**Ontario Cancer Research Ethics Board**

MaRS Centre, Suite 510 **|** 661 University Avenue

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416-673-6649 or 1-866-678-6427 ext. 6649 | www.ocreb.ca

**Monthly Centre Web/Teleconference Meeting Summary**

**May 7, 2021 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. CHEO, Ottawa 3. Hamilton Health Sciences 4. Health Sciences North, Sudbury 5. Lakeridge Health, Oshawa 6. London Health Sciences Centre 7. Markham Stouffville | 1. Niagara Health System 2. North York General Hospital 3. The Ottawa Hospital 4. Royal Victoria, Barrie 5. Sunnybrook Health Sciences Centre, Toronto 6. Trillium Health Partners, Mississauga 7. UHN (PMCC, TGH, TWH), Toronto |
| **OCREB:** | Beren Avci, Aurora de Borja, Natascha Kozlowski, Carrie Li, Cindy Sandel, Alison van Nie | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Grand River Hospital 2. Hospital for Sick Children, Toronto 3. Humber River Hospital, Toronto 4. Kingston General Hospital 5. Michael Garron Hospital, Toronto 6. St. Joseph’s Healthcare, Hamilton 7. Sinai Health System, Toronto 8. Southlake Regional Health Centre, Newmarket | 1. Thunder Bay Regional Health Sciences Centre 2. Unity Health (St. Michael’s/St. Joseph’s), Toronto 3. William Osler Health Centre, Brampton 4. Windsor Regional Hospital 5. Women’s College Hospital, Toronto |
| **OCREB:** | Yooj Ko (Chair) | |

OCREB Guidance Year 2 – May 2021

OCREB acknowledges the impact that the COVID-19 pandemic has had, and continues to have on the clinical research environment, and its ongoing impact on the daily conduct and oversight of clinical trials. The safety of participants is of primary importance, and the potential harms of initiating or continuing a trial should be weighed against the anticipated benefits in such a setting.

Investigators should work with their institutions and study sponsors to consider whether the start of a new study should be delayed, or if an existing study should be modified in light of the impact of COVID-19 related constraints on the clinical services, and to assess the impact of any changes on participant safety and data integrity.

This guidance is to assist the participating centres and the study sponsors in assuring the safety and well-being of study participants while maintaining compliance with good clinical practices.

**OCREB Activities during the Pandemic**

OCREB has policies and processes in place to continue with its reviews and ethics oversight during the current coronavirus (COVID-19) outbreak. All memos and guidance are accessible on [OCREB’s website](https://ocreb.ca/about-ocreb/whats-new/).

* OCREB oversight activities, including board meetings are continuing remotely, as per SOP 501 - [OCREB SOPs](https://ocreb.ca/about-ocreb/guidelines-templates-and-sops/).
* OCREB staff are continuing to work from home - please contact the relevant OCREB staff member directly by email or phone – access contact details at [OCREB Contacts](https://ocreb.ca/about-ocreb/contact-us/).
* News: OCREB is recruiting for another Research Ethics Coordinator (REC).

Note: OCREB is open to receiving/reviewing changes to the conduct of your research studies during the pandemic. Please do not hesitate to contact us if you have any questions or are unsure about the acceptability of the changes. We realize that it is difficult for everyone to be aware of the requirements that are often changing during this time, and which may differ among regulators, institutions, sponsors and REBs. As a central review board, the guidance that we provide is general and meant to be comprehensive rather than specific and we are open to receiving information about strategies that are being implemented at the centres.

**Submission requirements**

1. How covid has impacted the functioning of OCREB;

Due to the increase in the number of submissions both for new and ongoing studies, the OCREB monthly deadline criteria for PIAs and PAMs [requiring full board review] will be followed. Submissions that do not meet the deadline or if the agenda for the FB meeting already is full, will be moved to a subsequent meeting.

