches to community-university research and in ethical aspects of community-engaged research. We write with substantive feedback regarding the Draft 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

Thank you for this opportunity to provide feedback on the Draft. Please note that this is the second of two submissions from our group. In our first submission, we recommended an extension and expansion of the consultation process. We appreciate the three-month extension offered by the Interagency Panel on Research Ethics (PRE) and the Interagency Secretariat on Research Ethics (SRE). However, as indicated in our previous letter (March 18, 2009), we believe that a minimum extension of six months combined with targeted engagement of community members and community groups through existing research partnerships would be necessary to enable adequate community input on the Draft. We are disappointed that, despite the concrete suggestions we made and our offer to assist, we are not aware of an expansion of community consultation efforts regarding the Draft.

We enclose our substantive written comments on the Draft as an appendix to this letter (located at the end of the letter, after the signatures and cc list). As you can see from our comments, we believe

¹ Community-Campus Partnerships for Health (CCPH) is a nonprofit organization that promotes health (broadly defined) through partnerships between communities and higher educational institutions. See: www.ccpb.info. The Workgroup is developing a curriculum for administrators and members of Canadian and American Research Ethics Boards and Institutional Review Boards. The working title of the Curriculum is *IRB/REB Curriculum on Ethical Considerations in Community-Engaged Research*. See: <http://depts.washington.edu/ccph/irbhome.html#Committee>. The Canadian subcommittee was established to ensure that the curriculum is relevant and responsive to the Canadian context.

significant changes are needed in the final version. We also see the absolute need for greater public participation by community and community-based research partners, particularly Aboriginal partners. Please note that many of our specific comments overlap with those submitted by the *Intellectual Property Issues in Cultural Heritage Project*, due to our shared interest and expertise in community-based research and an overlap in our memberships.

We strongly encourage PRE and SRE to develop a **more strategic and wide-reaching consultation plan** to engage community research partners. We believe such an investment of time and resources will be both time- and cost-effective over the longer term and forestall problems that may arise in the future due to inadequate community input.

Again, we applaud the progress to date on developing the Draft. As before, we stand ready to assist you in this effort.

Thank you in advance for your consideration.

Sincerely,



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(Note: permission is hereby granted for posting this comment on the dedicated webpage for submissions to PRE on the Draft 2nd Edition of the TCPS)

APPENDIX:

Written comments on the Draft 2nd Edition of the TCPS submitted by the Canadian Subcommittee of the IRB/REB Workgroup on Community-Engaged Research, convened and supported by Community-Campus Partnerships for Health

The following compilation of comments is based on a critical review of the Draft from the **perspective of individuals who are involved in community-based research (CBR)**² and have expertise in ethical issues arising in CBR. Please note that there are a number of excellent improvements to the Draft 2nd Edition over the existing TCPS that are not specifically indicated here. One of these is that the proposed definition of “research” in the Draft is a significant improvement over that found in the existing TCPS. General comments about the entire Draft are compiled upfront and then specific comments are presented in tabular form according to chapter (with pages and lines indicated where relevant) for ease of reference.

A. GENERAL COMMENTS

The Draft begins, but does not go far enough, to incorporate the methods, language and sentiments of community-based research in a meaningful way. The Draft falls short on details about true research partnerships and the sharing of power and control that is integral to such partnerships. While there is a number of terms (discussed below) related to community involvement, there is no philosophical or practical consistency in how the terms are applied and what is intended by their use. The resulting impression is that “community-engagement” is recognized as important for a variety of reasons, but concrete and informed guidance for researchers seeking to do research involving communities is largely lacking in the Draft. It is a major oversight to partition community-based research into chapters (i.e., Chapters 9 and 10) since this approach to research may or may not be qualitative in nature (it is often a combination of qualitative and quantitative methods) and may or may not involve Aboriginal communities. There is helpful guidance on community-based research in Chapter 9 that should more generally be applied to research involving any community. **We strongly recommend that one or more respected individuals with expertise in community-based research be recruited to advise on further development of the Draft into its final form.** We would be pleased to assist you in this regard.

Generally, the term “**engagement**” as in “community-engagement” is overused and undefined, leaving the intentions too open to interpretation. While the term is ‘trendy’ at present (indeed, our workgroup chooses to use it to encompass multiple approaches to research conducted in communities and not to inadvertently imply the curriculum we are developing pertains only to one particular approach), we predict it will one day be passé, and a more prudent use of the term would strengthen and clarify the Draft, and make it more widely understood. As noted by a colleague from Uganda who was new to the use of the term community-engagement in a research context, “I’m interested in research, not marriage.” There are examples throughout where the term “engagement”

² We acknowledge multiple definitions exist for community-based research. We use the term (as described by the WK Kellogg Foundation Community Health Scholars Program) to mean a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBR begins with a research topic of importance to the community with the aim of combining knowledge and action for social change.

would be better substituted, a notable one is in Chapter 13 p.153 lines 5331-5332: “Researchers may have an ethical obligation to seek the engagement of leaders or representatives of the community...”

Throughout the Draft, various terms are used that refer to **community involvement in research**, such as: “community-based research,” “collaborative research,” “community-based projects,” “collaborative, community-based research,” “collaboration with communities,” “community-based and/or organizational research,” “participatory action research,” and “community-based concerns.” None of these terms are defined or explained to an adequate degree, leading to confusion as to the specific intention of their use by anyone who is familiar with community-based research. In general, the terms seem to be used interchangeably. A more purposeful use of each of these terms, and clarification as to their intended meaning, is needed throughout the Draft.

The term “**protocols**” is used extensively and variously in the Draft but not defined. This is a term that has also become trendy and tends to be overused as a catch-all for guidelines, ethical codes, codes of conduct and other guidance documents that codify expectations for behaviours, but it has very specific meaning in some contexts (particularly Aboriginal contexts) that may have nothing to do with research. There appears to be interchangeable use of the terms “protocols,” “research protocols,” “ethical protocols,” “community ethics codes and protocols,” “community protocols,” “Inuit and First Nations protocols,” “community, regional or organization protocols,” “established mechanisms or guidelines,” and “protocols under the authority of formal leaders, such as chiefs and band councils or hamlet councils.” At minimum, when the term “protocols” is used in the Draft, it should more accurately appear as “**research protocols**” in most cases to make clear what is being referred to. When other types of protocols are being discussed, they should likewise be clearly and consistently indicated. For example, also variously used but not defined are the terms “professional protocols,” “interview protocols,” “professional interview protocols,” and “operative protocols.” A careful review of the Draft for use of these terms, and an effort to be consistent and purposeful in their use, is needed to avoid confusion or assumptions that everyone reading the Draft somehow intuitively understands their meaning(s), despite coming from different backgrounds, experiences and cultures.

A **Glossary of Terms** is a vital section that is missing in the Draft. All key terms should be defined when first used in the Draft (many are not) and these should also be found in a Glossary for easy reference, to facilitate cross-disciplinary understanding, and to make the Draft more comprehensible to students, community members and others who may be new to research. Examples include:

- Aboriginal knowledge
- Community-based research (and associated terms)
- Community-engagement
- Conflict of interest
- Creative practice
- Critical inquiry
- Cultural heritage
- Cultural knowledge
- Cultural property
- Free and informed consent
- Identifying information (and associated terms)
- Incidental findings
- Indigenous knowledge

- Personal information
- Protocols (and associated terms)
- Quality assurance (and associated terms)
- Research
- Scholarly review
- Secondary use

We observe that many of the **Articles** are long and long-winded, diluting their impact. Given the extensive explanatory text included in most “Application” sections, each Article should be as concise, direct and prescriptive as possible. The introduction to the Draft makes it clear that there is interpretation and discretion involved in applying the Articles so it is not necessary to soften the impact of the Articles any further by frequent use of “should” or “consider.”

