**Ontario Cancer Research Ethics Board**

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

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**Monthly Centre Web/Teleconference Meeting Summary**

**November, 1, 2019 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. CHEO, Ottawa 2. Hamilton Health Sciences 3. Health Sciences North, Sudbury 4. Lakeridge Health, Oshawa 5. London Health Sciences Centre 6. Markham Stouffville 7. Niagara Health System 8. North York General Hospital | 1. The Ottawa Hospital 2. St. Michael’s Hospital, Toronto 3. Sunnybrook Health Sciences Centre, Toronto 4. Thunder Bay Regional Health Sciences Centre 5. Trillium Health Partners, Mississauga 6. UHN - Princess Margaret Cancer Centre, Toronto |
| **OCREB:** | Beren Avci, Cindy Sandel, Alison van Nie, Yooj Ko (Chair) | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. Grand River Hospital 3. Hospital for Sick Children, Toronto 4. Humber River Hospital, Toronto 5. Kingston General Hospital 6. Michael Garron Hospital, Toronto 7. Royal Victoria (Barrie) 8. St. Joseph’s Healthcare (Hamilton) | 1. St. Joseph’s Health Centre (Toronto) 2. Sinai Health System, Toronto 3. Southlake Regional Health Centre, Newmarket 4. William Osler Health Centre, Brampton 5. Windsor Regional Hospital 6. Women’s College Hospital, Toronto |
| **OCREB:** | Aurora de Borja, Carrie Li, Janet Manzo, Jacqueline Limoges (VC), Mihaela Mates (VC) | |

*If you temporarily have to leave the teleconference, please hang up and dial in again when you are able to re-join. Putting your phone on hold causes interference with all of the other lines.*

**NOTICES**

**Scientific Reviews**

In the PIA application Q.1.12, for the submission of academic trials: please indicate yes, if applicable, and submit a short summary of the scientific review, if available.

**REMINDERS**

**December deadline for the January 2020 meeting**

Due to the holiday schedule, the deadline for submissions for the January 10, 2020 meeting is **Tuesday, December 17, 2019.**

**Changes in number of participants at the centre level**

Submission of changes in the target number of participants enrolled at the centre is not required. Information re numbers enrolled is addressed on the CR.

**CR submissions**

Please ensure that there is a current staff person attached to the study while it remains open. There are ongoing difficulties with the submission of the CR reports when the staff person who is named in the application has been replaced.

**Study Closure**

Please ensure that the centres do not delay closure of their site due to contractual issues with the sponsor if all other sites have closed, and the study is no longer active at the centres - i.e., has been closed by the sponsor – and especially if the remaining site is not the PA.

**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 November 1, 2019

**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 November meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1952 | Aurora | IIS | REACT-Algorithm | Mark Clemons | TOH | Lisa Vandermeer |
| 1960 | Beren | Exelixis | XL184-312 (Cosmic-312) | Rachel Goodwin | TOH | Lisa Turriff |
| 1974 | Carrie | CCTG | MAC.26 (S1706) | Eileen Rakovitch | SHSC | Carolyn Lim |
| 1985 | Cindy | CCTG/NRG | HNC.2/NRG-HN004 | Eric Winquist | LRCP | MaryBeth Husson |
|  |  |  |  |  |  |  |

**Other Potential New Studies:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| COG | AGCT1532 |  |  |  |
| COG | AALL1731 |  |  |  |
| COG | AALL1732 |  |  |  |
| IIS | WOO-BET | Angel Arnaout | TOH |  |

**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 November 26 deadline for the December 13 meeting, and November 11 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 December Meeting**

For studies **expiring December 13, 2019 to January 09, 2020 inclusive**, provincial and centre continuing review applications are due by the November 26 deadline for the December 13 meeting, **unless a study closure has been or will be submitted.**

**Continuing Review Applications due for the January Meeting**

For studies **expiring January 10 to February 13, 2020 inclusive**, provincial and centre continuing review applications are due by the December 17, 2019 deadline for the January 10, 2020 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…