1. Provincial PIAs/PAMs vs. CIAs/CAMs as they relate to changes in the conduct of the study during the pandemic

* PIA:
  + the consent document only requires information related to COVID-19 testing and outcomes if this information is one of the study objectives and is specific to the conduct of the study;
  + information specific to potential changes to the conduct of the study, to be implemented during the pandemic, such as virtual visits, are not required to be included in the consent form – if required, a general statement, for e.g., ‘Any information regarding changes to the conduct of the procedures described will be discussed with you’, may be included.
* PAM:
  + an amendment for consent changes, are not required for information about the outcome of covid-19 testing completed during the trial unless the trial protocol mandates the collection of covid-19 testing and/or covid-19 outcomes as a new study objective;
  + an amendment for changes to the consent form are not required for potential procedural changes during the pandemic, for the conduct of the trial [which vary from site to site] such as the delivery of oral medications, oral/remote consent, etc.; oral consent for changes in any procedures related to the pandemic must be documented in the study record.
* CIA:
  + if the centre is proposing the implementation of a remote/virtual consenting procedure then a reference in the application to institutional policies that support this process is acceptable if these documents have been submitted to the Research Ethics Officer (REO) for review and are pre-approved. If the centre has not provided supporting policies to OCREB then a robust description of the process must be included in the application. Any changes in consenting procedures or other study conduct procedures that are not consistent with the provincial submission must also receive sponsor approval.
* CAM: an amendment for changes to the consent form are not required for potential procedural changes during the conduct of the trial, in response to the pandemic, [which vary from site to site], such as the delivery of oral medications, or virtual visits. For changes in the way in which consent is implemented during the pandemic, e.g., the implementation of oral/remote consent/the use of email communication, that were not addressed in the CIA, amendments are not required: please discuss the proposed process with the REC or the REO and note that the participant’s consent for this process, and the sponsor’s agreement must be documented in the study record;
* Note: if you have any questions about the introduction of pandemic-related changes to the conduct of the study at the provincial or the centre level please contact the responsible REC or the REO for more information.
* Note: please refer to the OCREB Guidance for Protocol Deviation Reporting for additional information re the submission of reportable events: e.g., a reportable event must be submitted for deviations that meet the reporting criteria, e.g., a CRE for changes in centre consenting procedures that were not approved in the CIA

<https://ocreb.ca/wp-content/uploads/2018/09/Guidance-for-protocol-deviation-reporting.pdf>

1. Principles of consent – As a central review board, OCREB requires the implementation of best practices which are based on the ethical criteria for the implementation of consent. The board reviews these practices in relation to the criteria found in the TCPS2, Health Canada regulations and guidance, and the US regulations as applicable. OCREB relies on specific institutional policies which may vary from site to site, when considering changes in the ways in which consent is implemented.
2. Reminder: the mandatory adoption of the OCREB ICF templates is required for all submissions.
3. Reference guidance – HC, FDA, OHRP

* Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors Updated: September 20, 2020

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html>

* FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards January 27, 2021 <https://www.fda.gov/media/136238/download>
* Secure Electronic Signature Regulations CANADA EVIDENCE ACT PERSONAL INFORMATION PROTECTION AND ELECTRONIC DOCUMENTS ACT 2021-01-21

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-30/page-1.html>

**NOTICES**

**CTO applications**

Please note that the annotated applications for the current CTO application documents have been posted.

**REMINDERS**

* Third party locator information – e.g., Omni trace - can be modified and included in the optional section of the main consent form; [instruction guide provides general information in requirements for including optional components – i.e., if elements of the main consent apply do not repeat]
* DILs /memos/ Investigator protocol clarification letters do not require submission [most sponsor correspondence to the centre indicates that the correspondence must be provided to the REB, if required– if you have questions about whether a document requires submission please contact the REC – e.g., if there are safety concerns;
* A translated version of the consent should not be submitted until after the English version is approved;
* Note: do not submit centre consents with the CIA; Please attach the institutional-specific memo provided to you by OCREB!!
* Note: centre specific documents/amendments generally are not required.

**OCREB Membership Changes**

The current and archived OCREB membership lists are posted on the OCREB website on the [“Meetings and Membership”](https://ocreb.ca/about-ocreb/meetings-and-membership/) page. The list was last updated on April 20, 2021.

