**Ontario Cancer Research Ethics Board**

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

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**Monthly Web Meeting/Teleconference Summary**

**December 1, 2017 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Grand River Hospital 2. Hamilton Health Sciences  * Juravinski Cancer Centre  1. Health Sciences North 2. Lakeridge Health 3. London Health Sciences Centre  * LRCP  1. Michael Garron Hospital/Toronto East Health 2. Niagara Health System | 1. The Ottawa Hospital  * Cancer Centre * Other (OHRI)  1. Sunnybrook Health Sciences Centre  * Odette Cancer Centre  1. Trillium Health Partners 2. UHN - Princess Margaret Cancer Centre  * Drug Development Program |
| **OCREB:** | Aurora de Borja, Janet Manzo, Cindy Sandel, Richard Sugarman (Chair), Alison van Nie, Kathie Zeman | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. Children’s Hospital of Eastern Ontario 3. Hospital for Sick Children 4. Humber River Hospital 5. Kingston General Hospital  * Kingston General – Pediatrics  1. Markham Stouffville 2. North York General Hospital 3. Royal Victoria Regional Health Centre 4. St. Joseph’s Healthcare (Hamilton) | 1. St. Joseph’s Health Centre (Toronto) 2. St. Michael’s Hospital 3. Sinai Health System 4. Southlake Regional Health Centre 5. Thunder Bay Regional Health Sciences Centre 6. William Osler Health Centre 7. Windsor Regional Hospital 8. Women’s College Hospital |
| **OCREB:** | Yooj Ko (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.*

**NOTEWORTHY ITEMS**

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

1. The Trial Registration Data Set (TRDS) has been expanded and now it contains 24 elements. The 4 new elements added are: **Ethics review, Completion date, Summary results, and IPD sharing statement.** A new version of the document 'International Standards for Clinical Trial Registries' is being drafted and will be published in 2018, it will include the changes done to the TRDS. Meanwhile, ICTRP and the primary registries are working to implement those changes by the end of 2019. <http://www.who.int/ictrp/network/trds/en/>

Please note that we have published a new version of the [ICTRP search portal](http://apps.who.int/trialsearch/). In the new version there are 4 main changes:

1. A better and improved [List by Health Topic](http://apps.who.int/trialsearch/ListBy.aspx?TypeListing=0) function, where we solved the speed problem, now all the pages load in 1 or 2 seconds.
2. A new field is added to the results display page: Results available, this will have the value Yes when the results are available and we have the information in ICTRP. Currently, we have results available data for about 28000 records coming from Clinicaltrials.gov
3. A new Results section is added to the bottom of the trial details page containing 3 results fields: results available, Date posted and URL. An example can be seen [here](http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT03231371) . The URL field is a text field and is not clickable for now, this will be fixed in the next release.
4. The export function in the home search was not exporting all the 20 items of the TRDS, this has been changed and now the export function in the home search exports the 20 items registration dataset. The 4 new items added to the TRDS will be added in Q2 2018, or when enough data is available for each item in the ICTRP database.
5. For Long Life: A new sample of supercentenarian genomes is to be available to researchers this week, the New York Times reports. <https://www.nytimes.com/2017/11/13/health/supercentenarians-genetics-longevity.html>
6. **Deadline Extended – TCPS 2: Proposed Revisions to Research Involving Human Cells and Cell Lines.** On October 2017, the Panel on Research Ethics launched a period of public comment on a set of proposed changes to the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – TCPS 2 (2014). This set of changes pertains to research involving human cells and cell lines. **The deadline for receipt of comments has been extended to January 5, 2018.** All comments received will be posted online unless the contributor requests that they remain confidential. Feedback received will be taken into consideration when the Panel submits recommendations to the federal research Agencies (CIHR, NSERC and SSHRC) that are responsible for approving revisions to the Policy.
7. E6 R2 and Division 5 Guidance: Health Canada draft guidance soon to be released – December2017
8. <https://elearning.cancercare.on.ca/> Aboriginal Relationship & Cultural Competency Courses Cancer Care Ontario. **Register for online courses.**
9. CIHR Sex and Gender : 'Sex' and 'gender' are often used interchangeably, despite having different meanings:

**Sex** refers to a set of biological attributes in humans and animals. It is primarily associated with physical and physiological features including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy. Sex is usually categorized as female or male but there is variation in the biological attributes that comprise sex and how those attributes are expressed.

