Comments by:
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Minor comments

Page 3, line 56: “includes” instead of “covers”
Page 5, line 141-2: Could perhaps add language or education as barriers
Page 5, line 142: Delete “certain”
Page 9, line 291: “guidance and, in some cases,”
Page 12, lines 369-71: The order of biological materials is not logical; skin should be
with nails, hair, etc. Should change everywhere this list appears.
Page 13, line 409: , after accessible
Page 14, line 439: “this type of” instead of “their”
Page 16, line 516: add “appropriate” before “cultural”
Page 17, line 548: ad hoc should be italicized here and elsewhere
Page 20, line 672: “resources and, correspondingly,”
Page 21, line 636: “increase” instead of “exacerbate”
Page 22, line 757: “ongoing or significant dependency” is not a completely logical
formulation. If ongoing dependency is not significant, why should it be a problem?
Page 22, line 761: “influenced by” instead of “linked to”
Page 23, line 779: “policy” should be capitalized as elsewhere
Page 25, lines 864-865: “pose questions” instead “pose any questions they may have”
Page 27, line 937: The term “maintained” consent is not entirely clear here. This could
perhaps be reformulated.
Page 28, line 1003: “details” is repeated in this sentence. Suggest deleting “in detail”
Page 30, line 1058: “as” instead of “so”
Page 31, line 1108: “should be invited to contact the REB” instead of “given contact
information for the REB”
Page 31, line 1118: “epidemic” instead of “crisis”
Page 34, line 1246: The term “advance directives” is not clear here
Page 36, line 1311: add , after however
Page 37, line 1352: add “sometimes” between “been” and “inappropriately”
Page 37, line 1360: The term “hosting” is not really accurate here for most cases.
Suggest different formulation.
Page 39, line 1424: “generalizable” instead of “generalized”
Page 40, line 1456: No hyphen between “life” and “expectancy”
Page 40, line 1460: “drugs” instead of “treatments”
Page 58, line 2070: “research components” instead of “components of research”
Page 58, line 2079: “but” instead of “and”
Page 80, line 2902: “chronic” not really a good word here; suggest instead “ongoing” or
“long-term”
Page 83, lines 3052-6: This sentence is too long and not clear
Page 84, line 3084: add , after disagreement
Page 135, line 5006: “commonly used treatments” I wonder if this term captures precisely what you want to say here. Perhaps can refer to these as currently considered “best, acceptable or usual practice”

Page 141, line 5240: Insert “at least some” between “involve” and “risk” or you could reformulate the sentence as follows: “Clinical trials usually involve risk to participants”

commonly used treatments” I wonder if this term captures precisely what you want to say here. Perhaps can refer to these as currently considered “best, acceptable or usual practice”

Substantive comments

Page 26, para 2, lines 890-895 and elsewhere (e.g. Page 42, para 5, lines 1560-1571): The involvement of community in ethical decisions may be important in certain types of studies. On the hand, it is often difficult to obtain representative views of the acceptability of a given study. There is often a tendency for outspoken but marginal viewpoints to be given undue weight which could block or limit otherwise acceptable research. These points need to be adequately, if briefly, expressed.

Page 51, lines 1865-1866: Perhaps you should suggest somewhere that computers storing sensitive data should not be connected to the Internet.

Page 51, Section D: In the HIV field, it became clear in the 1980s that HIV prevalence studies on specimens collected for other purposes could be invaluable in better understanding the distribution of infection. These methods were initially developed by the US Centers for Disease Control. Although controversial at first, a consensus soon developed around their acceptability though under certain conditions. Two such conditions were that access to HIV testing had to be readily available elsewhere and that the implementation of the study had to be adequately “gazetted” i.e. disseminated to a wide audience. In Canada, guidelines were developed to provide a foundation for such studies <1,2>. Several such studies were carried out in Canada, including one of my own <3>. I realize this is a very specific example but a brief mention may help to support the acceptability of such studies and the conditions that may apply.

Page 51, Section D: I suggest you should also deal with issue of using specimens collected in one study in a second later study. Consent for such use should initially be obtained from the subjects. There are some cases where the specimens may no longer be considered as being from human subjects if the original study has been completed and the specimens have been anonymized. In any case, the second study must be approved by a duly constituted REB. We carried out and published a study using such specimens from pregnant women in Bangkok; the protocol was approved by the REB at the US Centers of Disease Control and the University of Toronto. <4>
Chapter 6, Governance
Do you want to say anything about the compensation of REB members?

Page 66, Article 6.13
Are the proceedings of the REB confidential? If so (and I think they should be), document should indicate that.
In same Article 6.13, may want to include a description of “conditional approval”, i.e. approval in principle but subject to certain specified modifications. In my experience, this is what tends to occur most of the time.

Page 69, last para continuing on to Page 70, first para
Are the minutes in the public domain? I don’t think so. The text in this paragraph implicitly suggests this but it should be made explicit that the minutes should not be distributed to others not named here.

Page 71, Article 6.18
Do you want to say anything about the structure and membership of the appeal body?

References