OCREB Webinar

January 26, 2024

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Ontario Cancer Research Ethics Board…
safeguarding the rights and well-being of cancer research participants

Pre-Approved Changes and Pre-Approved Site-Specific Changes

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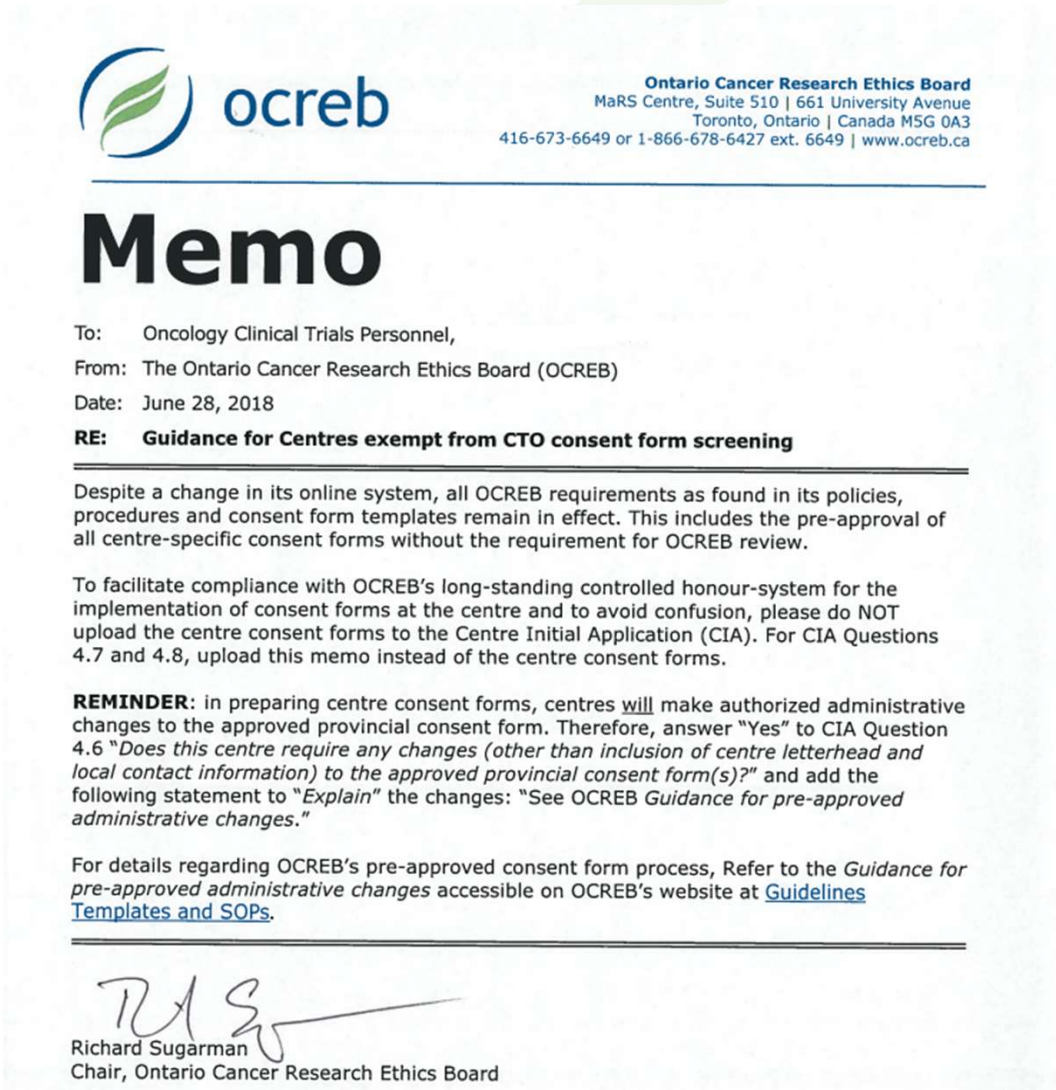
Pre-Approved Changes

- Addition of contact information, centre letterhead, removal of instructional text and correction of spelling errors.
- Highlighted areas of the consent form and detailed in the centre application.
- Inclusion of procedures/tests taking place at another centre
- Compensation/Reimbursement
- Optional sections – for study procedures that are optional for SITES e.g. use of 3rd party reimbursement or 3rd party locator
- Version date of document is maintained

Current



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Memo

To: Oncology Clinical Trials Personnel,

From: The Ontario Cancer Research Ethics Board (OCREB)

Date: June 28, 2018

RE: Guidance for Centres exempt from CTO consent form screening

Despite a change in its online system, all OCREB requirements as found in its policies, procedures and consent form templates remain in effect. This includes the pre-approval of all centre-specific consent forms without the requirement for OCREB review.

