

**Written Comments on the Draft 2<sup>nd</sup> Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Draft TCPSv2)**

**Submitted on behalf of the *Intellectual Property Issues in Cultural Heritage (IPinCH) Project***

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The [Intellectual Property Issues in Cultural Heritage \(IPinCH\) project](#) is a seven-year collaboration between more than 50 international scholars and 25 partners and was developed by George Nicholas (Simon Fraser University), Julie Hollowell (Indiana University) and Kelly Bannister (University of Victoria). Led by project director George Nicholas at Simon Fraser University and assisted by a Steering Committee of Indigenous and non-Indigenous researchers experienced in collaborative research, IPinCH brings together anthropologists, archaeologists, lawyers, experts in intellectual property, Indigenous communities and stakeholder groups. The methodologies and core principles adopted in the IPinCH project for community engagement and collaborative research are consistent with those developed by the previously SSHRC-funded “Protection and Repatriation of First Nations Cultural Heritage Project” led by Catherine Bell at University of Alberta. The core values include: collaboration through meaningful participation, respect (for individuals, community, and difference), equality (including different ways of knowing), empowerment of participants, and inclusiveness with a view to inform good practice concerning addressing intellectual property issues in cultural heritage.

As Indigenous communities and others work to protect their cultural heritage, IPinCH is investigating how culture, rights, and knowledge are interpreted. Rather than attempt to generalize varied international Indigenous perspectives on cultural heritage and knowledge, analyses are intended to identify common issues and themes. Studies will point towards broad implications and important lessons on fair and appropriate use of knowledge. In particular IPinCH is concerned with understanding how traditional and cultural knowledge is valued, transmitted, regulated, and protected by various societies and how its use – and misuse – by others impacts cultural heritage. How archaeologists and others respond to these issues has the potential to positively impact, rather than constrain, future research.

One of the important objectives of IPinCH is to contribute to knowledge, document issues and explore best practices including in the area of collaborative research, particularly in relation to archaeological practice and products of archaeological and other cultural heritage research. Research findings and recommendations for best practices emerging from the IPinCH experiences, including case studies, will be shared with PRE and the three Councils and included in the publications and knowledge base created by this project.

We see a revision of the TCPS as overdue and we are pleased that this is in progress. We also are encouraged by the indication that the new TCPS will continue to develop/evolve in future, in a more timely way. We appreciate the three-month extension to the public consultation process, enabling our collective submission, which would not have otherwise been possible. We also appreciate the necessary and invaluable involvement of the national Aboriginal organizations. But we are concerned about the apparent absence of meaningful engagement and consultation at the level of Aboriginal communities, especially given the length of the document, the extensive changes, and the limited time for feedback, despite the time extension. We fully understand the time, funds, personnel and forethought that would be required to undertake meaningful consultation, such as the process involved in developing the CIHR *Guidelines for Health Research Involving Aboriginal People* (2007), but we believe such investment is vital, especially as research with and within Aboriginal communities continues to increase. It is our view that the development of ethical guidelines for research involving Aboriginal communities is necessarily an organic deliberative process. We thus encourage PRE to revisit and review the TCPS on a regular basis with purposeful and meaningful involvement of Aboriginal communities and local Aboriginal organizations, in addition to the national Aboriginal organizations.

The particular perspectives we provide in our comments draw on our collective expertise in the areas of community-based participatory research (CBPR), Aboriginal research, qualitative research, multi-jurisdictional research, and research involving cultural heritage and intellectual property. IPinCH is particularly well-positioned to assess the Draft TCPSv2 from the angle of grounded ethical practice in research through a CBPR approach since IPinCH is one of few multi-jurisdictional research projects of its size that uses CBPR as its primary methodology in working with Indigenous and other communities.

Please note that we see a number of improvements to the Draft TCPSv2 over the existing TCPS that are not specifically outlined in our comments, such as the proposed definition of “research.” We also support the following aspects of the Draft TCPSv2, although we encourage elaboration on these aspects:

- The importance of **interpreting ethical guidelines within the broader movement of transforming the relationship between Aboriginal peoples and Canadian society**, including the Aboriginal and treaty rights of the Aboriginal peoples of Canada; the desire and importance of maintaining collective identity and continuity of cultures; the balance between the individual well-being of participants and broader concerns for the collective welfare of the community; and the potential imbalance of power between affected individuals, researchers, academic institutions, funding agencies and communities.
- The importance of **community engagement in addressing concerns relating to protection and control of cultural heritage as understood by affected communities** through respect for their laws, protocols, distinctiveness and diversity including their understandings of cultural heritage, research and protection priorities. This includes meaningful engagement of appropriate community authorities (which may or may not be officially recognized governing bodies) through meetings with researchers prior to initiating research activities and participation at all levels of the research program, including input on interpretation of outcomes and equitable distribution of benefits.

- The importance of **an intercultural understanding of voluntary (or “free”) informed consent** that respects the need to protect and balance the welfare and autonomy of individual participants with the autonomy and welfare of the collective, as understood by the parties involved, including through compliance with community research protocols.

Our comments are organized into two sections: (i) General comments on various aspects of the Draft TCPSv2; and (ii) Specific comments on individual chapters, including a tabulated summary of suggested revisions. Note that many of our comments overlap with the written comments submitted by the Canadian Subcommittee of the IRB/REB Workgroup on Community-Engaged Research, and those submitted by Catherine Bell (University of Alberta).