The Draft professes (p 94, lines 3233-3236) to provide “guidance on issues that have been raised ... in the *CIHR Guidelines for Health Research Involving Aboriginal People (2007)*”. Other than listing the *CIHR Guidelines* as references in Chapters 9 and 10, and use of information related to when an Article may apply in an Aboriginal context, there appears to be **no specific or general attempt to incorporate or refer to the *CIHR Guidelines* in any substantive way** in the Articles. We recommend that a strong linkage between the TCPS and the *CIHR Guidelines* be made and that reference to specific Articles in the *CIHR Guidelines* be made when substantive guidance overlaps with, or is absent in, the TCPS Draft. One important example is including reference in Chapter 9 to the sample research agreement provided as an appendix in the *CIHR Guidelines*.

B. SPECIFIC COMMENTS

Chapter 1: Ethics Framework

The three core principles are expressed in rather stark, legalistic and academic language. Written as is, they do not provide an inviting introduction to the Draft that inspires researchers to read the document.

The core principles are said to transcend disciplinary boundaries but are they cross-cultural? Missing up front is acknowledgement of the “collective” aspect to all of the core principles, extending ethical considerations beyond the self-interested rational individual (i.e., the fundamental unit of western society). This omission serves to alienate at the onset societies, cultures and communities in which collective welfare is a priority. The collective nature of “Autonomy” is described p. 3 (lines 106-111). An analogous description for “Welfare” is needed on p. 2 (after line 64), equivalent to that found in Chapter 9 (p. 91, lines 3127-3128) as this (i.e., concern for welfare must be broader than just the individual and consider individuals embedded in relationships) holds true beyond just an Aboriginal research context. It should be explicit and upfront in the Draft.

Specific recommended changes to Chapter 1 are tabulated for ease of reference:

Line	Page	Comment and/or change recommended
65	3	To extend the concept of welfare beyond the “individual” to collectives such as communities, insert text here that is equivalent to p. 91, lines 3126-3128: “Concern for welfare includes individual well-being, but broadens the focus of

		ethics to consider individuals imbedded in relationships in their physical, social, economic and cultural environments.”
77	3	Clarification is needed on what is meant by “Prior to the research’s being presented to prospective participants...” Assuming there is a typo and “research’s” should be “research”, it is still unclear the point in time/process that is being referred to here, especially in light of Article 10.6 “REB review is not required for the initial exploratory phase when the research is developing the research design.”
81-84	3	In some cases (e.g., community-based research), there is a collective aspect to risks (in addition to the individual aspect) that needs to be indicated here. It is elaborated in later sections but should be raised at the onset. Prospective research participants should be involved in identifying what the expected collective risks are as these may not be obvious to the researcher.
87-91	3	<p>“Respect for autonomy implies that participation in research should usually be voluntary – a matter of choice. To be meaningful, that choice should be informed. This means it should be based on as complete an understanding as reasonably possible of the purpose of the research, what it entails, and its foreseeable risks and benefits, both to the participant and to others.”</p> <p>Uninformed choice is not meaningful. The text should read: “To be meaningful, that choice <u>MUST</u> be informed.”</p>
112-113	3	<p>“This does not, however, imply that group consent is a condition of ethics approval.”</p> <p>It is unclear what is being implied here if group consent is not a condition of ethics approval. Restate in the positive and be explicit about the intention of the information.</p>
179-181	5	<p>“Finally, it is not enough to say that ethics review must be approached from the perspective of the participant. It is necessary to consider the context – social, economic, cultural or other – that shapes the participant’s life.”</p> <p>This important point needs to be emphasized throughout the Draft.</p>
185-186	5	What are the tools available to REBs to facilitate consistent interpretation of the TCPS?
194-201	6	Does the “Policy” that must be upheld consist of the Articles or the entire document including Application and References? This should be stated clearly and not assumed.

Chapter 2: Scope and Approach

Line	Page	Comment and/or change recommended
239-241	8	<p>“A determination of the <u>intended purpose</u> of the undertaking, as distinct from the use of potentially similar methods, is key for differentiating activities that require review by an REB and those that do not.”</p> <p>What is meant by “intended purpose” of the undertaking? This needs to be explicit since it is key to differentiating research (where the TCPS applies)</p>

		from other activities (where the TCPS does not apply). For example, does intended purpose mean peer-reviewed publication? Does it include other forms of public dissemination such as a conference or workshop presentation, an article in an academic newsletter, a publically-available report?
312-314	9	It is unclear what is meant by “research on the interface between environmental and human systems” which does not require REB review. Does this include ethnobiology (the study of relationships between humans and environment) or cultural ecology (the study of human interaction with ecosystems)? An example should be provided to clarify this text.
417-419	12	“The ethical acceptability of research is dependent on a <u>judgment</u> as to whether the potential benefits justify the risks...”
444-447	13	<p><i>and</i></p> <p>“Research in certain disciplines...may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.”</p> <p>It is important that the judgment of acceptability of risks/potential benefits is based on the participant’s as well as the researcher’s perspective since participants will have different awareness than the researcher. This is especially the case when interests of communities or other collectives are involved.</p> <p>Insert text equivalent to p. 14, lines 484-485 here (up front) but also include “<u>harms</u>”, i.e., “Risks and benefits must be evaluated in the context of research and, to the extent possible, from the perspective of participants, because both risks and benefits may be perceived differently by different individuals.”</p> <p>Sentiments expressed about privacy and confidentiality (p. 43, lines 1473-1476) should be paralleled here in terms of risk/benefit/harm/burden, i.e., “Researchers and research ethics boards (REBs) should identify and mitigate privacy risks, keeping in mind that a matter that is not considered sensitive or embarrassing in the researcher’s culture may be so in a prospective participant’s culture.”</p>
427	12	<p>“Participants should share both the <u>burdens</u> and the benefits of research.”</p> <p>The term “burden” is mentioned several times in the Draft but does not appear to be elaborated or discussed in any depth. It would be helpful to understand what is intended by the term (e.g., financial? time? workload?) because it is not intuitive to expect participants to take on a burden, rather it is intuitive that researchers work to minimize the burden of research participation. An elaboration of “burden” could be included in Chapter 4.</p>
582-585	16	<p>“<u>Nothing</u> in this section, however, shall be interpreted to mean that other relevant parts of this Policy – such as the need for REB review, interview protocols, free and informed consent and privacy – are <u>not applicable</u> to their research.”</p> <p>This sentence is convoluted and confusing. It should be restated with omission of double negative.</p>

612-613	18	Autoethnography is not an appropriate example to use for this exemption since it is possible but unlikely that most people would reflect only about his/herself without referring to any other person
619-622	18	Use of an example that involves community-based participatory research would be appropriate here

Chapter 3: Free and Informed Consent

The range and flexibility in demonstrating evidence of consent is appropriate. However, consent is separate from a **research agreement**. Research agreements should be written and should be discussed in this chapter and resources to assist in developing research agreements should be included.