To facilitate compliance with OCREB's long-standing controlled honour-system for the implementation of consent forms at the centre and to avoid confusion, please do NOT upload the centre consent forms to the Centre Initial Application (CIA). For CIA Questions 4.7 and 4.8, upload this memo instead of the centre consent forms.

REMINDER: in preparing centre consent forms, centres will make authorized administrative changes to the approved provincial consent form. Therefore, answer "Yes" to CIA Question 4.6 "*Does this centre require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial consent form(s)?*" and add the following statement to "*Explain*" the changes: "See OCREB *Guidance for pre-approved administrative changes.*"

For details regarding OCREB's pre-approved consent form process, Refer to the *Guidance for pre-approved administrative changes* accessible on OCREB's website at Guidelines Templates and SOPs.

Richard Sugarman
Chair, Ontario Cancer Research Ethics Board

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Coming Soon

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Memo

Date: Month DD, YYYY [initial version; previous version(s) Month DD, YYYY, Month DD, YYYY]

RE: Institution Name Centre: Pre-approved, Centre-specific changes

All provincially approved OCREB study documents, including participant materials such as wallet cards and consent forms, are pre-approved for use by all participating centres with the application of 'administrative changes' to the documents. The provincially approved document version date must be maintained once the administrative changes have been applied.

This process for applying centre-specific information to the provincially approved documents, without modifying the version dates, is based on a controlled honour system: i.e., centres are mandated to comply with the specified implementation of the centre-specific changes, which are pre-identified and approved by OCREB as indicated in the guidance and in other applicable centre-specific documentation. Periodic reviews or audits of centre study documents will be conducted at OCREB's discretion, to demonstrate compliance with the process.

For all participating centres, the following administrative changes to the provincially approved document(s) are pre-approved for implementation:

- modification of the Compensation (reimbursement) section of the provincially approved

- New Memo will clearly list pre-approvals for sites that have them, in addition to pre-approval applicable to ALL sites

CIA Q 4.9

4.9 ***Does this site require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial/CHEER consent form(s)?**

☐Yes ☐No

If 'Yes':

4.9.1 *Explain: Click here to enter text.

Q4.9: Always answer "YES" and include the following statement to "Explain" the changes:
"See OCREB Guidance for approved administrative changes"

CIA Q 4.10 - 4.11 (upload memo here):

If 'No' is selected in 4.1.1, questions 4.10-4.12 will appear:

4.10 ***Upload the proposed SITE-SPECIFIC consent form(s) with the proposed site-specific changes tracked:**

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

Q4.10: for Pediatric CIAs only that include the use of Satellite sites: upload the signed Centre PI Attestation form. **Remember to provide the designated Satellite CTO Stream Account-Holder with a "Centre Study Staff-Read Only" role in CTO Stream!**

4.11 ***Upload a clean version of the proposed SITE-SPECIFIC consent form(s) (e.g., with the proposed site-specific changes accepted):**

UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC CONSENT FORM

Q4.10 & 4.11: Upload ONLY your centre-specific OCREB Memo "Consent Guidelines for OCREB Centres-*centre name*", not your Centre consent(s). Contact OCREB if you do not have access to your site Memo.

Updates to CIA annotated Application Forms

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SECTION 6.0 – PRIVACY AND CONFIDENTIALITY

Provincial/CHEER (study-wide) information: The question below reflects information that has previously been provided to the REB and is here for reference purposes only.

6.0 *What (if any) Personal Information or Personal Health Information will be SENT TO or COLLECTED BY the lead researcher/research group/sponsor for the purposes of this study (select all that apply)?