## **PART I: GENERAL COMMENTS**

**Community-based research (CBR)** is given surprisingly little attention for its potential to meaningfully address the three core principles that guide the Draft TCPSv2, i.e., concern for welfare, respect for autonomy, and respect for the equal moral status of all humans. If one is to accord full meaning to “respect for autonomy” then it follows that individuals are the best judges of their own welfare. However, the Draft TCPSv2 does not discuss autonomy or welfare of research participants in a manner that adequately addresses the experiences of historically marginalized or at-risk communities who have been burdened with detrimental and exploitative research involvement in the past. Although the Draft TPSv2 acknowledges the burden of exploitative research on Aboriginal communities (e.g., in the discussion of protection of Indigenous knowledge and benefit to the community), it does not sufficiently impose obligations on the researcher or address ways that research can empower communities or research participants. Sharing of power and control is integral to meaningful partnerships but much of the language used (e.g., “should” instead of must, and “consider”) leaves the most significant power sharing considerations to the discretion of researchers. Community-based research is, unfortunately, largely relegated to Chapters 9 and 10 but its relevance extends beyond Aboriginal communities to all communities of place, interest or circumstance, and beyond qualitative research to include mixed qualitative and quantitative methods.

We note there are numerous **terms used in reference to the involvement or participation of communities** including: “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 is defined and there is no clear rationale for the use of one over another. The term “community-engagement” is widely used – if not overused – throughout the document, but not defined. Purposeful and consistent use of each of these terms, and clarification as to their intended meaning, is needed throughout the Draft TCPSv2.

It is also important that use of the term “**protocols**” be clarified, as in such terms or phrases as “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.” In most cases noted above, the term “protocols” would be more appropriate as “**research protocols**” to distinguish from other types of protocols, codified and not, especially those that exist in an Aboriginal community context where the

word “protocol” may or may not be used interchangeably with words such as “laws,” “practice” and “custom.”

Other types of protocols referred to in the Draft TCPSv2 include: “professional protocols,” “interview protocols,” “professional interview protocols,” and “operative protocols,” all of which require definition and more purposeful and consistent use to avoid confusion. It would be better still to choose an alternative term to refer to the above terms, to replace “protocols.”

A **Glossary of Terms** where all key terms used are defined for easy reference would eliminate some of the confusion noted above, but also improve clarity of meaning. We note that many key terms are not defined at all and some of these do not have a universally-accepted definition, making clarification of their intended meaning within the Draft TCPSv2 all the more important. Some examples are:

- Research
- Quality assurance (and associated terms)
- Creative practice
- Scholarly review
- Free and informed consent
- Incidental findings
- Critical inquiry
- Identifying information (and associated terms)
- Personal information
- Secondary use
- Protocols (and related terms as noted previously)
- Community-based research (and related terms, as noted previously)
- Community-engagement
- Conflict of interest
- Cultural heritage
- Cultural property
- Aboriginal knowledge
- Indigenous knowledge
- Cultural knowledge
- Local knowledge
- (etc)

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 TCPSv2** is not well-developed and we encourage further articulation in this regard. We suggest that the **Articles** be made more concise, direct and prescriptive. The introduction to the Draft TCPSv2 indicates that there is interpretation and discretion needed in their application, so this does not need to be repeatedly stated. As indicated subsequently, there are some Articles where “must” ought to replace “should.”

It is unclear how **incorporation of the CIHR Guidelines for Health Research Involving Aboriginal People (2007)** has been accomplished in the Draft TCPSv2. Stronger links in Chapter 9 are needed with the *CIHR Guidelines*. At minimum, we recommend making reference to the sample research agreement included as an appendix in the *CIHR Guidelines*.

The review of ethical guidelines that constitute national policy (i.e., the TCPS) should not occur in isolation of other arms of SSHRC, CIHR and NSERC. In order for researchers to meet the highest ethical standards and not to create disincentives for research through the imposition of ethical standards, it is crucial that **appropriate support be provided to researchers within academic institutions and through granting agencies**. This is an area where the ethical standards of the three Councils (as represented by the TCPS) need coordination with funding programs of the Councils. Specifically, funding needs to be available within all funding programs to facilitate preliminary discussions for building relationships and engaging the appropriate authorities in developing research programs. Also, if partners are to be engaged at various stages of the research program, timelines need to be extended to enable meaningful review and input at various stages which may take some time given the limited resources and various priorities within a given group or community. Additionally, the extra administrative cost that is incurred by projects when time extensions are given needs due consideration.

**The recent decision to eliminate Research Teaching Stipends has numerous implications** for the ability of faculty members to achieve some of the good practices and ethical standards called for in the Draft TCPSv2. For most faculty researchers, teaching release is essential for providing adequate time and opportunity to conduct fieldwork, research, analysis, publication and dissemination of research results. Shifting the burden of responsibility for the cost of teaching release at a time when many Canadian institutions are facing financial hardships means that those researchers who are successful in obtaining research funds but are not given teaching release by their university, will face the challenge of having to somehow do two jobs at the same time.

We suggest inclusion of **guidance on ethically appropriate public dissemination of research findings**, meaning sharing information without privacy or other cultural sensitivity issues. While there is some discussion about the public good of information sharing (including sharing negative findings or dissenting views) the manner of this dissemination is not discussed. Thus, what constitutes "publication" is under-specified. Open access publication and restricted access (subscription) publication regimes are very different. There are also licensing, terms and conditions of use, etc. that can restrict how "published" information can be used and accessed. Such restrictions can do little to promote the public good. We recommend inclusion of some language about the value of open and nonproprietary forms of publication and dissemination where ethically appropriate, given privacy and other concerns.

## **Part II. SPECIFIC COMMENTS**

### **Chapter 1: Ethics Framework**

We are pleased to see that the Draft TCPSv2 acknowledges the cultural and scientific contexts within which western codes of ethical conduct are developed, as well as the importance of flexibility in interpreting core principles of "concern for welfare, respect for autonomy, and equal moral status of all humans" in a manner cognizant of the distinctiveness and diversity of Aboriginal communities. However, we have concerns that the three core principles do not fully encompass or adequately replace the set of principles in the existing TCPS. Moreover, these core principles could and should be expressed using more familiar and engaging language (i.e., less academic and less legalistic) that

would more effectively draw the diverse readership and users into a place of understanding and/or a desire to understand what is ethical research, and what is an ethical research relationship.