* The [Canada](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDAsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEifQ.0eefa7VikZTfQaWI5tO66_AcGs1mimMXUf6vwIfdTFw/br/70322723093-l) profile in [ClinRegs](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDEsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvIn0.67m96s2wtVzBt2WV9-Sq5mZzfFPcQ47QYLxFOwkh_v0/br/70322723093-l) now includes the following guidance documents:
  + A Health Canada guidance document providing interpretations of the Food and Drug Regulations (See the [Quality, Data & Records Management](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDIsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjcXVhbGl0eSxfZGF0YV8mX3JlY29yZHNfbWFuYWdlbWVudCJ9.dmFlnJIJrZi2hTN0oN2cdTtXT-YClNCIufl_U097Lns/br/70322723093-l) and [Manufacturing & Import](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjbWFudWZhY3R1cmluZ18mX2ltcG9ydCJ9.B8ZPyylJb8agBoBB6BRdW8xhdvYncqMYWCcL0QILJZg/br/70322723093-l) sections)
  + The latest revision of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and an associated new guidance on how to address material incidental findings discovered in the course of research (See [Ethics Committee](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjZXRoaWNzX2NvbW1pdHRlZSJ9.4BGa0XJJbLss4bDhAV6OqKKCL9u_Y8iu5H0q8VbcE_U/br/70322723093-l), [Scope of Review](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjc2NvcGVfb2ZfcmV2aWV3In0.Lpb2hJZDTcIprJyLDs-DONLYDB1Eu0bIwSxwdnjQYyE/br/70322723093-l), [Trial Initiation](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjdHJpYWxfaW5pdGlhdGlvbiJ9.vXmxvNO44ZBGt1o_RupxDbmnw5Y-j7OK-iPr169HHRA/br/70322723093-l), [Safety Reporting](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjc2FmZXR5X3JlcG9ydGluZyJ9.1Ogg-ryxROfDK-1-7sdIoccCyMnvZM0763hMV0QOf5Y/br/70322723093-l), and [Informed Consent Documentation Requirements](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsImJ1bGxldGluX2lkIjoiMjAxOTEwMTguMTE3MDU3OTEiLCJ1cmwiOiJodHRwczovL2NsaW5yZWdzLm5pYWlkLm5paC5nb3YvY291bnRyeS9jYW5hZGEjZG9jdW1lbnRhdGlvbl9yZXF1aXJlbWVudHMifQ.onvv70PZhb5efxhoD_qFquU7E4lC2HA2iZEbVMuzqIE/br/70322723093-l) sections)
* Health and Biosciences Sector Regulatory Review Roadmap <https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/targeted-regulatory-reviews/health-biosciences-sector-regulatory-review-roadmap.html#a2>
* Compensating Clinical Trial Participant: the basics Get the basics [with this overview](https://hes32-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2femail.advarra.com%2fO0F0j4tI0100IFrG0p0d0PF&umid=d4618256-a90f-4628-ad78-3c6288134ac0&auth=264e636f8a7899a1bca3b66cba6e4e44ed141273-27468f452439bfa91e87293af2ca678d8ec98c33) of how a compensation program for clinical trial participants should function and understand what key areas the IRB will be examining closely. The Secretary’s Advisory Committee on Human Research Protections(SACHRP) recommendation to the FDA and Department of Health and Human Services’ Office for Human Research Protections (OHRP). <https://www.magiworld.org/resources/journal/2406_New133.pdf>
* Yay Canada! Within 120 days of approving or rejecting a new drug, biologic or device application, Health Canada will post clinical study reports on a new government online portal - this may put pressure on the FDA to do the same. HC will post clinical study reports/data on an online portal, similar to the EU Medicines Agency in a move towards transparency in clinical research and increased, appropriate data sharing.

<https://www.npr.org/sections/health-shots/2019/10/11/769348119/canadas-decision-to-make-public-more-clinical-trial-data-puts-pressure-on-fda>

**Next Web/Teleconference Session**

**December 6, 2019 @ 9am**