Line	Page	Comment and/or change recommended
739	23	ADD TEXT: “Such situations need to be made clear to the participants in advance of consenting.”
777	24	“The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research.” Is this a university staff person (third-party) or a member of the research team?
779-780	24	“Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research” Is this intended as a person or some other kind of resource? If a person, this should be explicit (this appears to be case based on p. 26 lines 849-852).
806	25	“The time required for providing <u>an</u> initial free and informed consent...” Is “an” a typo (it doesn’t make sense)?
834	25	“It is equally important that prospective participants be made aware of their right to withdraw from a research study at any time.” Participants also need to be made aware to limits to the ability to withdraw (if any) based on methodology.
903	27	Incidental findings may also arise in ethnobotanical research (e.g., commercializable products) and lead to important intellectual property and ownership issues. This example could be included along with the genetic research example.
1272	36	“Hence, written consent is not the norm in qualitative research. Rather, qualitative researchers use a range of consent procedures, including oral consent, field notes, and other strategies, for documenting the consent process.” It is not true that written consent is not the norm in qualitative research – it depends on the qualitative research being undertaken. It is true that qualitative researchers use a range of consent procedures, INCLUDING written consent. The first sentence should be deleted and the second sentence should be revised as: “Qualitative researchers use a range of consent procedures, including <u>written consent</u> , oral consent, field notes, and other strategies, for documenting the consent process.”

Chapter 4: Inclusion in Research

While there is nothing in Chapter 4 about community-based research, this approach facilitates “fairness of the distribution of benefits and burdens” of research in that community people are more grounded and better informed about what that fairness looks like and what the benefits and burdens are (which are often invisible to outside researchers).

Article 4.5 should include the notion of minimal burden, as included in The World Medical Association Declaration Of Helsinki (found in the Note, p. 41, line 1452)

Chapter 5: Privacy and Confidentiality

Line	Page	Comment and/or change recommended
1572-1574	46	Both researchers <u>and participants</u> should be aware of laws that require disclosure of information obtained in a research context.
1651-1654	48	<p>“In some instances, participants may wish to be identified for their contributions to the research. Where possible, researchers should negotiate agreement with participants about if and how participants may be identified to recognize their contribution.”</p> <p>The agreement should be spelled out in writing (i.e., in a written research agreement).</p>
1719-1720	49	The section on Secondary Use should address the ethical dilemma of use of published personal information that did not get into the literature by ethical means. Over the last century in some fields of study, such as ethnography or ethnobotany, personal and cultural information (e.g., traditional plant medicines, stories) held by individuals have been published without the awareness or consent of the participant. To ignore this point just because the information is in the public domain is to perpetuate further unethical research. It is a difficult and far-reaching problem to address this unfortunate legacy but it should be highlighted in this section to raise awareness and suggest a more ethical process for secondary use of such information. The recommendation found on p. 51, lines 1777-1778 “Consultation with representatives of individuals or groups about whom the information relates” would be an appropriate and ethical path forward in such cases.
1746-1754	50	<p>“Known objections to secondary use should be respected. An individual may express objection to future uses at the time of initial data collection or may, at some later point, contact the organization or individual who holds the data to request that it not be used for secondary research.”</p> <p>The onus should be equally if not more on the <u>researcher</u> to actively find out if there are objections for use, not on the participant who may only find out coincidentally that his/her information is being used. In the example used, how would an individual living in a non-urban location with more limited access to news or in a location geographically distanced from the where the research is</p>

		taking place (making it unlikely that the research project would make it into the local news in the first place) even find out about a study being done?
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Chapter 6: Governance of Research Ethics Review

We believe there is a strong case for reconsideration of this important chapter, based on the area of discourse ethics and discussions during the recent NCEHR conference in Ottawa (Feb 21-22, 2009). More than just a new version of the TCPS is needed - a new governance model is needed that is less concerned with the possibilities of litigation (i.e., legalistic/regulatory model), and more concerned with ensuring that research ‘gets it right’ in the first place for the dignity of all those implicated. This is the highest order principle, and the most important principle where community-based research is concerned.

In his plenary talk on “governance” at the NCEHR conference, Greg Koski (Harvard University) suggested there may be a role for professionalization of ethics review - ensuring that resources and ethics expertise are properly allocated to research ethics (i.e., a model in which people are hired to manage the ethics review system as their primary function/role/profession). This might mean transferring voluntary peer review processes to an enhanced system that pays professionals to review ethics. The allocation of resources to ethics or the development of a research ethics profession to fulfill review roles is an institutional or organizational management decision, and not in conflict with the TCPS as far as we can tell.

Governance of research ethics review should be referring to ensuring the principles expressed in the TCPS (which hopefully represent the best interests and vision of Canadian society) are enacted as intended, and do not get sidetracked into meeting the perceived needs of the institution or assuming that all roads concerning ethics may lead to litigation. The governance itself relates to having a vision and principles, and upholding and sometimes defending the vision and principles of the organization (in this case those of the TCPS). We do not see that governors of research ethics boards at the institutional level or the national level should necessarily do the work of the organization but their job is to ensure that the work is done as intended. Their roles as governors are then to be accountable and transparent, meaning also that these governors are positioned in such a way that their responsibilities are to participants, researchers and society as a whole, rather than to the institutions.

Governance is intended to be a flexible and responsive concept but this chapter severely limits institutional responses (e.g., Article 6.5 lines 1945-1954 on p. 57 that specifies REB composition). Representation is important, as is participation, but representation is not sufficient in itself. Perhaps there is a role for specialty boards. Perhaps individual institutions can organize themselves to oversee ethics review in the way they see fit, including professionalization of ethics (preview) and review, but the role of governance of research ethics is always to ensure dignity, integrity, transparency etc. in research, and to fulfill the characteristics of ‘good’ governance. We recommend that “professionalization” of research ethics review, as described above, be fully explored and considered as an option in Canada.

Line	Page	Comment and/or change recommended
1906-1908	56	<p>“In order to ensure that REBs are able to operate effectively and independently, institutions should dedicate the <u>appropriate</u> financial and human resources to their support.”</p> <p>The word “appropriate” should be replaced with “adequate” or sufficient”. What is the mechanism to ensure sufficient resources are dedicated by each institution? Should there be an ongoing independent assessment conducted by SRE (e.g., surveys of REB members and staff) to determine this and encourage institutions in this direction if resources are determined inadequate by those staff and volunteers who are bearing the burden of work?</p>
1964	57	<p>Article 6.4 states that for REBs “At least one member is knowledgeable in ethics.” Is this sufficient given the diversity of ethical issues that arise across different disciplines? Does this put an unreasonable burden on one individual to be able to “guide an REB” (as indicated p.58, line 1982)? Given the acknowledgement on p. 58 lines 1987-1989 that “a member knowledgeable in ethics serving on a social sciences and humanities REB may have different contextual and disciplinary knowledge in ethics than has a member of a biomedical REB”, we recommend that Article 6.4 be changed to <u>at least two members from different disciplinary backgrounds are knowledgeable about ethics.</u></p>
1952-1954	57	<p>Article 6.4 states that for REBs “At least one member has no affiliation with the institution, but is recruited from the community served by the institution and has relevant experience or training.”</p> <p>We believe that only one community representative is insufficient. How can one person represent the diverse communities involved in the research that an REB reviews? Further, will that one person be a demographically selected representative and thus not particularly invested in 'the community'? If that person were recruited based on their investment in 'the community', which community would that be? Does this put an unreasonable burden on one individual to represent 'the community'? The requirement appears to be more one "of non-university affiliation" than "of community."</p> <p>The phrase "the community <u>served</u> by the institution" is unclear and raises questions of potential conflict of interest (it also appears p. 61 line 2097). We suggest the language be changed to "<u>members that reflect the diverse communities involved in the research that an REB reviews.</u>" We further recommend that a person with expertise in community-based research be considered as one of the required members of every REB that reviews research involving communities. We suggest specifying a minimum percentage of the REB that should be comprised of community members. For example, Community-Campus Partnerships for Health has been recommending at least 25% of Institutional Review Board members in the USA be community members.</p>
1969	57	<p>ADD TEXT: “Community representation should be proportionate to the size of</p>