The core principles claim to transcend disciplinary boundaries but we question if they also transcend cross-cultural boundaries. There is a fundamental gap in the Draft TCPSv2 in that there is a lack of explicit acknowledgement that **all of the core principles have a collective aspect**. The collective nature of “Autonomy” is described p. 3 (lines 106-111) but an analogous description for “Welfare” is needed on p. 2 (after line 64). We note that this appears in Chapter 9 (p. 91, lines 3127-3128) in the context of Aboriginal research (i.e., concern for welfare is beyond just the individual because individuals are embedded in relationships) but this point may hold true for all community contexts; this should be made explicit in the first chapter, as well as in Chapter 9.

Line	Page	Comment and/or change recommended
65	3	Insert text equivalent to p. 91, lines 3127-3128 to extend the concept of welfare beyond the “individual” to collectives such as communities
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 (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 they may not be obvious to the researcher.
88	3	How can uninformed choice ever be meaningful? Text should read: “To be meaningful, that choice <b>MUST</b> [to replace “should”] be informed.”
112-113	3	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.
179-181	5	Raises an important point that should be re-emphasized throughout, i.e., that considering the perspective of the participant includes the context (social, economic, cultural or other) that shapes the participant’s life.
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	“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.”

		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) 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, or 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...” <i>and</i>
444-447	13	“Research in certain disciplines... may present risks that go beyond the individual and may involve the interests of communities, societies or other defined groups.”  It is important that the judgment of acceptability of risks/potential benefits is based on the <u>participant’s</u> – 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.  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.”  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.”
427	12	“Participants should share both the <u>burdens</u> and the benefits of research.”  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.
523-545	15	Continuing ethics review is a good idea in principle but it is questionable the degree to which any given REB can uphold the requirement outlined in Article 2.8 due to capacity limits, which will vary across institutions.
582-585	16	“ <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.”  This sentence is convoluted and confusing. It should be restated with omission of double negative.
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

Free and informed consent must be addressed within an intercultural context. While the range and flexibility in demonstrating evidence of consent is appropriate, the focus should be on assuring the fundamental principles that these criteria address (e.g. not coerced, persuaded, aware of how work will be used) are met rather than the format, strategies or mechanisms for evidencing their implementation (e.g., voice recorded, written forms). This requires flexibility by REBs and other authorizing bodies and a willingness to engage in alternative strategies that are more consistent with the practices of a specific group.

There is more to free and informed consent in the context of research involving Aboriginal participants. A careful documentation of the rationale for offering different interpretations of requirements such as “free and informed consent” arising from First Nation laws and protocols, and collective interest and responsibility can be included in detailed REB applications and required in some instances in subsequent applications and elaborations. Moreover, when appropriate community authorities are engaged in research involving Aboriginal participants, informed consent should include advising participants about how community authorities will be engaged in review and validation of work. It should also include mandatory discussions about use, responsibility, and ownership of data and products of research. Special consideration also needs to be given to the word “free” as in “voluntary” when it comes to proper compensation for elder knowledge. We discuss these and other Aboriginal research issues in our comments on Chapter 9.

It should be made clear that **consent is separate from a research agreement**. While we are not proposing that research agreements should be required, we think research agreements are an important tool for clarifying mutually-agreed terms of research and thus should be discussed in this chapter, with inclusion of key resources to assist in development of research agreements.

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.”  Please clarify if this is this a university staff person (third-party) or a member of the research team.

779-780	24	<p>“Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research”</p> <p>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).</p>
806	25	<p>“The time required for providing <u>an</u> initial free and informed consent...”</p> <p>Is “an” a typo (i.e., it doesn’t make sense)?</p>
834	25	<p>“It is equally important that prospective participants be made aware of their right to withdraw from a research study at any time.”</p> <p>Participants also need to be made aware to limits to the ability to withdraw (if any) based on methodology.</p>
903	27	<p>Incidental findings may also arise in ethnobotanical research (e.g., commercializable products) and lead to important intellectual property and data ownership issues. This example should be included along with the genetic research example.</p>
1272	36	<p>“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.”</p> <p>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: “<u>Qualitative</u> researchers use a range of consent procedures, including <u>written consent</u>, oral consent, field notes, and other strategies, for documenting the consent process.”</p>

#### **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**

Regarding how data are to be used and all secondary uses, if permission cannot be obtained for any academic use then researchers should be required to get further consent. Copies of the data and other research products should be provided if requested and researchers should be obligated to discuss issues of ownership and any limitations that may be imposed by researchers’ institutions, funders, etc (e.g., limitations on what we can negotiate, possible means of co-ownership, copyrights).

Issues raised by secondary use and in need of elaboration in this chapter include: accuracy of data; attribution (when desired by the source); an obligation to critically analyze the data against the “ethical standard of the day” when the data was collected; transparency (i.e., letting people know of the secondary use); and protection of research from political influences (noting there are power imbalances within communities and the ability to conduct research independent of internal mechanisms of authority remains important).

There is a danger that the policies here will be applied outside the context of research involving human participants and result in the denial of funding. For example, it is possible that an assessor will consider these criteria any time issues of Aboriginal identity or community are invoked, despite the absence of human participation in the research (e.g. archival research). Not all research concerning Aboriginal peoples involves human participants, nor, in our view, should this be required. Encouraging a diversity of approaches to research and opinions is fundamental for the benefit and advancement of knowledge within and outside of Aboriginal and other communities. It is important to acknowledge that there are also power imbalances within communities and the ability to conduct research independent of internal mechanisms of authority remains important.

