**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**

**February 1, 2019 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Hamilton Health Sciences 2. Health Sciences North, Sudbury 3. Kingston General Hospital 4. Lakeridge Health, Oshawa 5. London Health Sciences Centre 6. Markham Stouffville 7. Michael Garron Hospital, Toronto | 1. Niagara Health System 2. North York General Hospital 3. The Ottawa Hospital 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, Janet Manzo, Cindy Sandel, Maret Oser-Tamm, Alison van Nie | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. CHEO, Ottawa 3. Grand River Hospital 4. Hospital for Sick Children, Toronto 5. Humber River Hospital, Toronto 6. Royal Victoria (Barrie) 7. St. Joseph’s Healthcare (Hamilton) 8. 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:** | Richard Sugarman (Chair), Aurora de Borja | |

*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**

**New OCREB Research Ethics Coordinator – Welcome Maret!**

Maret Oser-Tamm joined OICR/OCREB on January 21, 2019. Maret has an MA (Hons) in Philosophy (Australia) and a MHSc in Bioethics (U of T). She worked in a research ethics office in Australia. She has a sound understanding of research procedures and policies in Canada, in particular the TCPS.

**OCREB Staff Absence**

Aurora de Borja is off for another week, returning February 11, 2019.

**New Consent Form Template**

The new nationally developed consent form template is almost ready for release (slides attached).

**TCPS Update**

PRE expects to publish TCPS 2 (2019) on their new website in April.  At that time, they will also post a companion document to highlight the most significant revisions.

**REMINDERS**

**April OCREB Meeting**

Because of a conflict with the Canadian Association of Research Ethics Boards annual conference, the OCREB meeting was moved to April 5. The deadline is March 19. This has not changed since the meeting schedule issued in late 2018.

**Changes in Study Staff**

Please ensure that changes to study staff are updated in CTO Stream by submitting a provincial and/or centre amendment.

**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 on January 1, 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 January 23, 2019.

**NEW STUDIES**

**New studies submitted for the March 8, 2019 meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1720 | Aurora | IIS | SMARTCare RCT | Monika Krzyzanowska | UHN | Melanie Powis |
| 1704 | Beren | Merck | MK-8353-014 | Lillian Siu | UHN | Sonya Nakoneczny |
| 1709 | Maret | Janssen | 56021927PCR3011 | Robert Nam | SHSC | Mala Singh |
| 1738 | Beren | Ayala | AL-ACC-01 ACCURACY | Eric Winquist | LHRI | Mary Beth Husson |
| 1749 | Beren | Merck | MK-7902-006 (LEAP-006) | Mihaela Mates | KGH | Kristina Kulik |
| 1753 | Cindy | Zymeworks | ZWI-ZW25-201 | Rachel Goodwin | TOH | Lisa Turriff |
| 1754 | Beren | Abbvie | M14-239 | Paul Wheatley-Price | TOH | Lisa Turriff |
| 1756 | Cindy | AZ | D933RC00001 (NIAGARA) | Michael Ong | TOH | Lisa Turriff |
| 1768 | Cindy | IIS | LUOSICNS (OZM-094) | Adrian Sacher | UHN | Nanthini Tharahan |

**Other Potential New Studies:**

|  |  |  |
| --- | --- | --- |
| COG | AGCT1532 | HSC |
| NRG | GU-005 | WRH |

**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 February 19th deadline for the March 8th meeting, and after the February 8th 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 March Meeting**

Studies **expiring March 8, 2019 to April 4, 2019 inclusive**, provincial and centre continuing review applications are due by the February 19, 2019 deadline for the March 8, 2019 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 Food and Drug Administration (FDA) is extending the comment period for the proposed rule entitled “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations”. The proposed rule can be accessed at [https://www.gpo.gov/fdsys/pkg/FR-2018-11-15/pdf/2018-24822.pdf](http://app.info.fda.gov/e/er?utm_campaign=Extension%20of%20Comment%20Period%20Waiver%2FAlteration%20IC%20NPRM&utm_medium=email&utm_source=Eloqua&s=2027422842&lid=5966&elqTrackId=856FEFD84788B60A828EFF598BB49CAE&elq=40983b5596c04425bd30e8ca8cfb9f08&elqaid=6234&elqat=1). Comments on the proposed rule may be submitted at [https://www.regulations.gov](http://app.info.fda.gov/e/er?utm_campaign=Extension%20of%20Comment%20Period%20Waiver%2FAlteration%20IC%20NPRM&utm_medium=email&utm_source=Eloqua&s=2027422842&lid=683&elqTrackId=39DD6DF00D4A60BD729C2C13249F4D4E&elq=40983b5596c04425bd30e8ca8cfb9f08&elqaid=6234&elqat=1) and are **now due by February 13, 2019**.

The clinical investigation involves no more than minimal risk to the subjects;

* the waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects;
* the clinical investigation could not practicably be carried out without the waiver or alteration of informed consent; and
* whenever appropriate, the subjects will be provided with additional pertinent information after participation.
* OHRP Frequently Asked Question and Answer (FAQ): “How should IRBs approach the continuing review of research that remains active beyond long-term follow-up or data analysis, but that is eligible for expedited review under categories 8(b) or 9 of the 1998 OHRP Expedited Review List in light of the new provision at §46.109(f)(1)(i) of the 2018 Requirements, which eliminates the requirement for such continuing review unless an IRB determines otherwise.”

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html>

* Who needs to apply the revised Common Rule? <https://www.advarra.com/do-i-need-to-comply-with-the-revised-common-rule/>
* **Compliance for the revised Common Rule is in effect as of January 21, 2019.**

Review OHRP’s draft **guidance on transitioning to the revised Rule** to find out how this might affect regulated research at your institution:  
[www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-revised-common-rule-compliance-dates-transition-provision-45-cfr-46-1011/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-revised-common-rule-compliance-dates-transition-provision-45-cfr-46-1011/index.html)  
  
A list of helpful **Q&A’s** is available on OHRP’s website and is being updated and expanded regularly. Access them here: [www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html](https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html)

* AstraZeneca has hired Dr. José Baselga, the former chief medical officer at Memorial Sloan Kettering, to lead its cancer research unit. [**Read More...**](https://nyti.ms/2GVRMaS?smid=nytcore-ios-share)

**Next Web/Teleconference Session**

**March 1, 2019 @ 9am**