		<p><u>the REB AND SHOULD BE COMPRISED OF INDIVIDUALS FROM A DIVERSITY OF BACKGROUNDS AND COMMUNITY AFFILIATIONS.</u>”</p> <p>Note that we strongly support the recommendation on p. 58-59, lines 2005-2016 that the community REB member be a former research participant. However, we note also that it is common practice for the community REB member to be a paid staff person from a highly organized community group, such as a health authority, which is invaluable but does not necessarily provide the vital perspective of a research participant.</p>
2017-2019	59	<p>ADD TEXT: “To maintain effective community representation, the number of community representatives should be commensurate with the size of an REB and should increase as the size of an REB increases <u>AND WITH THE FREQUENCY OR EMPHASIS ON COMMUNITY-BASED RESEARCH.</u>”</p>
2152	62	<p>ADD TEXT: “For some types of methodologies, such as in qualitative research or fields of research such as those involving Aboriginal peoples <u>AND OTHER COMMUNITIES WHERE RESEARCHERS FORM A PARTNERSHIP WITH THOSE AFFECTED BY THE ISSUE UNDER STUDY</u>, the design of the study may not be known at the onset, but only after the researcher has engaged with prospective participants.”</p>

Chapter 7: Conflict of Interest

Line	Page	Comment and/or change recommended
2585-2587	75	<p>“Although the potential for such conflicts has always existed, pressures to commercialize research or suspend dissemination of research outcomes heighten concerns.”</p> <p>This is an important point that needs to be elaborated on later in the chapter by discussing and giving guidance on conflict of interest and intellectual property.</p>
2625	76	<p>Explanation of “firewalls” is needed, or use a widely understood term instead.</p>
2696-2706	78	<p>“Research involving small communities... ..may be sufficient to management conflict.”</p> <p>This entire paragraph should be relocated from Section B “REB Members and Conflicts of Interest” to the end of Section C “Researchers and Conflicts of Interest” since it is not referring to community REB members but to community members who have multiple roles in advising, reviewing, managing and/or participating in research on behalf of the community involved (not on behalf of the university).</p> <p>A very important point is raised in this paragraph that needs to be clarified very carefully. Community advisory boards (in addition to members of research ethics boards) provide important input into ethical issues.</p>
2746-2747	79	<p>“Care should also be exercised in developing relationships between researchers and <u>authorities</u>...”</p> <p>It is unclear what/who is intended by “authorities” in this sentence. Please clarify/elaborate.</p>

Chapter 8: Multi-jurisdictional Research

Line	Page	Comment and/or change recommended
2290-2994	86	<p>“Some organizations or groups have established <u>mechanisms or guidelines</u> (e.g., school boards, <u>Aboriginal communities</u>, correctional services, service agencies and <u>community groups</u>) to review requests for research prior to allowing access to their members or individuals, or access to data about them, under their authority.”</p> <p>Is the use of the term “mechanisms and guidelines” here equivalent to use of the terms “protocols” elsewhere when referring to research involving Aboriginal and other communities? Please see our previous comment on confusing use of protocols and associated terms in the General Comments section.</p>
3083	89	<p>“Researchers should pay special attention to cultural or other values that differ from their own.”</p> <p>This is an important point but it is unclear how it relates specifically to the preceding and subsequent text on benefit-sharing. The intention should be clarified with additional text.</p>
3086-3090	89	<p>“Researchers should normally provide copies of publications or other research <u>reports</u> arising from the research to the institution or organization – normally the host institution – that is best suited to act as a repository and disseminator of the results within the participating communities. This may not be necessary in countries when the results are readily available in print or electronically.”</p> <p>We suggest changing “reports” to “<u>products</u>” since there may be other products besides research reports.</p> <p>ADD TEXT: “<u>However in all cases researchers should ensure that individual study participants and participating communities are informed of how to access the results.</u>”</p>

Chapter 9: Research Involving Aboriginal Peoples

As noted earlier, there is a poor fit between the three core principles and research involving Aboriginal peoples due to a focus on individual autonomy and lack of a sense of understanding regarding community expectations for collective consent. There is still a biomedical model underlying the new framework of the Draft. In this regard, the rationale from moving from the principles of the current TCPS (1998) to the new Draft is not well-developed.

In general, the introductory sections (A, B and C) for Chapter 9 are well developed but the Articles are not. The Articles do not translate the broad concerns and issues into clear guidance, moreover the Article are generally weak given the use of “may” rather than “ought” or “should.”

In a number of instances (tabulated below), the term “rights” appears. In general, rights should be linked with “responsibilities” (i.e., rights and responsibilities) to be consistent with Aboriginal worldviews.

As we raised in our letter of March 19, 2009, it remains unclear as to what has been the consultation strategy involving Aboriginal communities on the Draft, particularly Chapter 9. We hope this point will be clarified in due time and that proper and sufficient consultation has taken place during the extended consultation period.

As previously stated in the general comments, there appears to be **no specific or general attempt to incorporate or refer to the *CIHR Guidelines* in any substantive way** in the Articles. We recommend that a strong linkage between the TCPS and the *CIHR Guidelines* be made and that reference to specific Articles in the *CIHR Guidelines* be made when substantive guidance overlaps with, or is absent in, the TCPS Draft. One important example is including a very strong recommendation in this chapter to using the research template agreement provided as an appendix in the *CIHR Guidelines*. This agreement also includes a commitment on behalf of the researchers to promote community capacity building within the research project.

Examples of other cross-linkages with the *CIHR Guidelines* that would significantly strengthen the integrity of the new TCPS are:

- **Recognition of the notion of collective autonomy**, similar to *CIHR Guidelines Article 4*: “Research involving traditional, sacred knowledge or community members requires prior consultation and consent of the community followed by individual free, prior and informed individual consent.”

The Draft does not address the issue of group consent. We note that **Article 9.2** requires the researcher to inform the REB but does not require the researcher to obtain community consent, and the related Application aims to minimize the influence of the group on individual autonomy. We note that in **Article 9.4** there is a requirement for free and informed consent of individual participants, in addition to group engagement, where appropriate. Thus, the focus of the Articles is on individual free and informed consent and consultation with communities. We support the *CIHR Guidelines* in outlining a two-stage consent process involving first the community in recognition of its jurisdiction then the individual.

- **Respect for Aboriginal world views**, as in *CIHR Guidelines Article 1*: “Researchers should show respect for Aboriginal world views”

While Introductory text and parts of the Application in the Draft touch upon differences between Aboriginal and non-Aboriginal views, these do not carry the force of an Article, which is directive in nature.

- The **option of a participatory approach**, as in *CIHR Guidelines Article 3*: “Communities should be given the option of a participatory-research approach:

The *CIHR Guidelines* are grounded in community and researcher partnerships that require communications and meaningful consultations with community compared with the Draft TCPS

Articles that specify consultations as a requirement only when Aboriginal government has authority or jurisdiction. The Draft provides little guidance on when community engagement is necessary and how to decide on what is an appropriate level of community engagement