<b>Line</b>	<b>Page</b>	<b>Comment and/or change recommended</b>
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>An expectation of attribution and due credit is often the case in community-based research. The assumption of anonymity is an influence of the medical and psychological research models and should be removed.</p> <p>SUGGESTED REVISION: “In <del>some</del> instances; <u>WHERE</u> participants <del>may</del> wish to be identified for their contributions to the research. <del>Where possible</del>, researchers should negotiate agreement with participants about <del>if and</del> how participants <del>may</del> <u>WISH TO</u> be identified to recognize their contribution.”</p>
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 participant should never be in a situation of finding out coincidentally that his/her information is being used secondarily. The onus should be equally (if not more) on the <u>researcher</u> to take reasonable steps to actively find out if there are objections for use. This should always be discussed as part of informed consent and participants must be advised once something is available on the web, published, or placed in a public archive since secondary use is hard to control. It is clearly unethical to engage in a secondary use when the objection to such use is known at the time of obtaining consent and was addressed in the</p>

		<p>consent process. In the example used, the situation is open-ended, i.e., how would an individual living in a non-urban location with more limited access to news or in a location geographically distanced from where the research is 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? The use of “must” be respected (to replace “should”) is essential here.</p> <p>“Known objections to secondary use <del>should</del> <b>MUST</b> be respected <b>BY THE RESEARCHER AND HIS/HER EMPLOYER WHERE SUCH OBJECTIONS ARE KNOWN AT THE TIME OF OBTAINING CONSENT</b>. 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>
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## Chapter 6: Governance of Research Ethics Review

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.”</p> <p>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)? What is the measure of such knowledge? 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> <p>Additionally, we suggest the need for <u>at least one person with expertise conducting research involving Aboriginal peoples</u> where REBs consider applications in this context.</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>

		In research that invokes community engagement, we believe that only one community representative is insufficient. A person with expertise in community-based research should be considered as one of the required members of every REB that considers applications that involve community-based research.
1969	57	ADD TEXT: “Community representation should be proportionate to the size of the REB <u>AND SHOULD BE COMPRISED OF INDIVIDUALS FROM A DIVERSITY OF BACKGROUNDS AND COMMUNITY AFFILIATIONS.</u> ”  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.
2017-2019	59	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> ”
2152	62	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.”

## Chapter 7: Conflict of Interest

Line	Page	Comment and/or change recommended
2585-2587	75	“Although the potential for such conflicts has always existed, pressures to commercialize research or suspend dissemination of research outcomes heighten concerns.”  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.
2625	76	Explanation of “firewalls” is needed, or use a widely understood term instead.
2696-2706	78	“Research involving small communities... ..may be sufficient to management conflict”  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).

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>
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## 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 <b>protocols</b> (and associated terms) in the General Comments section. It needs to be emphasized that these may or may not be in written form and researchers need to take reasonable steps to discover what they are.</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 reports 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><u>ADDITION: “However in all cases researchers should ensure that participating communities are informed of how to access the results.”</u></p> <p>We also encourage researchers to provide project results to the community in culturally appropriate and meaningful formats, such as project results written in lay language rather than (or in addition to) technical reports.</p>

## Chapter 9: Research Involving Aboriginal Peoples

Generally, there is an inadequate 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. We support the recognition that concern for welfare may include more than individual physical and psychological well being in some Indigenous contexts (i.e. collective, spiritual). However, it is important to also note that each

Indigenous culture is unique and that there may, as a consequence, be diversity in understandings about the nature of research that calls for community engagement at a collective and individual level, and how concepts such “individual,” “communal” (e.g., family, group, broader community) and “spiritual” or “sacred” are understood.

As indicated in the table below, Aboriginal constitutional and treaty rights must be respected but normative and ethical obligations extend beyond the rights regime. A danger in emphasizing legal rights is that some may interpret ethical obligations narrowly within this context. It should be clear that: (i) the law in this area is complex and dynamic, and (ii) emphasis given to legal rights is not intended to enable a narrow interpretation of ethical obligations to only those obligations that are clearly required by law. **We recommend in general that “rights” should be linked with “interests” to avoid narrow rights based approaches to the interpretation of ethical obligations and linked also with “responsibilities” to be consistent with Aboriginal worldviews of multi-generation obligations to ancestors and future generations (i.e., “Aboriginal rights, interests, and responsibilities”).**

It is good that the Draft TCPSv2 underscores the importance of community engagement in the context of cultural heritage research, but also needed is an understanding that the concept of “**cultural heritage**” can be quite broad and diverse. The concept of cultural heritage is not adequately defined and the use of the word "property" in the Draft TCPSv2 is not always appropriate. Further, over the last ten years, cultural diversity and protection and promotion of Indigenous cultural rights have become a major focus of debate taking place among international and regional organizations. Bodies that have examined this include the G8; the Council of Europe; and the United Nations including the Human Rights Commission, the Working Group on Indigenous Populations, and the Permanent Forum on Indigenous Issues. This progressive international affirmation culminated in UNESCO’s 2005 Convention on the Protection and Promotion of the Diversity of Cultural Expressions, responding to the growing concerns of civil societies and governments regarding the preservation of cultural diversity as a common heritage of humankind, in a similar manner to biodiversity, as well as the promotion of living cultures and creative capacity. For these reasons we strongly recommend including a definition of cultural heritage with reference to international instruments such as the UN Declaration on Rights of Indigenous Peoples and the work of Erica Daes, the [2001 Declaration on Cultural Diversity](#) (and Action Plan), and UNESCO’s [2005 Convention on the Protection and Promotion of the Diversity of Cultural Expressions](#).

Given the diversity of Indigenous cultures it is important that community engagement and development of ethical frameworks be **context specific, collaborative** and **deliberative**. The Draft TCPSv2 is commendable in the emphasis it gives to obtaining culturally-informed advice appropriate to the context of the work. Not all communities have research protocols, and depending on the nature of the research, protocols may have to be revisited (e.g., in review of work by elders, it may end up that selecting one representative is most appropriate because of the size of the work).

