**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**

**November 2, 2018 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. CHEO, Ottawa
2. Grand River Hospital
3. Hamilton Health Sciences
* Juravinski Cancer Centre
* McMaster Children’s
1. Health Sciences North, Sudbury
2. Kingston General Hospital
3. Lakeridge Health, Oshawa
4. London Health Sciences Centre
* Lawson
* LRCP
* Nuclear Medicine
 | 1. Michael Garron Hospital, Toronto
2. Niagara Health System
3. The Ottawa Hospital Cancer Centre
4. Royal Victoria (Barrie)
5. Southlake Regional Health Centre, Newmarket
6. Sunnybrook Health Sciences Centre, Toronto
7. Trillium Health Partners, Mississauga
8. UHN - Princess Margaret Cancer Centre, Toronto
* Clinical Trial Support Unit
1. William Osler Health Centre, Brampton
2. Windsor Regional Hospital
 |
| **OCREB:** | Beren Avci, Aurora de Borja, Janet Manzo, Alison van Nie, Kathie Zeman |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital
2. Hospital for Sick Children, Toronto
3. Humber River Hospital, Toronto
4. Markham Stouffville
5. North York General Hospital
 | 1. St. Joseph’s Healthcare (Hamilton)
2. St. Joseph’s Health Centre (Toronto)
3. St. Michael’s Hospital, Toronto
4. Sinai Health System, Toronto
5. Thunder Bay Regional Health Sciences Centre
6. Women’s College Hospital, Toronto
 |
| **OCREB:** | Cindy Sandel, Richard Sugarman (Chair) |

*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**

**January Meeting Deadline**

Because of the holiday break, submissions for the January 11, 2019 meeting are due by Tuesday, December 11, 2018.

**OICR/OCREB Holiday Hours**

The OCREB office will be closed from noon December 24, 2018 to January 1, 2019, inclusive.

**CTO Stream Project Owner Transfers**

Although this was covered in the October meeting, we have new information. Changing the Main Study Contact in an amendment does not change the Project Owner; the Project Owner must be changed by the current Project Owner using a transfer Project Owner activity, or with assistance from CTO. **NEW!** Once project ownership is transferred, the study will no longer be visible to the previous Project Owner unless he/she already has a study staff role on the study/centre. To regain access, the previous Project Owner must be given access (e.g., a study staff role) by a colleague with access.

**Access to Currently Approved/Acknowledged Documents in CTO Stream**

On the applicant side of CTO Stream, users can access all of the currently approved or acknowledged documents in one location. At the highest project level (one level above the Provincial Initial Application), click on the Project Documents tab, to access only the currently approved or acknowledged documents. This list automatically updates as new documents are approved or acknowledged by the REB – e.g., following approval of a provincial amendment. See screenshot below.



**PIA Question 1.12 - previous scientific reviews**

Please include information about any previous scientific reviews regardless of whether the review is considered independent or not. The sponsor can provide information for a response to this question. Uploading a review is not mandatory.

**REMINDERS**

**Participant withdrawal**

The withdrawal of a participant from treatment and/or from all further study activities including follow-up must be documented by the study staff. Sponsors increasingly are reliant on survival status for study outcomes and for ensuring the validity of the data when it is required for supporting an application to the FDA. Because of the importance of survival data, please ensure that participants who choose to withdraw from the study are provided with the appropriate options and that the participant’s choice is documented. A template to guide the discussion and documentation will be posted on the OCREB website within the next few weeks after a review of existing templates.

**Document Naming**

Because the document name in CTO Stream defaults to the file name if a name is not typed into the application upload field, please name the file appropriately, or type in an appropriate “document name” when uploading a document. The name of the document is important because it auto-populates into the approval letter.

**Examples of inappropriate document names**

* CA209-907 Main Consent - REB tc 11MAY2018-ck22MAY2018 clean
* ca209907-revprot01
* CA2CA209-907 Provincial Consent Update REB tracked 11MAY2018 (1) TP edit-ck24MAY2018 clean

**Examples of appropriate document names**

Please note: the study ID, and the document version date, which is entered into a separate field, populate to the approval letter and this information does not need to be included in the document name.

* Protocol <<*version number / Amendment number*>>
* IB <<*product name/edition*>>
* Consent – Main << Part 1 / Part 2>>
* Consent – Optional
* Consent Update Form
* EQ-5D-5L Questionnaire

**New ICF Template**

The new ICF template is under review by the various partner organizations. It was presented to OCREB at its October meeting and no comments have been received. It will be submitted to the CCTG Executive in November with a target of early December to issue the template.