- ☐ None, study participant ID only
- ☐ Full name
- ☐ Full initials
- ☒ Partial initials
- ☐ Full date of birth
- ☒ Partial date of birth
- ☐ Full date of death
- ☐ Partial date of death
- ☒ Age
- ☒ Sex and/or gender
- ☐ Full postal code
- ☐ First 3 digits of postal code
- ☒ Pathology specimen number
- ☐ Medical device identifier
- ☒ Admission date
- ☒ Discharge date
- ☐ Medical record number
- ☐ Health card number
- ☐ Driver's license number
- ☐ Address
- ☐ Telephone number
- ☐ Fax number
- ☐ E-Mail address
- ☐ Full face photograph
- ☐ Voice/audio recording
- ☐ Social Insurance Number (SIN) number
- ☐ Device identifier
- ☐ Internet Protocol address (IP address)
- ☐ Race and/or ethnicity
- ☐ Family/caregiver names and/or contact information
- ☒ Other

CIA Q 6.2

6.2 ***As per institutional privacy policies, which of the identifiers that were approved provincially/CHEER (study-wide) (shown above in question 6.0) are you authorized to disclose on the study data collection tools leaving the institution?**

- ☐ None, study participant ID only
- ☐ Full name
- ☐ Full initials
- ☐ Partial initials
- ☐ Full date of birth
- ☐ Partial date of birth
- ☐ Full date of death
- ☐ Partial date of death
- ☐ Age
- ☐ Sex and/or gender
- ☐ Full postal code
- ☐ First 3 digits of postal code
- ☐ Pathology specimen number
- ☐ Medical device identifier
- ☐ Admission date
- ☐ Discharge date
- ☐ Medical record number
- ☐ Health card number

Q6.2: (NEW)
Please select what identifiers your site will be collecting and disclosing outside the institution for study purposes, and as per your institutional policies. If the response or the identifiers chosen here DO NOT match the identifiers approved at the Provincial level (as noted in Q#6.0), then please also select: **OTHER,** and specify in Q#6.2.1 what identifier/s is/are collected and provide an explanation for the discrepancy

CIA Q 8.1-8.1.1

8.1 ***Will study participants and/or substitute decision makers (SDMs) be provided with compensation or reimbursement in a different amount or method than that described in the Provincial Initial Application/CHEER Initial Application?**

☐Yes ☐No

If 'Yes':

(NEW) 8.1 Please always respond **YES** here

8.1.1 ***Please Describe:** Click here to enter text.

(NEW) 8.1.1: Provide details on how your participants will be reimbursed, including what they will be reimbursed for ; approximate $ amount that may be provided and any other information that will be added to the **Compensation/reimbursement section** of your Centre consent form. If no reimbursement is provided, then please indicate that the template statement ***('You will be reimbursed for..)*** will be removed from the Centre consent.

CIA Q 8.3

8.3 ***Who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided if a participant suffers an injury as a result of participation in this study?**

- ☐ Sponsor
- ☐ Funder
- ☐ Institution
- ☐ Other

If 'Other':

8.3.1 ***Please describe other:**

Clinical Trial Centre Initial Application Form
Version 21 (20AUG2020)

(NEW) Q. 8.3: If selecting 'Other', then please describe in 8.3.1 who will cover these expenses e.g. Provincial health plan ; private insurance etc. Participants should NOT be asked to pay for these types of study-related expenses.

REMINDERS

- PRE submissions :
  -audits with findings to be submitted as PREs; not as part of the CR applications
- Tracked consent updates should be included with resubmissions ; not at initial PAM submission
- Submission of New studies – these are prioritized based on when they were received ; sites/applicants are notified if studies are bumped to next meeting ; contact OCREB for any urgent ones ;
- For PIAs: include your centre in number of participating sites

- OCREB Membership changes are on the website
- Consultations with OCREB Staff for upcoming submissions are available ; contact information for staff are on the website
- Interested in OCREB membership? Contact Natascha or Aurora

Next Steps:

- New Centre memos will be sent out in the next month or so
- Expect CIA application changes to be requested by OCREB staff
- Next webinar: TBA

Thank you!

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