It is good that the guidelines refer to "**appropriate authorities**" and recognize that the formal institutions of Indigenous government may not be the appropriate or only body with authority to act in relation to research. It is important for researchers to be provided with the necessary information and resources to do preliminary work to ensure all appropriate authorities are identified and engaged. If it is to be on the territory of a particular people, we agree that the recognized legal authorities must be consulted, otherwise there may be trespass issues.

Regarding “**free and informed consent**”, we agree that “community or organizational agreement” cannot replace “free and informed” consent of individuals, but suggest “informed consent” is more complex in an Aboriginal research context. Researchers should be obliged to inform individual participants about the mechanism for community authority review and/or approval as part of the principle of informed consent. Given increased concern about appropriation of cultural knowledge, misrepresentation, and use of data concerning human participants and matters of cultural heritage, researchers should be obliged to: (a) discuss ownership of data, use of data (including possible secondary uses), and copyright with appropriate community authorities; and (b) if requested and where possible and appropriate given the nature of the research, to find alternatives to sole institutional and author ownership that are more inclusive of community collaboration and control of outcomes of research. Although written or recorded consents are preferred, there should be flexibility for REBs to approve mechanisms for evidencing consent that are more culturally appropriate to the communities and individuals engaged in the research. In matters of cultural heritage researchers should be obliged to take reasonable steps to inform themselves of individuals with the capacity to speak to the issues being researched in accordance with the laws and protocols of the community

Our experience is that **flexibility of application is extremely important** because of the diverse understandings and traditions Aboriginal communities have concerning cultural heritage, laws and protocols for sharing and control over information, and the desire and interest to engage at various stages of the research program. Concerns for protection and control of research and products of research vary among communities, with some having research protocols similar to those adopted by academic institutions for research involving human participants, and others requiring greater consideration of collective interests and control over use, sharing and communication of information (e.g. by elder panels, ceremonial societies). Protocols do not always present themselves in a manner with which western academics are most familiar, i.e., they are not always written down or codified and may be evidenced through action and ceremony. The principle of being culturally informed is imperative and it is essential to acknowledge that compliance with law and protocol may still be required absent formal written codes and protocols. **There should be an obligation on the researcher to take all reasonable steps to be informed of oral and performance based protocols as well.**

**The importance of engaging with the community prior to the actual research activities through community events (e.g., feasts, celebrations, informal meetings) and planning meetings can not be overstated** in terms of relationship building; clarity of the research program including goals, outcomes, and conduct of the research; and conflict resolution and avoidance. These activities have associated costs, however, that should be specifically recognized as part of Aboriginal research, as well as part of community-based research more generally. In addition, many Aboriginal communities are already hard pressed to meet demands on their time and resources for reviewing other proposals (e.g., forestry, mining).

Although community engagement is key in research involving human participants, it is important to note that not all research concerning matters Indigenous calls for community engagement. At the same time, given the inadvertent harm that can arise from cultural heritage research, further thought needs to be given to ethical obligations in the context of archival research, archaeological research, and research that draws on what western perspectives identify as objects. The concept of “humanity” itself is not a value neutral term (e.g., animate *versus* inanimate nature, and landscapes).

Furthermore, the usual “western” dichotomies of nature/culture; people/environment; natural world/supernatural world may not exist in an Aboriginal worldview. Having said this, we believe more consideration needs to be given to applying these norms to scholarship concerned with identity and other matters of cultural heritage that do not involve human participants.

We have a **concern about emphasizing numbers in terms of engagement of community**, i.e.. "proportionate" community engagement. The reference to "significant numbers" must be omitted and this aspect of community engagement requires elaboration (see our detailed comments in the table below).

There needs to be a mechanism to **recognize the validity and importance of elders’ knowledge in research and provide appropriate compensation**. Elders who contribute their expertise should be treated as collaborators not “subjects” in research. Respect for different knowledge systems and appropriate payment for elder knowledge should be taken into account by REBs in assessing issues of payment for participation and voluntariness.

Fuller consideration is needed as to **what is meant by “academic integrity” and “rigour” in the context of collaborative research that seeks to respect different ways of knowing**. Credibility in academia has commonly been understood as deriving conclusions free of influence by “participants” but this idea of critical inquiry and credibility may be at odds with the objectives of collaborative work. Critical inquiry should be understood as engaging not just academic tools but those within the communities with whom we partner (e.g. mechanisms for validating veracity of elder knowledge). It would be helpful to point this out to researchers.

**A provision is needed to address appropriate intercultural dispute resolution**. If meaningful engagement with appropriate authorities and participants seeks to find a common ground, anticipate differences, and agreement on process, what procedures can be taken in the event of conflict? PRE should explore the creation of a dispute resolution mechanism that seeks to resolve conflict in a manner that gives equal weight and respect to Aboriginal and academic ways of knowing and ethical norms. When research relationships break down, Aboriginal participants are most often disadvantaged in that the only recourse they have is against geographically distant institutions that have vested interests in supporting the researcher and tend to rely on legal rather than ethical arguments in face of conflict. To engage in dispute resolution in a meaningful way is costly and may involve legal intervention. These and different cultural norms create significant imbalance of power. We acknowledge that the matter of independent, cost effective, and interculturally legitimate dispute resolution in this context requires significant research, consultation, and planning, but we suggest it is a necessary next step for inclusion in the TCPS.

