**Ontario Cancer Research Ethics Board**

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

Toronto, Ontario | Canada M5G 0A3

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

**Monthly Centre Web/Teleconference Meeting Summary**

**June 7, 2019 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. CHEO, Ottawa 2. Hamilton Health Sciences 3. Hospital for Sick Children, Toronto 4. Humber River Hospital, Toronto 5. Kingston General Hospital 6. Lakeridge Health, Oshawa 7. London Health Sciences Centre 8. Niagara Health System | 1. North York General Hospital 2. The Ottawa Hospital 3. Royal Victoria (Barrie) 4. Sunnybrook Health Sciences Centre, Toronto 5. Thunder Bay Regional Health Sciences Centre 6. Trillium Health Partners, Mississauga 7. UHN - Princess Margaret Cancer Centre, Toronto |
| **OCREB:** | Beren Avci, Aurora de Borja, Carrie Li, Janet Manzo, Cindy Sandel, Richard Sugarman (Chair), Alison van Nie | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. Grand River Hospital 3. Health Sciences North, Sudbury 4. Markham Stouffville 5. Michael Garron Hospital, Toronto 6. St. Joseph’s Healthcare (Hamilton) 7. St. Joseph’s Health Centre (Toronto) | 1. St. Michael’s Hospital, 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:** | None | |

*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.*

**REMINDERS**

**Dear Investigator Letters (DIL) and Protocol Clarification Letters (PCL)**

Please note that OCREB does not accept DIL and PCL as independent, stand-alone submissions. Refer to the May meeting summary for details. They may be submitted as supporting documents with a relevant amendment.

**Consent Forms at the Time of Initial Submission of a New Study (PIA)**

Please submit clean copies of consents with the initial PIA, not tracked consents with sponsor comments.

**OCREB Membership Changes**

The OCREB membership lists are posted to [https://ocreb.ca](http://www.ocreb.ca/) under the “OCREB Meetings and Membership” link. The list was last updated in March 2019.

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

The list of active studies and active study-centres is posted to [https://ocreb.ca](http://www.ocreb.ca/) under the “Investigators and research teams” link. The current version is May 29, 2019

**NEW STUDIES**

**New studies submitted for the June 14th meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1804 | Aurora | Merck | MK-7902-008 | Andrew Robinson | KGH | Kristina Kulik |
| 1839 | Cindy | LHIR | PRESERVE | David Palma | LHS | Mary Beth Husson |
| 1848 | Beren | PPD | 18-214-10/CA-045-012 | Srikala Sridhar | UHN | Sabina Naqvi |
| 1865 | Carrie | CCTG | PLATON | Patrick Cheung | SHSC | Senny Chan |
| 1874 | Carrie | Amgen, INC | AMG420 | Arleigh McCurdy | TOH | Krystina Trites |
| 1876 | Beren | Novartis | CLEE011A2207 | Asma Ali | HSN | Cathy Simeoni |
| 1884 | Carrie | Roche | CO41012/IPATunity150 | Som Mukherjee | HHS | Yvonne Kinrade |
| 1885 | Beren | Triumvira Immunologics | TACTIC19 | John Kuruvilla | UHN | Claudia Thiruchelvam |
| 1888 | Cindy | Jounce Therapeutics | JTX-2011-201 | Natasha Leighl | UHN | Tuhina Paul |

**Other Potential New Studies:**

|  |  |
| --- | --- |
| COG | AGCT1532 |
| NRG | GU-005 |
| CCTG | ALC.6/A041501 |
| CCTG | HNC.2/NRG HN004 |
| IIS | TOPCOP2 |

**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 June 25 deadline for the July 12 meeting, and following the June 14 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 July Meeting**

For studies **expiring July 12 to August 8 2019, inclusive**, provincial and centre continuing review applications are due by the June 25 deadline for the July 12 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…

* Medical Devices: Health Canada is exploring how to best address longstanding stakeholder concerns regarding the current regulatory framework for medical devices and how it may be unintentionally limiting investigational testing activity in Canada.

Please direct your responses to hc.policy.bureau.enquiries.sc@canada.ca. A response by June 21, 2019 is requested.

 

* Accelerated reviews: Health Canada has opened a consultation on new draft Guidance.



* Release of Draft (Step 2) ICH Guidance: E19 Optimization of Safety Data Collection

The above referenced draft guidance was released by the International Council for Harmonisation (ICH) Assembly for consultation and is being posted on the [ICH website](https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html#19) for information and comment in accordance with Step 2 of the ICH process.

All comments forwarded to Health Canada will be transmitted to the ICH as is, with the disclaimer that they are provided for information and do not necessarily represent the views of Health Canada, except as specifically indicated in separate comments. Comments provided to Health Canada should be submitted by Friday, September 13, 2019 Comments should be directed to: Health Canada - ICH Coordinator: [hc.ich.sc@canada.ca](mailto:hc.ich.sc@canada.ca)

* “CRISPR babies”: What does this mean for science and Canada? Bartha Maria Knoppers JD PhD, Erika Kleiderman LLB BSc n Cite as: CMAJ 2019 January 28;191:E91-210.



* [Taking stock of the implications of genomic advances](https://genomicsandhealth.us8.list-manage.com/track/click?u=e2039d5b8bd9f7751e553357f&id=f571d0fa09&e=fb7115d27b)
* ['DNA genie left bottle with ancestry testing', says Wellcome ethics researcher](https://genomicsandhealth.us8.list-manage.com/track/click?u=e2039d5b8bd9f7751e553357f&id=2c04efc604&e=fb7115d27b)
* As you may know, the Regulatory and Ethics Work Stream is currently updating several of the GA4GH Policies in light of scientific, regulatory and ethical developments. To this end, we have developed a draft of the [revised Data Privacy and Security Policy](https://genomicsandhealth.us8.list-manage.com/track/click?u=e2039d5b8bd9f7751e553357f&id=58ecf8f624&e=fb7115d27b), which was first published in June 2015. A copy of that original Policy may be viewed [here](https://genomicsandhealth.us8.list-manage.com/track/click?u=e2039d5b8bd9f7751e553357f&id=ecf794247b&e=fb7115d27b).
* Cancer isn't an 'invader,' and you're not at war with it <http://flip.it/FDUIBw>

**Next Web/Teleconference Session**

**September 6, 2019 @ 9am**

No sessions in July or August.