**Gender** refers to the socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender diverse people. It influences how people perceive themselves and each other, how they act and interact, and the distribution of power and resources in society. Gender is usually conceptualized as a binary (girl/woman and boy/man) yet there is considerable diversity in how individuals and groups understand, experience, and express it. <http://cihr-irsc.gc.ca/e/8677.html>

[](http://cihr-irsc.gc.ca/e/documents/igh_s17_infographic_gender_sex-en.pdf)

**NOTICES**

**Contact List**

We are aware that some study staff did not receive the agenda for this meeting. We are working with CTO to ensure that our report shows all study staff. The web meetings/teleconferences are held at 9am on the first Friday of every month. If you do not receive the agenda notice, please contact Alison van Nie.

**OCREB Review Fees**

Please remind sponsors that as of October 13, 2017, all invoices related to OCREB reviews will be managed by Clinical Trials Ontario (CTO). CTO (<http://www.ctontario.ca/>) provides the infrastructure to allow for a single ethics review of all multi-centre clinical trials in Ontario. As one of the CTO Qualified REBs, CTO’s review fees will apply to the OCREB reviews of all new studies. CTO also will manage the ongoing OCREB review fees for applicable legacy/historical studies. For information on the CTO review fees, go to [www.ctontario.ca/streamlined-research-ethics-review-system/cto-reb-of-record-review/#fees](http://www.ctontario.ca/streamlined-research-ethics-review-system/cto-reb-of-record-review/#fees)

**OCREB # versus CTO Project ID**

By popular request, a spreadsheet is available showing the OCREB numbers corresponding with the new CTO Project IDs for the studies that were migrated into CTO Stream. It is posted under the Project List page - [Project Lists](https://ocrebonline.ca/prod_eREB/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5B1616551484600843A4F624C186A7DA35%5D%5D). Please note that the original OCREB number without the hyphen also is attached to the end of the short study title – e.g., IND.22417003, which is OCREB # 17-003.

**Submission of NOL and CT registration number**

Please note that the submission of the NOL and the CT registration number are not required for initial approval (or for approval of amendments for which an NOL is applicable). The NOLs and registration numbers should be submitted when available – as an administrative amendment.

**REMINDERS**

**2018 Meeting Dates & Deadline**

The 2018 OCREB meeting dates and submissions deadlines are posted on O2 Home at [Deadlines & Meeting Dates](https://ocrebonline.ca/prod_eREB/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5BOID%5BEEA2628E18BD7C48B472DC0D09E3EBB6%5D%5D). To accommodate the holiday schedule, the deadline for the January 12, 2018 meeting is **December 15, 2017**.

**Consent Update/New Information Forms**

Consent update forms are required to provide relevant new information to participants already on study. They are a mechanism to focus solely on the relevant new information, rather than wading through the revisions to an entire multi-page main consent form. They also assist the participating centres that were not involved in the provincial amendment in focusing the discussion of the new information. Consent updates do not always require the participant’s signature. Re-consent depends on whether the information might affect the participant’s decision to continue on study. At times the update is for the participant’s information only and does not require the participant’s signature.

**Main Consent Form Template Revisions**

The national consent working group has been reconvened to begin revisions to the main ICF template.

**Urgent Communication with OCREB Office**

Please do not use the CTO Stream correspondence to send urgent information to the OCREB office. Every OCREB Research Ethics Coordinator is bombarded with duplication notifications in the system and thus they are unable to separate background noise from important messages.

**CTO Stream Signature Requirements**

We are aware of the substantial concerns with the number of times that the PA/PI is expected to log into CTO Stream to sign off on submissions and resubmissions, even for administrative changes to the PIA and CIA. We also are aware that the system allows applications to be submitted without requesting the PI’s signature and that some applicants are by-passing the PI signatures.

The signature requirements were based on the recommendations of a CTO advisory group in 2014, and were rooted in a desire to demonstrate PI accountability and oversight in the REB submission process. CTO screens the initial submission of each PIA to ensure that the PI has signed off and that the correct Institutional Rep has been entered into Question 1.16. CTO also screens the initial submission of each CIA to ensure that the PI, a Department Approver and the Institutional Rep have signed off on it.