It is important that the recommendations of the TCPS are taken into consideration in developing **criteria for funding research engaging Aboriginal participants and communities as participants** in research. Inability to acquire sufficient funds or time to comply with the highest standards for community engagement may result in reluctance to engage in important research, narrow construction of ethical obligations, unintentional harm, and unequal relationships – many of the dangers the TCPS is intended to avoid. The issues highlighted below are implicated by the TCPS and that must be taken into consideration beyond the realm of research ethics:

- **The importance of engaging with the community prior to the actual research activities through community events (e.g. feasts, celebrations, informal meetings) and planning meetings can not be overstated in terms of relationship building; clarity of the research program including goals, outcomes, and conduct of the research; and conflict resolution and avoidance.** As this process is integral to the research it is crucial that this be taken into consideration in setting amounts for funding, eligible expenses, and duration of grants, as well as in establishing timelines and project milestones. Not all institutions are able to fund the pre-application phases necessary to support truly collaborative research.
- **Ongoing, culturally appropriate means of communication are fundamental for the successful community engagement in collaborative research. Such communication is rarely effective using only electronic means, such as the internet or telephone.** Follow up letters, calls, and visits are required throughout the research program as collaborative research is time consuming and the end product often issues many years after the research is initiated. Such communication is necessary for the meaningful engagement called for by the TCPS. This needs to be taken into consideration in allocation of funds, eligible expenses (e.g. administration costs for Aboriginal organizations engaged in research; customary gift giving) and time lines. **Of particular concern in this regard is the proposed elimination of research stipends and the impact this could have on effective engagement.**
- Research ethics that give meaningful interpretation to **respecting the integrity of Indigenous knowledge systems and protection of cultural heritage extends beyond procedure to communication of ideas and application of standards for academic rigor.** Meaningful community engagement means providing a mechanism for community input at **all** stages including interpretation of results. This raises complicated and lengthy process of review and challenges both academic institutions and researchers to re-examine what we mean by academic rigor and negotiating space for difference of opinion.

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 generally 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</p>

		<p>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 have <u>IN MANY CASES</u> led to the development of ethical protocols to guide community–researcher relations. <u>IN OTHER CASES, ETHICAL PROTOCOLS ARE EMBEDDED IN INDIGENOUS LEGAL ORDERS AND MAY BE UNWRITTEN AND VARY DEPENDING ON THE SUBJECT MATTER OF THE RESEARCH.</u>”</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 implicated, making <u>community engagement</u> a priority.”</p> <p>It should be made clear that there are circumstances in which issues of 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	<p>ADD TEXT: “Resulting harms are <u>REAL BUT</u> seldom intentional.</p>
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</p>

		fully encompass the intentions and subject matter of Chapter 9.
3166-3168	92	<p>ADD TEXT: “Affirmation of Aboriginal rights and respect for community ethics codes and protocols, <u>LAWS, PRACTICES 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.”</p> <p>We must also realize the importance of Indigenous law (which may be oral) and practice, neither of which may not be codified or understood as “protocol.”</p>
3170	92	<p>ADD TEXT: “Aboriginal peoples have rights, <u>RESPONSIBILITIES</u> and interests that deserve recognition and respect by the research community.”</p> <p>We suggest this statement needs further revisions to account for the point that increasingly Aboriginal individuals are themselves university researchers.</p>
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 AND HAVE</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	<p>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 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 note that commercialization can be a positive situation in a community’s view (e.g., some cultural tourism), and that 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</p>

		involved.
3227-3228	93	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...”
3230-3231	93	<p>“...researchers should seek <u>culturally informed advice appropriate to the 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	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.”
3244-3246	94	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> ”
3251-3256	94	<p>“<b>Article 9.1</b> <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 cultural heritage, the integrity of Indigenous knowledge systems, and the diversity that exists among and within Aboriginal communities.”</p> <p>If this is intended to be a case-by-case determination then it is essential that the determination NOT be left only to the discretion of the researcher and REB. A representative of that prospective Aboriginal participant population must be included to ensure an emic (i.e., from within the culture) understanding. In such cases, it is vital that REBs have members with experience working with Aboriginal communities as well as some mechanism for Aboriginal representation of the REB, and that researchers be required to indicate how they intend to engage appropriate community authorities in all levels of the research program.</p> <p>This article re-enforces our point that the three core principles of the</p>

		<p>Draft are a forced fit that appears to be imposed on Chapter 9 without due consideration of the implications and the issue of dual approval and validation. Without such changes, the imposition of the core principles on research involving Aboriginal peoples is not an improvement over the existing version of the TCPS.</p> <p>Regarding the reference made in this article to demonstrate respect for “<u>Aboriginal rights</u> and cultural heritage,” although some Aboriginal communities ground research concerns and initiatives affecting their cultural heritage in the assertion of inherent Aboriginal rights, and legal arguments in support of such rights have been developed, it is important to note that the scope of constitutionally protected Aboriginal rights is emerging and not yet clearly defined from the perspective of Canadian courts. To date we do not have legislation or case law that clearly recognizes Aboriginal constitutional rights to protection and control of their cultural heritage. Given the challenges and controversy associated with increased Aboriginal participation in research and control over products of research originating in their communities there is a potential danger that the language of “rights” will be narrowly construed by researchers and REBs to refer only to existing, recognized rights in Canadian law. Therefore both in the discussion of the policy preceding these articles and in all articles <b>we recommend referring to “Aboriginal rights, <u>responsibilities and interests</u>” in cultural heritage to avoid narrow rights based approaches to the interpretation of ethical obligations.</b></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>
3261-3262	94	<p>“(a) Research is conducted on a <u>defined First Nation territory</u>, Inuit land claims territory or Métis settlement”</p> <p>It is not clear what is meant by “defined First Nation territory.” Defined by whom? Traditional territories as defined by Aboriginal peoples extend beyond boundaries recognized in Canadian law (e.g., reserves) and overlap. As currently stated it is not clear when this consideration is to be invoked. We suggest linking the definition of territory to that adopted by the participants’ community.</p>
3256-3266	94	<p>“The research involves <u>cultural property</u>, Indigenous knowledge, or input from an Aboriginal community”</p>