**List of Active Studies and Active Study-Centres**

For a list of active studies and active study-centres, contact the OCREB office.

**NEW STUDIES**

**New studies submitted for the May 14, 2021 meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CTO ID** | **REC** | **Sponsor** | **Study ID** | **PA** | **Site** | **Study Contact (PIA)** |
| 3485 | Aurora | Bayer | 20289 NAVIGATE | Richard Tozer | HHSC | Amanda Boyes |
| 3489 | Beren | IIS | LANCE | Taymaa May | PMCC | Sharin Collins |
| 3519 | Beren | CCTG | NRG-GY006 | Eric Leung | SHSC | Nithla Mohanathas |
| 3556\* | Beren | CCTG | CO.29 | Derek Jonker | TOH | Lisa Turiff |
| 3567 | Cindy | Pfizer | C3651010 | Camilla Zimmermann | UHN | Ailin Mao |
| 3570 | Cindy | Profound Medical Inc | CAPTAIN / GCP-10296 | Joseph Chin | LHSC | Catherine Hildebrand |
| 3588 | Aurora | Merck | KEYNOTE-B49 | David Cescon | UHN | Aleksandra Topalovich |
| 3605 | Cindy | Pfizer | C3441052 (Talapro-3) | Christina Canil | TOH | Lisa Turriff |
| 3623 | Beren | Syndax Pharmaceuticals | AGAVE-201 / SNDX-6352 | Frank Michelis | UHN | Aleksandra Topalovich |
| 3631 | Aurora | GSK | Molecular Disease Characterization Initiative (MDCI) (213299/02) | Adrian Sacher | PMCC | Niwethaa Nadesan |
| 3639 | Aurora | IIS | REaCT-HER TIME | Sharon Magee | TOH | Lisa Vandermeer |
| 3640 | Aurora | Seagen | SGNSTNV-001 | Neesha Dhani | PMCC | Bonnie Kwan |
| 3643 | Beren | IIS | REaCT-70 | Marie-France Savard | TOH | Lisa Vandermeer |
| \*Deferred study from a previous meeting | | | | | | |

**New studies for the June 11th 2021 meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CTO ID** | **REC** | **Sponsor** | **Study ID** | **PA** | **Site** | **Study Contact (PIA)** |
| 3641 | Cindy | IIS | AQuOS-II | William Chu | SHSC | Anam Shahid |
| 3636 | TBD | Repare Therapeutics | RP-6306-01 | Stephanie Lheureux | PMCC | Bonnie Kwan |
| 3628 | TBD | Roche | WO42758 (INTRINSIC) | Eric Chen | PMCC | Bonnie Kwan |
| 3554\*\* | TBD | OHRI | VIP Study | C.Arianne Buchan | TOH | Abi Vijenthira |
| \*\* possibly Delegated review | | | | | | |

**Other Potential New Studies:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sponsor** | **Study ID** | **PA** | **Site** | **Contact** |
| Merck | MK-6482-011 |  |  |  |
| Immunomedics | TROPICS-043 | R.Fernandes | LHSC | MaryBeth Husson |
| COG | AGCT1532 |  | HSC |  |
| COG | ANHL1931 | Punnett | HSC |  |
| COG | ANHL1931 | Punnett | HSC |  |
|  |  |  |  |  |
|  |  |  |  |  |

**CONTINUING REVIEW APPLICATIONS**

Even though CTO Stream sends automatic courtesy reminders 45, 30 and 15 calendar days before the expiry date, CR applications should be submitted as close to the relevant meeting deadline as possible, and not until after the imminent OCREB meeting at the earliest (i.e., close to the meeting deadline for the upcoming meeting, and after the current meeting at the earliest). If you need to submit the CR earlier due to absences or other reasons, please contact the responsible OCREB REC.