There is no regulatory requirement for the PI to sign off on applications to the REB and there have not been any related Health Canada inspection findings. Below is from a response to OCREB from Health Canada on this question:

“The delegated duties, captured on a delegation log, are dependent on the trial, and may include correspondence with REB. As per section 4.15 of ICH E6: GCP, the investigator should maintain a list of persons to whom the investigator has delegated **significant trial-related** duties. The delegation log should be completed before commencement of the study and updated as necessary in a timely fashion. As a best practice, the QI should sign and date the log on or before the date a task is delegated, not after a task is delegated. Site personnel should not initiate a trial task until the QI has documented that they have delegated it.”

It is not an OCREB requirement for the PI to sign off on resubmissions of the PIA or the CIA, or on initial submissions or resubmissions of post-approval applications. However, the PI remains responsible for all REB related activities and must be aware of and authorize others to sign off on REB applications on his/her behalf by documenting such delegation to a member/members of the study team who are appropriately qualified and trained.

**OCREB Membership Changes**

The OCREB membership list was last updated on October 1, 2017. The current and archived membership lists can be accessed from [https://ocrebonline.ca](https://webmail.oicr.on.ca/OWA/redir.aspx?C=193daae2cfb44249869f16742f54e9d5&URL=https%3a%2f%2focrebonline.ca) via the “Member Lists” link.

**Project List**

The list of studies and centres is available on [O2 Home](https://webmail.oicr.on.ca/OWA/redir.aspx?C=193daae2cfb44249869f16742f54e9d5&URL=https%3a%2f%2focrebonline.ca). The current version is November 23, 2017.

**STUDY SUBMISSION STATUS**

For a list of all studies with OCREB, see the Project Submission spreadsheet at <https://ocrebonline.ca>

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1306 | Kathie | Merck | KEYNOTE 679/ECHO 302 | Andrew Robinson | KHSC | Carrie Lindsay |
| 1337 | Aurora | COG | AML1421#4 | Johann Hitzler | HSC | Farzaana Ali |
| 1350 | Aurora | Merck | Keynote-698/ECHO 303 | Susanna Cheng | SHSC | Jennifer Woo |
| 1362 | Kathie | Lilly | I3Y-MC-JPCF | Joanne Yu | NYGH | Fion Tang |
| 1352 | Aurora | DDP (IIS) | WI222910 | Srikala Sridhar | UHN | Bonnie Kwan |
| 1372 | Kathie | IIS | DENIM | Srikala Sridhar | UHN | Bonnie Kwan |
| 1359 | Cindy | AZ/Quintiles | D0816C00020 OPINION | Stephanie Lheureux | UHN | Bonnie Kwan |
| 1361 | Kathie | CCTG | MAC21 (Alliance A011502) | Katarzyna Jerzak | SHSC | Carolyn Lim |
| 1356 | Cindy | AbbVie | Abbvie M15-862 | Albiruni Razak | UHN | Mohammad Ahmad |
| 1378 | Cindy | AbbVie | M16-298 MERU | Amin Kay | WRH | Krista Naccarato |
| 1365 | Aurora | COG | ALTE15N2 | Paul Nathan | HSC | Subitha Rajakumaran |
| 1371 | Cindy | CCTG | CO.38 | Sunil Patel | KGH | Meghan McKay |

**New studies submitted for the January meeting:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1340 | Immunomedics | ASCENT - IMMU-132-05 | Ellen Warner | SHSC | Carolyn Lim |
| 1380 | NRG | NSABP B-51/RTOG 1304 | Steven Latosinsky | LHRI | Mary Beth Husson |

**Other Potential Studies:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | COG | AALL1621 |  | HSC |  |

**CONTINUING REVIEW APPLICATIONS**

Be sure to keep track of study (and participating centre) expiry dates. CTO Stream sends courtesy alerts 45, 30 and 10 days before the REB approval expiry date to remind the research team to submit their provincial continuing review (PCR) application. Centre continuing review (CCR) application alerts are sent 45 and 30 days prior to the REB approval expiry date. Unfortunately the alerts do not stop once the CR application has been submitted.

**NOTE:** CR applications are due by the meeting deadline. To ensure that the information is current, please make every effort to submit the CRs as close to the deadline as possible. 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 January Meeting**

For studies **expiring January 12 to February 8, 2018 inclusive**, provincial and centre continuing review applications are due by the December 15, 2017 deadline for the January 12, 2018 meeting, **unless a study closure has been or will be submitted.**

**Next Centre Web Meeting/Teleconference**

**Friday, January 5, 2018 @ 9am**