Line	Page	Comment and/or change recommended
3126	91	<p>“Concern for welfare includes individual well-being, but broadens the focus of ethics to consider individuals imbedded in relationships in their physical, social, economic and cultural environments.”</p> <p>As we noted earlier, this important statement applies more widely to all communities, not just Aboriginal communities and should be made explicit in Chapter 1 (lines 56-64).</p>
3130	91	<p>“This Policy acknowledges the important role of Aboriginal communities, particularly those that exercise local or regional governing authority, in promoting <u>collective interests</u> that also serve individual well-being.”</p> <p>Revise to “<u>collective interests, rights and responsibilities</u>” to underscore that Aboriginal worldviews incorporate a sense of reciprocal rights and responsibilities as part of well-being. Use of the word “interests” alone does not adequately reflect this important point.</p>
3140-3147	91	<p>“Where the social, cultural or linguistic distance between the community and researchers from outside the community is significant, the potential for misunderstanding is likewise significant. Engagement between the community involved and researchers, initiated prior to the actual research activities and maintained over the course of the research, can enhance ethical practice and the quality of research by promoting mutual trust and communication, establishing mutually beneficial research goals, and ensuring that the conduct of research is respectful of the well-being of individuals and the welfare of the collective, as understood by all parties involved.”</p> <p>This well-written paragraph very clearly articulates key elements of research involving any community (i.e., not just Aboriginal communities) and should be given greater profile and emphasis in Chapter 1 of the Draft.</p>
3149-51	91-92	<p>ADD TEXT: “First Nations, Inuit and Métis concerns for their continuity as peoples with distinctive origins, identities and rights <u>IN MANY CASES</u> have led to the development of ethical protocols to guide community–researcher relations.”</p>
3152-3155	92	<p>ADD TEXT: “Community engagement in these situations, particularly when First Nations, Inuit or Métis communities with local governments are involved, may take the form of <u>REVIEW AND</u> formal approval of a research undertaking.”</p>
3156-3159	92	<p>“A key consideration for researchers, research ethics boards (REBs) and participants is determining when voluntary, informed consent of individuals is sufficient and when the welfare of the relevant group is</p>

		<p>implicated, making <u>community engagement</u> a priority.”</p> <p>It should be made clear that there are circumstances where permission and collective consent are involved, which may become clear through community engagement, but the point here is that community-engagement may not be sufficient in itself (noting, however, that it is not clear what is meant by community-engagement since it is not defined in the Draft).</p>
3161-3162	92	ADD TEXT: “Resulting harms are <u>REAL BUT</u> seldom intentional.
3162-3166	92	<p>ADD TEXT: “In the case of Aboriginal peoples, abuses have historically included appropriation of cultural <u>KNOWLEDGE AND</u> property such as songs, stories and artifacts, devaluing of Indigenous knowledge as primitive or superstitious, violation of community norms regarding the use of human tissue and remains, and dissemination of information that stigmatized whole communities.”</p> <p>The use of “cultural property” on its own is problematic since if left undefined it evokes the western legal notion that does not necessarily fully encompass the intentions and subject matter of Chapter 9. For specific advice on this terminology we defer to the written comments of law professor Catherine Bell (U Alberta) and the written comments of the <i>Intellectual Property Issues in Cultural Heritage Project</i> submitted by archaeology professor George Nicholas (SFU) that have been contributed as part of this TCPS consultation.</p>
3166-3168	92	ADD TEXT: “Affirmation of Aboriginal rights and respect for community ethics codes and protocols, <u>AND DECISION-MAKING PROCESSES</u> are means to better ensure balance in the relationship between researchers and participants and mutual benefit in researcher–community relations.”
3170	92	ADD TEXT: “Aboriginal peoples have rights, <u>RESPONSIBILITIES</u> and interests that deserve recognition and respect by the research community.”
3183	92	ADD TEXT: “Research conducted ethically <u>AND EQUITABLY</u> can benefit Aboriginal people and communities.”
3187-3190	92	ADD TEXT: “Aboriginal people have <u>OFTEN NOT BEEN INFORMED OF THE RESULTS</u> , had little opportunity to correct misinformation or to challenge ethnocentric and racist interpretations. In light of such experience, many Aboriginal people feel apprehensive about the activities of researchers.”
3193-3194	93	ADD TEXT: “Community initiatives are grounded in the assertion of inherent Aboriginal rights <u>AND RESPONSIBILITIES</u> and go beyond protective measures to ensure that research does no harm.”
3213-3215	93	ADD TEXT: “ <u>APPROPRIATION, COMMODIFICATION AND</u> Commercialization of Indigenous knowledge without <u>INVOLVEMENT OF OR</u> benefit to communities from which the knowledge originated has prompted efforts to protect the interests <u>AND RESPONSIBILITIES</u> of

		<p>holders of Indigenous knowledge.”</p> <p>Referring only to commercialization here is too narrow. Knowledge appropriation is the beginning of the ‘chain of production’ that can lead to commercialization. But there are harms that may happen in the absence of commercialization – in fact most traditional plant knowledge that has been appropriated has not resulted in commercial products, yet harms have still resulted. Written as is gives the impression that Aboriginal people are mainly interested in a share of benefits from commercialization. The larger ethical issue begins with knowledge appropriation, and in particular, a lack of understanding by those who appropriate of the spiritual and sacred dimension of the knowledge. This ignorance and the taking of the knowledge out of context and disassociating it from its origins holds the potential for significant harms and offenses, whether or not commercialization is involved.</p>
3227-3228	93	<p>ADD TEXT: “In light of ethical obligations to respect the rights <u>AND RESPONSIBILITIES</u> of Aboriginal peoples as expressed in community codes and protocols...”</p>
3230-3231	93	<p>“...researchers should seek culturally informed advice appropriate to the <u>context</u> when their work involves Aboriginal participants.”</p> <p>We question if this statement provides a sufficient level of guidance to researchers. We acknowledge it is impossible to be too specific but at minimum the section could elaborate using “such as” and/or through use of examples.</p>
3233-3235	94	<p>“This Policy provides guidance on issues that have been raised frequently in public consultations on revision of the original version of this Policy (1998), in the <i>CIHR Guidelines for Health Research Involving Aboriginal People</i> (2007)...”</p> <p>As noted above, we disagree that the Draft provides guidance on issues that have been frequently raised in the <i>CIHR Guidelines</i> – or if it does then the linkages between the Draft and the <i>CIHR Guidelines</i> need to be much more explicit through out Chapter 9.</p>
3240-3242	94	<p>ADD TEXT: “Applying this Policy in a way that accommodates the diversity of Aboriginal cultures and communities is complex. <u>FOR EXAMPLE</u>, the fit between community protocols and institutional policies may be unclear, requiring researchers to adapt conventional practice or broker agreements.”</p>
3244-3246	94	<p>ADD TEXT: “Researchers and REBs are reminded that ethical judgment must be attentive to the specific context of a proposed project. <u>THIS APPLIES TO BOTH QUALITATIVE AND QUANTITATIVE RESEARCH.</u>”</p>
3251-3256	94	<p>“Article 9.1 <u>Researchers and research ethics boards</u> should consider whether application of the core principles of this Policy require interpretation or adaptation in the context of proposed research involving Aboriginal participants, to demonstrate respect for Aboriginal rights and</p>