		<p>The reference to research involving “cultural property” invites a narrow legalistic interpretation as cultural property is defined in domestic legislation concerning international movement of cultural objects and international treaties concerned with trade and recovery. Our research and that of others has demonstrated that the concept of property is not necessarily understood or consistently applied between western and Indigenous legal systems and among Aboriginal communities.</p> <p>The discussion of ethical concerns (lines 3199 – 3215) defines the broader concept of cultural heritage, including cultural property, with reference to the United Nations Declaration on the Rights of Indigenous Peoples. Use of the broader concept of “cultural heritage” is important because “cultural property” to varying degrees is incomprehensible, inappropriate, and inadequate when understood as a western legal, social or economic concept and applied to some forms of aboriginal cultural heritage. <b>For consistency with the general discussion of ethical concerns and clarity in the adoption of the definition of cultural heritage we suggest any time the phrase “cultural property” is used it be replaced by “<u>cultural heritage as understood by the participants’ community.</u>”</b></p>
3282-3288	95	<p><b>“Article 9.2</b> In research proposals involving one or more Aboriginal communities <u>or 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>The reference to "significant numbers" must be omitted. It is not clear what is intended and we have concerns about emphasizing numbers in terms of engagement of community. The idea of "proportionate" community engagement is troubling if this is a category that is determined outside of the context of community engagement when any number of human participants are involved in the research. The significance of the number may vary with the nature of the research being conducted. For example there may be few people, who have the authority within a community to discuss matters being investigated, but the information shared and how it is used could impact on a larger population. 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. “Significant numbers” is a Eurocentric approach to measuring impact, e.g., Indigenous conceptions of community and impact may have nothing</p>

		<p>to do with numbers, the appropriate cultural authority to speak on a given matter may be few in number but what they say could potentially impact a larger group.</p> <p>Article 9.2 should include a requirement that researchers inform the REB how they will engage the community or why such engagement is inappropriate given the number of participants and community affected. Emphasis on “level of Aboriginal involvement” again invites a Eurocentric quantitative analysis. Helpful examples would be those that demonstrate where such engagement may not be appropriate (e.g. research that incidentally affects a small proportion of Aboriginal participants but is not intended to single out or describe Aboriginal people in the study such as the effectiveness of therapies to control blood pressure). It may be that community engagement is not necessary or need not be as extensive in some cases, but to fulfill the goals of the policy the rebuttable presumption should be that <b>community engagement is always appropriate when there are Aboriginal participants in a study unless established otherwise by the researcher.</b></p>
3282-3288	95	<p>“<b>Article 9.2</b> In research proposals involving one or more Aboriginal communities <del>or a significant number of</del> Aboriginal participants, 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 <u>type of community</u> and proportionate to the <u>level of Aboriginal involvement</u> in the research.”</p> <p>Again we have concerns about reference to a “<b>significant number of Aboriginal participants</b>” and for the reasons stated above suggest this qualifier should be removed. It should simply refer to “Aboriginal participants.” In addition, <b>this Article should include a requirement that researchers inform the REB how they will engage the community or why such engagement is inappropriate given the number of participants and community affected.</b></p> <p>Emphasis on “level of Aboriginal involvement” again invites a Eurocentric quantitative analysis. Helpful examples would be those that demonstrate where such engagement may not be appropriate (e.g. research that incidentally affects a small proportion of Aboriginal participants but is not intended to single out or describe Aboriginal people in the study such as the effectiveness of therapies to control blood pressure).</p> <p>The importance of flexibility is reflected in the notion that the “<u>nature and extent of community engagement should be appropriate to the type of community.</u>” However, it is not clear what is meant by “type” of community. For consistency with the policy articulated, we <b>suggest an appropriate amendment would be “<u>the research protocols, laws and</u></b></p>

		<p><b><u>practices of the participants’ community.</u></b></p> <p>Text should be added to Article 9.2 (consistent with the CIHR Guidelines) to give communities the option of a participatory approach.</p> <p>SUGGESTED REVISION: “<b>Article 9.2</b> In research proposals involving one or more Aboriginal communities or <del>a significant number of</del> Aboriginal participants, 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, <u>OR WHY SUCH ENGAGEMENT IS INAPPROPRIATE GIVEN THE NUMBER OF PARTICIPANTS AND COMMUNITY AFFECTED.</u> The nature and extent of community engagement should be appropriate to the <del>type of community and proportionate to the level of Aboriginal involvement in the research</del> <u>RESEARCH PROTOCOLS, LAWS AND PRACTICES OF THE PARTICIPANTS’ COMMUNITY. ALL COMMUNITIES SHOULD BE GIVEN THE OPTION OF A PARTICIPATORY RESEARCH PARTNERSHIP.</u>”</p>
3289	95	<p>“First Nation, Inuit, Métis, urban and rural communities differ significantly from one another, and they are characterized by increasing <u>internal diversity</u>. 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>It may not be clear what is meant by “internal diversity.” Engagement throughout the research process should be the norm in all contexts and not just in those where there is “internal diversity.”</p> <p>Clarify what is meant by <u>throughout the research process</u> by specifically including “i.e., finalizing 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</p>

		video.
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 and include examples of the nature of support (e.g. hiring and training people from the community to engage in the research). Without clarification the question is whether the obligation falls on the researcher or some other entity? If on the researcher, is this feasible? Should this onus more reasonably rest on the institution of the researcher or a combination of researcher and institution?</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? We suggest amending the text to “... the responsibility for <u>TAKING REASONABLE STEPS TO SECURE</u> culturally informed advice...”.</p>
3427-3429	99	<p>ADD TEXT: “<b>Article 9.5</b> Where prospective participants signify that a community ethics code, <u>GUIDELINE, POLICY, LAW, or RESEARCH</u> protocol OR PRACTICE is in effect, researchers and research ethics boards shall take <u>SUCH</u> into consideration <del>the code, or protocol that</del> AS applies in the territory or organization.”</p>
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” of ethical codes (etc) by all parties. It should be recognizes that there are different legal orders at play and to the extent possible, and absent conflict with the funder and University obligations, community research protocols and practices should be given effect. Where this cannot happen in entirety, researchers should have an obligation to explain why not and seek a solution that meets the diverse interests at play by using the “consideration” of ethical codes to inform negotiation of mutually-agreed terms, which would preferably take 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.</p>

