CLINICAL TRIALS ONTARIO

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CTO REB Qualification Manual

Version 4: April 15, 2016
Summary of Key Changes

Impact of Changes on Qualified REBs

The changes to the updated CTO REB Qualification Manual do not impact the Qualification status of CTO Qualified REBs.

A. Changes to Qualification process

1. Clarification regarding process of requesting Qualification
("Requesting Qualification" section, page 7)

Added wording:

Requesting Qualification

1. Please contact CTO when the REB is ready to undergo the Qualification process, ideally at least 4 weeks prior to the desired dates for the on-site visit.

Rationale:

To clarify that REBs will ideally request to undergo the Qualification process at least 4 weeks prior to the desired date for the on-site visit, to assist CTO in accommodating the desired visit date. The timeline for submitting REB documentation remain unchanged at 2 weeks prior to the visit.

2. Clarification regarding recipients of Qualification Reports and Qualification designation
("Qualification Report and REB Qualification" section, page 8)

Revised wording (new text in italics):

1. Following the Qualification visit, CTO will provide the REB with a Qualification Report. *This report will be provided to the REB Chair(s) and the REB Contact person.*
2. If the Qualification Report does not contain any findings, the REB will be designated as a CTO Qualified REB *and the designated institutional contact(s) will be copied*.
4. Once the CAP has been reviewed by CTO and all findings have been resolved, the REB will be designated as a CTO Qualified REB. *Confirmation of this designation will be provided to the REB Chair(s), the REB Contact Person, and the designated institutional contact(s).*

Rationale:

To clarify that the REB will be provided with the Qualification Report, and the designated institutional contact(s) will be notified when the REB is designated a CTO Qualified REB.

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3. Specification of option for CTO to conduct a post-qualification follow-up visit ("Qualification Report and REB Qualification" section, page 9)

Added wording:

Depending on the nature or extent of Findings identified during the review, CTO may conduct a follow-up visit at a later date to ensure that the corrective action has been successfully implemented. CTO will inform the REB if this is the case.

Rationale:

In some cases, CTO may conduct a follow-up visit to ensure that the corrective action has been successfully implemented by the REB. This could occur if, for example, there were a significant number of findings or if the corrective action constitutes major change(s) in process. The REB would be informed if this were the case.

B. Changes to preliminary questionnaire

4. Addition of the Canadian Food and Drugs Act and applicable Regulations and Tri-Council Policy Statement in Section 9

Added wording:

Canadian Food and Drugs Act and applicable Regulations	Yes☐	No☐
Tri-Council Policy Statement (TCPS 2)	Yes☐	No☐

Rationale:

This was inadvertently omitted from the previous version.

5. Addition of Institutional Contacts section in Section 10

Added wording:

SECTION 10 – Institutional Contacts			
a) Please provide the name of the institutional contact(s) for the REB (such as the Vice-President, Research), for the institution hosting the REB and institution(s) the REB serves:			
Contact Name	Contact Role	Contact Email	Institution Name

Rationale:

This will ensure that CTO has the correct contact information for the designated institutional official(s) who will ultimately be notified when the REB has achieved the CTO Qualified designation.

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C. Changes to the CTO REB Qualification Checklist

A number of administrative changes, primarily to better correlate the checklist wording with the source element(s), move elements to a more suitable category, and minor formatting revisions, have been made throughout. The list below highlights key change; a complete list of changes is retained by CTO.

6. Revisions to reflect the updated TCPS 2 (2014)

Previous wording:

D5: The REB may approve research without requiring that the researcher obtain the participant's consent where the REB is satisfied, and documents, that all of the following apply:
a) the research involves no more than minimal risk to the participants;
b) the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information, at which point they will have the opportunity to refuse consent; and
e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

Revised Wording:

D5: The REB may approve research that involves an alteration to the requirements of written informed consent (e.g., research that waives the requirement to obtain the participant's consent) where the REB is satisfied, and documents, that all of the following apply:
a) the research involves no more than minimal risk to the participants;
b) the alteration to consent requirements is unlikely to adversely affect the welfare of the participant;
c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
d) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined, and whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information, at which point they will have the opportunity to refuse consent;
and
e) the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or biological specimens is in accordance with the requirements the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

The REB shall be satisfied that the necessary criteria have been met when consent is waived for the secondary use of identifiable information, and secondary use of identifiable biological

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specimens (consent is not required for research that relies exclusively on secondary use of non-identifiable information).

Added wording:

D6: Debriefing must be part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate.
Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or biological specimens whenever possible, practicable and appropriate.

Rationale:

These changes ensure consistency with the updated version of TCPS 2 (2014). As outlined in the 'highlights of changes' document dated December 2014, the revisions included dividing Article 3.7 into two articles to clarify the range of alterations to consent and guidance regarding debriefing in the context of alterations to consent. Changes to Chapter 5 included making it explicit that consent is not required for research that relies exclusively on secondary use of non-identifiable information.

7. Clarification of an element

Added wording:

D40: All REB decisions concerning an application shall be communicated in writing to the applicant in a timely manner and shall contain the following information:
a) unambiguous identification of the application reviewed
b) whether the application was reviewed at a convened meeting of the REB and, if so, the date of that meeting
c) a statement of the decision reached by the REB, and
d) A statement that the REB meets the requirements of this Standard and is in compliance with the applicable statutes and regulations.

Rationale:

This element was previously considered to be part of element D39, but has been separated to clearly identify the requirements as outlined in CGSB 4.4.5.2 (a-d)

Questions about these changes may be directed to:
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