		<p>cultural heritage, the integrity of Indigenous knowledge systems, and the diversity among and within Aboriginal communities.”</p> <p>If this is intended to be a case-by-case determination then it is essential for a representative of the prospective Aboriginal participant population to be a part of this decision (i.e., not left only to the discretion of the research and REB). However, this article re-enforces our point that the three core principles of the Draft are a forced fit that appears to be imposed on Chapter 9 without due consideration of the implications. As such, the imposition of the core principles on research involving Aboriginal peoples is not an improvement over the existing version of the TCPS.</p>
3257-3260	94	<p>“Protections for human research participants set out in this Policy apply to research involving Aboriginal people, with the provision that application of the principles and requirements <u>may require interpretation or adaptation, in situations such as the following:</u>”</p> <p>There is insufficient guidance provided here. Each of the examples (which are all labeled “a” but should be “a” through “g”) should explain the potential need for interpretation/adaptation. The concrete guidance provided on p.95, lines 3276-3280 is the level of elaboration that is needed for each of points a through g.</p>
3282-3288	95	<p>“Article 9.2 In research proposals involving one or more Aboriginal communities or <u>a significant number of Aboriginal participants</u>, researchers shall inform the research ethics board of how they have engaged or intend to engage the community in approving, advising on or managing the project. The nature and extent of community engagement should be appropriate to the type of community and proportionate to the <u>level of Aboriginal involvement</u> in the research.”</p> <p>There may be cases where research only involves one person or a small number of individuals simply because these are the only living experts (e.g., elders) in the community on the topic of study (e.g., language or traditional plant medicines). Thus, it is not just the level of Aboriginal involvement, but the cultural significance of the research focus that should trigger the need for community engagement.</p>
3282-3288	95	<p>ADD TEXT: “Article 9.2 In research proposals involving one or more Aboriginal communities or <u>a significant number of Aboriginal participants</u>, researchers shall inform the research ethics board of how they have engaged or intend to engage the community in approving, advising on or managing the project. The nature and extent of community engagement should be appropriate to the type of community and proportionate to the <u>level of Aboriginal involvement</u> in the research. <u>ALL COMMUNITIES SHOULD BE GIVEN THE OPTION OF A PARTICIPATORY RESEARCH PARTNERSHIP.</u>”</p> <p>As included in the <i>CIHR Guidelines</i>.</p>

3289	95	<p>“First Nation, Inuit, Métis, urban and rural communities differ significantly from one another, and they are characterized by increasing internal diversity. Engagement with the relevant community <u>throughout the research process</u> is the preferred means of ensuring that the ethical protections incorporated in a project respect the identities, interests and circumstances of participants.”</p> <p>Clarify what is meant by <u>throughout the research process</u>, i.e., determining research questions, collecting data, interpreting results, and disseminating the findings.</p>
3298-3353	95-97	<p>The format of Lists A and B (i.e., that they are separate lists) makes it difficult to follow the connection from the example of Aboriginal involvement to what is considered proportionate community engagement. The example of Aboriginal involvement should be followed directly by the relevant example of proportionate community engagement, instead of being separated into the two lists.</p>
3384-3353	97	<p>Reference should be made to the Scientific Research Licence required for research in NWT.</p>
3354-3357	97	<p>“The evidence of community engagement in a project may vary from a formal agreement setting out terms of co-management, to verbal approval of the proposed research in a group setting (<u>which should be recorded</u>), to informal advice from an ad hoc committee.”</p> <p>Replace “recorded” with “documented” since recorded implies audio or video.</p>
3368-3371	97	<p>“The least organizationally developed communities are the most vulnerable to exploitation and should be <u>supported</u> in expanding their capacity to participate rather than suffering dilution of ethical safeguards.”</p> <p>Clarify <u>who</u> has the onus to support communities in expanding their capacity to participate – the researcher or some other entity? If the researcher, is this feasible? Shouldn’t this onus more reasonably rest on the institution of the researcher?</p>
3372-3375	97	<p>“Where Aboriginal participants or communities do not designate an organization or individuals to represent their interests, the responsibility for <u>securing culturally informed advice</u> on ethical protections rests with the researcher or the sponsoring institution.”</p> <p>This is important but a tall order. Are there any general resources available to researchers and their institutions to assist in their understanding of how to go about securing culturally informed advice on ethical protections in such circumstances?</p>
3427-3429	99	<p>ADD TEXT: “Article 9.5 Where prospective participants signify that a community ethics code, <u>GUIDELINE, POLICY</u> or <u>RESEARCH</u> protocol is in effect, researchers and research ethics boards shall take into consideration the code, <u>GUIDELINE, POLICY</u> or <u>RESEARCH</u> protocol</p>

		that applies in the territory or organization.”
3430-3432	99	<p>ADD TEXT: “The similarity, divergence or overlap of such code, <u>GUIDELINE, POLICY</u> or RESEARCH protocol with this Policy, and clarification of mutual expectations, <u>should be considered</u> by all parties <u>AND USED AS THE BASIS OF NEGOTIATING MUTUALLY-AGREED TERMS</u> in advance of launching a particular project.”</p> <p>It is insufficient to only suggest “consideration” by all parties – it is vital that the considerations then be used to inform negotiation of mutually-agreed terms, preferably taking the form of a written research agreement.</p>
3439-3466	99-100	<p>These three paragraphs intend to describe applications in First Nations, Inuit and Métis, respectively, but the intent is not clear at the onset. Subheadings or bolded key terms at the start of each paragraph (i.e., First Nations, Inuit and Métis, respectively) would help orient the reader.</p> <p>The single sentence paragraph on Inuit Tapiriit Kanatami (lines 3459-3460) needs additional context to make it clear why (among the many guides, guidelines, codes, etc in existence) only this one is highlighted. It may be clear to those who already work with Inuit communities, but it will not likely be clear to those who don’t.</p>
3469-3474	100	<p>ADD TEXT: “Having reference to parallel codes, <u>GUIDELINES, POLICIES</u> and <u>RESEARCH</u> protocols in institutions and communities is likely to pose questions of which code should prevail when expectations and/or requirements diverge. Maintaining respectful relationships will be dependent on all partners being prepared to reflect on what is essential to achieving common goals and on what degree of flexibility is consistent with their core values.”</p> <p>It is also essential that all parties involved are fully aware of their own and each others’ institutional, professional and community obligations, since these will sometimes be non-negotiable. The <i>CIHR Guidelines</i> (p.12 second para) notes: “Ensuring that all parties are aware of and understand existing institutional, professional and community standards will be important to achieving consensus.” A similar statement is needed in the TCPS.</p>
3524-3225	101	<p>ADD TEXT: “The good offices of trustworthy persons who have moral authority in the community can often be enlisted to find ways to proceed with research that preserves respect for all parties. However, in some cases the risks involved simply outweigh the benefits to be derived from proceeding with the research <u>AND THE RESEARCH SHOULD NOT BE UNDERTAKEN.</u></p>
3570-3572	102	<p>“Researchers should <u>inform</u> communities and individuals what arrangements are made in partnered research to respect privacy of individuals and communities.”</p> <p>Researcher should <u>decide these arrangements with</u> communities and</p>

		<p>individuals, not simply “inform” them.</p> <p>SUGGESTED REVISION: “Researchers should <u>DECIDE WITH</u> communities and individuals what arrangements <u>WILL BE</u> made in partnered research to respect privacy of individuals and communities</p>
3607	103	<p>“Protection of Indigenous <u>and</u> Cultural Knowledge”</p> <p>The inclusion of “and” in the subheading is confusing since it implies two distinct kinds of knowledge being discussed, i.e., “Indigenous knowledge” and “cultural knowledge” What is the intended difference between these? Since there is no single agreed definition of either term, both need to be explained. Or if the intention is to refer to “Indigenous cultural knowledge”, the “and” should be removed. We note that this subtitle is the only place that the term “cultural knowledge” appears in the document (i.e., it is not used anywhere in the text). Introductory information for Chapter 9 uses the terms “Aboriginal or Indigenous knowledge” and “Indigenous knowledge” (p.93, lines 3205-3215 and 3227-3231). However, the term “cultural heritage” is used (p. 93, lines 3199-3204) and described as including “artifacts, cultural property, collective knowledge and skills, and other intangibles that are transmitted from one generation to the next, such as folklore, customs, representations or practices.”</p> <p>SUGGESTED REVISION: “Protection of Indigenous <u>Knowledge</u> and <u>Cultural Heritage</u>”</p> <p>The above seems a more appropriate subheading for this section whereby “cultural heritage” is understood as the broader term that includes cultural property (making it consistent with the introductory text to Chapter 9, as well as common usage).</p> <p>Further consistency and clarification of terms used in this section are needed.</p>
3608-3647	103-104	<p>“Article 9.10 Researchers should consider, and research ethics boards should review, whether <u>tangible or intangible cultural property</u> of Aboriginal persons or communities is at risk of misuse or misappropriation when collected in the context of research involving Aboriginal participants or communities. Researchers should include measures to mitigate such risks of misuse or misappropriation in the research ethics review proposal.”</p> <p>The term “tangible or intangible cultural property” should be replaced with “<u>Indigenous knowledge or cultural heritage</u>” so that the broadest category is being encompassed in Article 9.10, and also for consistency with the subheading since is the first instance where the term “tangible or intangible cultural property” is used so it is confusing in light of its ‘sudden’ appearance (see also our comment about lines 3162-3166 p 92).</p>