**Continuing Review Applications due for the <<Month>> Meeting**

For studies **expiring June 11th to July 8th, inclusive**, provincial and centre continuing review applications are due by the Mary 25th deadline for the June 11th meeting, **unless a study closure has been or will be submitted.**

**NOTEWORTHY ITEMS**

A place for sharing new information, updates and other noteworthy items affecting the research community…

* CIHR is pleased to share the first video in a new “**Ask a Scientist series**”, where Dr. Michael J. Strong, CIHR President, answers, “**Was the COVID-19 Vaccine research rushed?**” New video series: Ask a Scientist [watch the video here](https://can01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsuivi.lnk01.com%2Fc%2F443%2Fa0f77b8725d5af2fe72386ab064756d85cff5ea4bfff1e0d3f3223e6597ac0f0&data=04%7C01%7Calison.vannie%40oicr.on.ca%7Ccef53d9154b44e00c81a08d90e5d3757%7C9df949f8a6eb419d9caa1f8c83db674f%7C0%7C0%7C637556616682379196%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=3ezqJw3%2FBTwdIDKIwgONGJCV%2BL2RmBZe52brYBaf32k%3D&reserved=0)
* Health Canada is advancing targeted amendments to the [*Food and Drug Regulations*](https://urldefense.com/v3/__https:/laws.justice.gc.ca/eng/regulations/C.R.C.*2C_c._870/index.html__;JQ!!CjcC7IQ!bDHyaO777gQL2xVhrTsu9OG4GLLh-9MP5TLi2rDgFciZDUuisp4JqjaCAi7BfL0BatR4At1zlQ$) and the [*Natural Health Products Regulations*](https://urldefense.com/v3/__https:/laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/__;!!CjcC7IQ!bDHyaO777gQL2xVhrTsu9OG4GLLh-9MP5TLi2rDgFciZDUuisp4JqjaCAi7BfL0BatT-tCOmNw$) through the clinical trials Interim Order transition regulations. As part of these amendments, Health Canada is proposing to reduce the records retention requirement for clinical trials, from 25 to 15 years. This requirement would apply to sponsors of clinical trials of all drugs involving human subjects, COVID-19 drugs, and natural health products.

You can view Health Canada’s proposed policy [online](https://urldefense.com/v3/__http:/gazette.gc.ca/rp-pr/p1/2020/2020-12-12/html/notice-avis-eng.html__;!!CjcC7IQ!bDHyaO777gQL2xVhrTsu9OG4GLLh-9MP5TLi2rDgFciZDUuisp4JqjaCAi7BfL0BatQZTFFcsg$)

* FDA glossary: <https://www.fda.gov/about-fda/oncology-center-excellence/patient-friendly-language-cancer-clinical-trials>
* CIHR glossary



* **The Participators-Enter the Study**: In recognition of International Childhood Cancer Day on February 15, 2021, N2 launched the new pediatric clinical trials video officially, The Participators - Enter the Study.

N2 would like to give a big thank you for all the hard work from the Clinical Trials Education and Awareness (CTEA) N2 Committee who spearheaded the development of the video. Any research group or clinicians can share this video! The video doesn’t focus on any disease or disorder but is kept general so it can be used by as many pediatric research and clinical groups as possible.

The Participators – Enter the Study is a 3:28 minute animated video, produced by Rich Murray (RichToons; @richtoonstv) in partnership with N2 Clinical Trials Education and Awareness Committee (CTEA) Pediatric Working Group.

To develop the storyboard and script for the video, Rich worked with Linda Warner, one of the N2 CTEA Pediatric Working Group members, as well as with Nate Hudson and his mother, Antonia Palmer, (our patient/family volunteer members) to discuss the characters, script, design elements and overall development.

[English](https://n2canada.us14.list-manage.com/track/click?u=3701881b24851f487859ab8c8&id=97a2516b14&e=595341e145)    |    [French](https://n2canada.us14.list-manage.com/track/click?u=3701881b24851f487859ab8c8&id=80eb161b60&e=595341e145)

|  |  |
| --- | --- |
| |  | | --- | | [**Download Fact Sheet**](https://n2canada.us14.list-manage.com/track/click?u=3701881b24851f487859ab8c8&id=477941b2b7&e=595341e145) | |

**Next Web/Teleconference Session**

To be announced. Please check the OCREB website for future meetings.