		<p>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, LAWS</u> and <u>RESEARCH</u> protocols OR PRACTICES 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 (e.g., there may be cases where the institutions claim first rights to the intellectual property or products of a researcher’s discoveries). 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>
3475-3478	100	<p>“<b>Article 9.6</b> Researchers should consider entering into research agreements with those Aboriginal communities <u>who have adopted</u> ethics codes, <u>GUIDELINES, POLICIES, LAWS</u> or <u>RESEARCH</u> protocols OR PRACTICES, as a means of clarifying and confirming mutual expectations and commitments between researchers and communities.”</p> <p>It is unclear why research agreements are only to be considered with Aboriginal communities who have adopted ethics codes or protocols. When an existing community code (etc) is in place, best practice is that it should form the basis of mutually-agreed terms, as represented in a research agreement where appropriate (given the cultural context and expectations of the community). In the absence of an existing community code (etc), the basis of mutually-agreed terms (whether represented in a research agreement or not) must be discussed, co-developed or negotiated, not ignored.</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>We suggest that researchers should <u>develop these arrangements with</u> communities and 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><b>“Protection of Indigenous <u>and</u> Cultural Knowledge”</b></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 and perhaps “Indigenous knowledge” is sufficient. 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: <b>“Protection of Indigenous <u>Knowledge and Cultural Heritage</u>”</b></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 (see also our previous comments on replacing cultural <u>property</u> with cultural <u>heritage</u>).</p> <p>Further consistency and clarification of terms used in this section are needed, as indicated below.</p>
3608-3647	103-104	<p><b>“Article 9.10</b> 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.</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>WHERE AGREEABLE TO COMMUNITY AUTHORITIES 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 where agreed by Aboriginal participants, represented in a written research agreement.</p> <p>We note also that it is important to determine what constitutes Indigenous knowledge for the community.</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</p>

		<p>perspectives. In many cases, this would be an appropriate and vital place for use of <i>ad hoc</i> REB members, as indicated in <b>Article 9.14</b> (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>“Cultural property often does not fit the criteria of sole ownership, innovation and representation in a tangible work that are necessary to claim protection for intellectual property rights. National laws and international consensus on these issues are evolving. The definitions of tangible and intangible cultural property over which Indigenous peoples arguably have rights are broader than the definitions of intellectual property protected under national law and international agreements. Intangible cultural property, such as traditional knowledge of the medicinal properties of plants or traditional clothing design, that is collectively held is often regarded as “folk knowledge” that is available in the public domain and that may be adapted through commercial processes to produce marketable commodities without consent of the originators.”</p> <p>There is redundancy and some confusion in the above paragraph. For example, it would make more sense if the above paragraph began: “Intangible aspects of cultural property does not always fit the criteria of sole ownership, innovation and representation in a tangible work that are necessary to claim protection for intellectual property rights under Canadian law.” Some re-ordering and revisions (such as we have suggested) would increase clarity and accuracy and avoid confusion.</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.</p> <p>SUGGESTED REVISION: “Researchers should afford the community an opportunity to react and respond to research findings before the completion of the final report, in the final report, <del>or</del> <b>AND even</b> 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 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.</p>

		<p>It is not clear what is a “collaborative research report.” Does this mean co-authored or does it refer to any report that emerges from the collaboration, regardless of authorship? Please clarify.</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>“<b>Article 9.11</b> 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 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>

		We believe secondary use of data is appropriately dealt with as a matter of increased control over Indigenous knowledge by source communities and thus should be governed by principles concerned with appropriation, misrepresentation and protection of Indigenous knowledge. These are areas which the IPinCH project seeks to explore in further detail as part of the research program.
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 “cultural <u>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 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.”</p>
3700-3702	105	ADD TEXT: “ <b>Article 9.12</b> 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>“<b>Article 9.13</b> 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> . <del>Implementing a rational program of training to enhance autonomous research initiatives is less common.</del> <u>WHENEVER POSSIBLE, TRAINING SHOULD BE PROVIDED TO</u>

		<u>PROMOTE CAPACITY-BUILDING TO ENABLE AUTONOMOUS RESEARCH INITIATIVES.</u>
3734-3737	106	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.”  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.
3756-3760	107	ADD TEXT: “ <b>Article 9.14</b> 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	“For example, research on the interface between environmental and human systems that does not involve individual participants does not require REB review.”  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.
3797	108	REFERENCE TO ADD: World Health Organization, Indigenous peoples and participatory health research <a href="http://www.who.int/ethics/indigenous_peoples/en/index6.html">http://www.who.int/ethics/indigenous_peoples/en/index6.html</a>

## 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. More of the chapter should focus on ethical issues that arise in qualitative research, rather than its description. Given the length of the Draft, a more specific focus seems important.

Line	Page	Comment and/or change recommended
3820	109	“Researchers in <u>HEALTH</u> , social sciences and humanities, <del>such as sociology, psychology, criminology, business administration, political science, communications, education and history,</del> 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

		<p>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><b>“General Principles and Methodological Requirements and Practices”</b></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, even paternalistic. Participatory action research (used as one of the examples of qualitative research) is about a more collaborative process of “regaining and/or claiming voice” where “collaboration” is not viewed as simply “working together” but requires sharing of power and decision making.</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>

		This paragraph is about power, not consent – it is unclear why it is under the subheading for consent.
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, <b>MUST</b> be based on mutual understanding of the project’s intentions.</p>
4114-4116	116	<p><b>“Article 10.5</b> 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 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	ADD TEXT: <b>“Article 10.7</b> 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> ”
4195-4196	118	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> ”

## Chapter 11: Clinical Trials

We do not have expertise in this area of study but we request the name of the section called “Sharing New Information” be revised so as not to confuse people who (understandably) may take information sharing as something broader than this context.