3514-3619	103	<p>“Researchers should <u>negotiate</u> with communities mutual understandings of appropriate respect for cultural <u>property</u> including Indigenous knowledge, how to proceed with community review of findings, terms of ownership of research products, and any limits on publication of materials, including how intellectual property rights to research products will be assigned: whether to community sources, to researchers, or to both on a shared basis.”</p> <p>SUGGESTED REVISION: “Researchers AND communities should <u>DEVELOP</u> mutual understandings of appropriate respect for cultural <u>HERITAGE</u> including Indigenous knowledge, <u>AND NEGOTIATE</u> how to proceed with community review of findings, terms of ownership of research products, and any limits on publication of materials, including how intellectual property rights to research products will be assigned: whether to community sources, to researchers, or to both on a shared basis. <u>THE FINAL AGREEMENT SHOULD BE IN A WRITTEN DOCUMENT.</u>”</p> <p>Mutual understandings should be <u>developed</u> (not “negotiated”) while how to proceed should be <u>negotiated</u> and represented in a written research agreement.</p> <p>Some members of our group suggest that the final written agreement should be signed by the researcher's institution and the community's designated representative.</p>
3620-3622	103	<p>“REBs should review the measures researchers put in place to recognize and protect Indigenous <u>or local</u> knowledge in the conduct of the project and the dissemination of findings.”</p> <p>This is the only instance where “local knowledge” appears in the Draft. It is unclear how “local knowledge” is intended here to be different from “Indigenous knowledge,” which is the focus of this section. Certainly there are parallel ethical issues and protective measures that are needed to respect and protect local community knowledge, but these should be placed in context and discussed purposely in relevant sections of the Draft where research involving communities is discussed (especially but not only in Chapter 10).</p> <p>It is very important that REBs have the appropriate expertise to be able to evaluate the measures proposed from both university and community perspectives. In many cases, this would be an appropriate and vital place for use of <i>ad hoc</i> REB members, as indicated in Article 9.14 (P. 107, lines 3758-3760) “through ad hoc consultation with knowledgeable academic and community advisors, or through collaboration with community ethics review bodies.”</p>
3623-3634	104	<p>“<u>Cultural property</u> often does not fit the criteria of sole ownership,</p>

		<p>innovation and representation in a tangible work that are necessary to claim protection for intellectual property rights.”</p> <p>Use of “cultural property” here is confusing.</p> <p><u>SUGGESTED REVISION: “INTANGIBLE ASPECTS OF CULTURAL PROPERTY OFTEN DO not fit the criteria of ...”</u></p>
3635-3647	104	<p>This entire paragraph applies to all research involving Aboriginal communities, not just to research involving Indigenous knowledge. Move paragraph to p. 100, insert at line 3498. Moreover, this paragraph also applies to community-based research generally, whether or not the communities are Aboriginal.</p> <p>SUGGESTED REVISION: “Researchers should afford the community an opportunity to react and respond to research findings before the completion of <u>ANY PRODUCTS THAT REPORT THOSE FINDINGS</u>, in the final report, or even in all relevant publications. (See Article 3.2 in Chapter 3 [“Free and Informed Consent”] on information disclosure.) <u>Collaborative research reports</u> are regarded as a product of both community and researcher contributions rather than the sole property of the researcher. Communities consider that their review and approval of reports and academic publications is essential to validate findings, protect against misinterpretation, and maintain respect for Indigenous knowledge, which may entail limitations on its disclosure. If disagreement <u>ABOUT INTERPRETATION</u> arises between researchers and the community <u>AND IT CANNOT BE RESOLVED</u>, researchers should afford the group <u>COMMUNITY</u> an opportunity to make its views known, or they should accurately report any disagreement about the interpretation of the data in their reports, or publications <u>OR OTHER RESEARCH PRODUCTS</u>.</p> <p>It is not clear what is a “collaborative research report.” Does this mean co-authored or does it refer to any report or product that emerges from the collaboration, regardless of authorship? We support the latter and ask that it be clarified.</p> <p>Presuming that “disagreement” refers to interpretation, first researchers and community members should seek to resolve the disagreement or misunderstanding. If it cannot be resolved, then opportunities to express all perspectives should be found.</p>
3649-3656	104	<p>“Article 9.11 Consistent with the general provisions set out in Chapter 5 (“Privacy and Confidentiality), secondary use of data collected initially for other purposes, from which personal identifiers have been removed, does not require research ethics board (REB) review. Secondary use of data that is identifiable as originating from a specific community, or a segment of the Aboriginal community at large, requires REB review and</p>

		<p>may warrant seeking culturally informed advice about protection of <u>cultural property</u> or representations of Indigenous knowledge or society.”</p> <p>Replace “cultural property” with “<u>cultural heritage</u>” for consistency and inclusiveness.</p>
3669-3678	105	<p>“Misrepresentation of Aboriginal peoples, unauthorized use of data, and lack of reporting to communities on research outcomes have created ongoing sensitivity about secondary use of data collected for approved purposes. For example, members of Nuu-chah-nulth communities in British Columbia provided blood samples for research on rheumatic disease. They vigorously protested use of the blood components for subsequent genetic research that pronounced on their ancient origins and challenged traditional knowledge about their identity. There are additional fears in First Nation communities that general consent to use health data for purposes other than treatment will facilitate unauthorized government surveillance.”</p> <p>Another common example of unauthorized secondary use of data that is identifiable as originating from a specific community is the practice of accessing traditional plant knowledge from the published literature to inform commercial development of new products, called “literature-based bioprospecting.” As indicated in our earlier comments on Chapter 5, it is well-known in fields such as ethnobotany that there is a significant amount of traditional knowledge found in the early published record that was not published with the awareness or consent of the original knowledge holders.</p> <p>This important example should be highlighted following line 3678, to raise awareness amongst the research community that appropriate redress can be found in Article 9.11, i.e., by “seeking culturally informed advice” before use of such data, to determine if harms or offenses may result and if there benefit-sharing should be explored with the original source community/ies.</p>
3679-3680	105	<p>“In light of sensitivity about harms ensuing from identification of communities, potential misuse of <u>cultural property</u> or misrepresentation of Indigenous knowledge...”</p> <p>Replace “cultural property” with “<u>cultural heritage</u>”</p>
3695-3698	105	<p>There is overuse of the word “context” in this paragraph:</p> <p>“Autonomous research would enhance the exploration, articulation and application of Indigenous knowledge in its own context, with translation to other contexts following a parallel process. Articles 9.12 and 9.13 specify benefits that may accrue in the context of partnerships between Aboriginal communities and external researchers.”</p> <p>SUGGESTED REVISION: Autonomous research would enhance the</p>

