BC Clinical Research Informed Consent Form Guide and Template: Summary of Changes (September 2013)

As part of the BC Ethics Harmonization Initiative's (BCEHI) activities, the clinical informed consent template work group (previously comprised of UBC-affiliated and Fraser Health REBs) was expanded to include representatives from Northern Health, Interior Health, and Vancouver Island Health Authority. The intent was to create a common clinical ICF template for use across BC. This current version, dated September 12, 2013, has been endorsed for use by all of these institutions.

Below is a brief summary of key changes from the previous two versions of the common template, "Consent Form Guide and Template for UBC Clinical REBs and Fraser Health Authority REB" (version date July 2011 or October 2012).

Summary of Changes

1. All BC health authorities have now adopted the common ICF template; in addition to all UBC REBs and the Fraser Health Authority REB (added in 2011), the form now can also be used for studies involving Interior, Northern and Vancouver Island Health Authorities. Specific wording relevant to those health authorities has been added to the template:
2. Formatting updated for readability. Links checked and updated/fixed where needed.
3. Whenever possible, required wording has been standardized across all REBs. The REBs will continue to work on increasing the standardized language throughout.
4. **Emergency telephone numbers**: additional clarification has been provided around provisioning of emergency contact information. Researchers are encouraged to ensure that study participants seeking emergency assistance are not directed to a central &/or automated switchboard.
5. **For studies that recruit adults who lack capacity**: additional guidance and recommended wording have been provided to address their participation.
6. Terminology; use of study "participant" rather than study "subject": the template has been updated in line with TCPS2 guidance, to reflect preferred usage when describing study members.
7. Role of researcher vs. medical doctor: Recommended text provides clarification.
8. **Background**: recommendations for inclusion have been modified to improve information being made available to the prospective participant. Additional guidance/clarification regarding:
    - Standard/usual treatment, known therapeutic effects, duration of the effect, and treatments undertaken in the study
    - Participant's role in the study
9. **Optional Studies**: Added clarification/additional examples for use of individual data, records, or personally identifying information in another study.
10. **Mandatory/Optional Blood or Tissue Collection and/or Biobanking**: Added recommendation for how to deliver the information (in flow charts or other graphic display).

11. **Palliative Care or Best Supportive Care** (BSC): Added recommended text to explain.

12. **Withdrawal from study**: Updated recommended wording for explaining withdrawal options to study participants.

13. **Can I be asked to leave the study**: Added recommended text for explaining reasons and having opportunity to ask questions.

14. **Protection of personal information**: Added clarifying statement regarding study participant ID number. "This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.)."

15. **US regulated studies:** revised wording about the US FDA having the right to remove records, including personal information, as part of certain investigations.

16. **Reportable Diseases**: Added guidance specifically to clarify legal obligations. "Your personal information or information that could identify you will not be revealed without your express consent ***unless required by law***."

    Reportable diseases guidelines also include: "Insert examples of any foreseeable instances where such reporting of communicable diseases may be required."

17. **After the study is finished**: Added guidance to researchers regarding providing access to a lay summary of the study results, date when available, and method of distribution.

18. **Who do I contact**: Specific contact information where required has been added for all the REBs.

19. Guidance regarding third-party consent has been modified. Text being referred to is:

    > Old text: ***Where Third Party Consent is Being Obtained:*** *For incompetent subjects who are capable of assent/dissent and aged 14 and older, there must be a separate page with an assent statement attached to the end of this consent form. Refer to the local REB's guidance notes (links in Appendix I) for clarification of assent policies and for assent guidelines for subjects who are under 14 years of age.*
    >
    > *New text:* ***Where Third Party Consent is Being Obtained and Participants Have Capacity To Assent/Dissent:*** *Refer to the local REB's guidance notes (links in Appendix I) for clarification of assent policies and guidelines.*

20. **Witness Signature**: Added allowance for cultural barriers to signing contracts ("or for cultural reasons so that they either cannot or will not sign the consent form").

21. **Investigator Signature**: Requirements vary depending on the REB for this section. An explanation has been added for clarification to investigators of when their signature is needed. Researchers should check local REB policy.

22. Appendices have been updated with additional REB links.

23. **Appendix III**: Added clarification regarding responsibilities of the "person obtaining consent."