**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 October 1, 2018

**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 October 25, 2018.

**NEW STUDIES**

**New studies submitted for the November 9 meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1645 | Aurora | IIS | TAS-102 (MOCHA) | Yooj Ko | SHSC | Kate Besel |
| 1678 | Cindy | BMS | CA025006 | Jim Biagi | KGH | Kristina Kulik |
| 1679 | Beren | Merck | MK7902-004  | Anna Spreafico | UHN | Claudia Thiruchelvam |
| 1680 | Kathie | AZ | D081RC00001 (DUO-O) | Stephanie Lheureux | UHN | Bonnie Kwan |
| 1682 | Kathie | AZ | D081SC00001 (PROpel) | Urban Emmenegger | SHSC | Carolyn Lim |
| 1684 | Aurora | Merck | MK-7339-001-00 / ENGOT-ov43 | Stephanie Lheureux | UHN | Bonnie Kwan |
| 1686 | Cindy | Rna Diagnostics | RnaDx -BRV-BC-01 (BREVITY) | Andrea Eisen | SHSC | Carolyn Lim |
| 1689 | Cindy | IIS | BiniPembro  | Natasha Leighl | UHN | Roxanna Fernandes |
| 1696 | Beren | COG | AHEP1531 | Furqan Shaikh | HSC | Nivetha Ramachandran |
|  |  |  |  |  |  |  |
| Delegated Review 1683 | Aurora | IIS | HPVDNA02 | Eric Leung | SHSC | Sasha Manohar |

**New studies submitted for the December 14 meeting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1644 | Beren | Endocyte | PSMA-617-01 (VISION) | David Laidley | LHRI | Sarah De Brabandere |
| 1668 | Beren | Idera | 2125-MEL-301 (ILLUMINATE) | Scott Ernst | LHRI | Mary Beth Husson |

**Other Potential New Studies:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ISOFOL | ISO-CC-007 | Derek Jonker | TOH | Lisa Turriff |
| AMGEN | 20170543 – Phase 1 | Scott Laurie | TOH | Lisa Turriff |
| IIS | SABR-COMET 10 | David Palma  | LHRI | Mary Beth Husson |
| Esperas  | ESPS-001(h) | Hal Hirte | HHS | Yvonne Kinrade |
| COG | AGCT1532 |   |  HSC |   |
| NRG | GU-005 |   | WRH |   |
| IIS | TAS-120 | Mark Doherty | SHSC | Kate Besel |
| Merck | MK7902-002 | Jennifer Knox | UHN |   |
| CCTG | REC.4 / ECOG-ACRIN 8143 (PROSPER RCC) | email Oct 17 |   |   |

**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 27 deadline for the December 14 meeting, and November 12 at the very 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 14, 2018 to January 10, 2019, inclusive**, provincial (9) and centre (27) continuing review (CR) applications are due by the November 27 deadline for the December 14 meeting, **unless a study closure has been or will be submitted.**

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

For studies **expiring January 11 to February 7, 2019, inclusive**, provincial (23) and centre (64) continuing review (CR) applications are due by the December 11 deadline for the January 11 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…

* Version 3.0 of the International Clinical Trials Registry Platform (ICTRP) Standards document “**International standards for clinical trial registries**” has been published. It can be downloaded from the WHO [ICTRP website](http://www.who.int/ictrp) or from the following link [WHO ICTRP Standards document(PDF)](http://apps.who.int/iris/bitstream/handle/10665/274994/9789241514743-eng.pdf)
* **New York Times**: [Congratulations. Your Study Went Nowhere.](https://oicr.us15.list-manage.com/track/click?u=54fb380abd3cb4f7ea271cf4d&id=e98a780832&e=f8e3be7dc4)
Researchers should embrace negative results instead of accentuating the positive, which is one of several biases that can lead to bad science.
* **GIZMODO**: [Your Genetic Testing Results Can Change—Here's Why](https://oicr.us15.list-manage.com/track/click?u=54fb380abd3cb4f7ea271cf4d&id=9d4892d464&e=f8e3be7dc4)
The first wave of routine genetics testing has already helped millions of people learn about their hereditary risk for certain diseases like cancer. But a new study published Tuesday in JAMA suggests that as our knowledge of genetics expands, these initial results sometimes need to be revised.
* **CentreWatch Weekly**: [Sponsors Who Don’t Report Trial Data Face Fines](https://www.centerwatch.com/cwweekly/2018/09/24/sponsors-who-dont-report-trial-data-face-fines/)

Researchers who fail to file trial data with ClinicalTrials.gov on time could be fined up to $10,000 per violation—and the FDA says it will aggressively pursue those penalties.

* **STAT News:** [With big-name backing, a startup launches to match cancer patients with clinical trials](https://oicr.us15.list-manage.com/track/click?u=54fb380abd3cb4f7ea271cf4d&id=9c0fb19100&e=70b5417530)
Driver, as the company is called, will charge cancer patients $3,000 upfront plus a $20 monthly fee — all out of pocket — for a service that analyzes their tumor sample and their medical record. Driver uses that information to recommend options for both approved treatments and clinical trials as well as facilitate referrals via an app that patients can access on their phones
* **Health & Science:** [Should I worry about radiation exposure from X-rays, mammograms and other scans?](https://www.washingtonpost.com/national/health-science/should-i-worry-about-radiation-exposure-from-x-rays-mammograms-and-other-scans/2018/09/28/cf17ea26-b536-11e8-a2c5-3187f427e253_story.html?noredirect=on&utm_term=.1f92e88d8f2a) The difficulties in predicting the effects of radiation since they don’t add up in a linear way. Massive doses are harmful but the small does in routine tests usually are safe in spite of the risks.
* Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705849>

**Next Web/Teleconference Session**

**Friday December 7, 2018** **@ 9am**