		exploration, articulation and application of Indigenous knowledge <u>IN SITU</u> , with translation to other contexts following a parallel process. Articles 9.12 and 9.13 specify benefits that may accrue <u>THROUGH</u> partnerships between Aboriginal communities and external researchers.”
3700-3702	105	ADD TEXT: “ Article 9.12 Communities should have access to data important to their own planning and development processes, with protections for privacy and confidentiality of personal data <u>AND OWNERSHIP PROVISIONS</u> as noted in this chapter.”
3708-3711	106	<p>“Article 9.13 Researchers should endeavour, where appropriate and possible, to share costs and benefits of research equitably...”</p> <p>Delete “where appropriate and possible” as this is assumed by use of the term “should endeavour.”</p> <p>We note that this endeavour should be a joint effort shared in a coordinated way by the researcher, the researcher’s institution and the research funder, since personnel and administrative costs of ethics review coordination and project oversight are not typical budget line items in many small grants. This endeavour should be a concerted effort by all involved.</p>
3722-3725	106	SUGGESTED REVISION: “Employing Aboriginal research assistants and translators is already common practice in community-based projects <u>THAT SHOULD CONTINUE</u> . Implementing a rational program of training to enhance autonomous research initiatives is less common. <u>WHENEVER POSSIBLE, TRAINING SHOULD BE PROVIDED TO PROMOTE CAPACITY-BUILDING TO ENABLE AUTONOMOUS RESEARCH INITIATIVES.</u>
3734-3737	106	<p>ADD TEXT: “Direct funding <u>BY THE GRANTING COUNCILS</u> to community entities conducting research is anticipated in some current programs, although the requirement for ethics review is still met through researcher affiliation with institutions adhering to this Policy, collaborating with the community organizations.”</p> <p>There are many sources of funding for community-based research outside of the three academic granting councils and outside of the academic system so a slight clarification seems helpful and less presumptive.</p>
3756-3760	107	ADD TEXT: “ Article 9.14 Research ethics boards (REBs) reviewing research involving Aboriginal participants and communities on a recurring basis should ensure that they have access to relevant expertise within regular REB membership, through ad hoc consultation with knowledgeable academic and <u>ABORIGINAL</u> community advisors, or through collaboration with <u>ABORIGINAL</u> community ethics review bodies.”
3780-1781	107	ADD TEXT: “The membership of <u>ABORIGINAL</u> community review bodies will not necessarily duplicate the membership criteria set out in this Policy.”

3787-3789	108	<p>“For example, research on the interface between environmental and human systems that does not involve individual participants does not require REB review.”</p> <p>As noted earlier in our Chapter 2 comments regarding (p.9, line 312-314), it is not clear what is being referred to here. An example should be provided to clarify this text.</p>
3797	108	<p>REFERENCE TO ADD: World Health Organization, Indigenous peoples and participatory health research http://www.who.int/ethics/indigenous_peoples/en/index6.html</p>

Chapter 10: Qualitative Research

We wonder about the need to educate readers of the Draft about qualitative research since other types of inquiry are not explained/described in the Draft. The fundamental principles are the same regardless of methodology but they may require special attention or interpretation because of research methods. More of the chapter should focus on ethical issues that arise in qualitative research, rather than a description of what qualitative research is. Given the length of the Draft, we think a more specific focus is important. However, if qualitative research requires a chapter of its own, then this suggests the possibility that so does quantitative research. We request careful consideration on this matter in the revision.

Line	Page	Comment and/or change recommended
3820	109	<p>“Researchers in <u>HEALTH</u>, social sciences and humanities, such as sociology, psychology, criminology, business administration, political science, communications, education and history, have a common belief in the desirability of trying to understand human action through systematic study and analysis. Some researchers use quantitative research approaches, others opt for qualitative research methods, and some use a combination of both.”</p> <p>It is important to include health researchers. The examples of disciplines should be deleted as they add length but are not essential to list.</p>
3825-3828	109	<p>“Qualitative research has a long history in many well-established disciplines in the social sciences and humanities, as well as many areas in the health sciences (e.g., nursing). Research developments point to an increasing prevalence of qualitative approaches, whether in health research or in social sciences and humanities disciplines.”</p> <p>This text is redundant and should be deleted for reasons of length.</p>
3843-3845	109	<p>“Researchers and research ethics boards (REBs) should also consult other relevant chapters of the Policy for additional details on principles, norms and practices applicable to qualitative research.”</p> <p>These other sections should be specified. There are a number of relevant details spread through out the Draft but it seems impractical to expect researchers to read the Policy from start to finish to find them all.</p>

3860	110	<p>“General Principles and Methodological Requirements and Practices”</p> <p>This section should focus specifically on the ethical issues raised for each subsection.</p>
3878	110	<p>ADD TEXT: “The term “qualitative research” covers a wide range of overlapping paradigms or perspectives. <u>THESE MAY ALSO HAVE A QUANTITATIVE COMPONENT (E.G., PARTICIPATORY ACTION RESEARCH).</u>”</p>
3920-3923	111	<p>“The intended goals of qualitative projects may include “<u>giving voice</u>” to a particular population, engaging in research that is critical of settings and systems or the power of those being studied, affecting change in a particular social environment, or exploring previously understudied phenomena to develop new theoretical approaches to research.”</p> <p>The term “giving voice” sounds quite researcher-driven. Participatory action research (used as one of the examples of qualitative research) is about a more collaborative process of <u>regaining and/or claiming voice</u>.</p>
3929-3938	112	<p>“In some cases, research participants hold equal or greater power in the researcher–participant relationship – for example, in <u>community-based and/or organizational research when a collaborative process is used to define and design the research project and questions, or where participants are public figures or hold other positions of power (for example, research involving economic, social, political or cultural elites).</u>”</p> <p>This sentence is too complex – need to break “community-based research” and “organizational research” apart into two separate sentences to avoid confusion due to unintended conflation of the terms.</p> <p>This paragraph is about power, not consent – it is unclear why it is under the subheading for consent.</p>
3975-3977	113	<p>“The consent process should usually reflect trust between the research participants and the researcher. <u>Often</u> this is based on mutual understanding of the project’s intentions.”</p> <p>The consent process, by definition, MUST be based on mutual understanding of the project’s intentions.</p>
4114-4116	116	<p>“Article 10.5 Subject to the research context and the scholarly traditions used in the research proposal, research ethics board review should acknowledge that individuals may want to be identified for their contribution.”</p> <p>Why should this be subject to the research context and the scholarly traditions used? Any individual is entitled to due credit for their contribution.</p>
4166-4174	118	<p>“For instance, in research in Aboriginal communities or with Aboriginal populations (see Chapter 9 [“Research Involving Aboriginal Peoples”]) or other types of <u>community-based collaborative research</u>, it may be desirable to obtain permission to proceed from community leaders, elders or representatives before seeking individual consent. A researcher might use a community</p>

		<p>gathering to <u>inform the group</u> about the research and <u>gain agreement</u> from the group to proceed with the actual research before seeking to obtain individual consent as a second step of the research implementation.”</p> <p>The nature of community-based research as a collaborative process does not show through clearly enough in this paragraph, which seems to describe a more “researcher-driven” process, i.e., researcher “informing” the group and “gaining” agreement, with a lack of forethought as to how that agreement will be gained (e.g., through consensus-based decision making?). While the Draft speaks to permission that may be needed from leaders or representatives, it does not address situations in which collective/community consent is involved.</p>
4186-4188	118	<p>ADD TEXT: “Article 10.7 When researchers are using emergent designs in data collection, research ethics boards should review and approve the general procedure in accordance with appropriate professional and disciplinary standards, <u>AND IN LIGHT OF COMMUNITY RESEARCH PARTNERSHIPS.</u>”</p>
4195-4196	118	<p>Rather, REBs should ensure that the data collection is conducted according to disciplinary and professional standards, <u>AND IN LIGHT OF COMMUNITY RESEARCH PARTNERSHIPS.</u>”</p>