**Ontario Cancer Research Ethics Board**

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

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

**Monthly Centre Web/Teleconference Meeting Summary**

**December 7, 2018 @ 9am**

**ATTENDEES**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. CHEO, Ottawa 2. Hamilton Health Sciences  * Juravinski Cancer Centre * McMaster Children’s Hospital  1. Health Sciences North, Sudbury 2. Kingston General Hospital  * Kingston General – Pediatrics  1. Lakeridge Health, Oshawa 2. Niagara Health System 3. The Ottawa Hospital  * Cancer Centre * Other (URO, HEM, OHRI) | 1. Southlake Regional Health Centre, Newmarket 2. Sunnybrook Health Sciences Centre, Toronto  * Human Research Protections Program  1. Trillium Health Partners, Mississauga 2. UHN - Princess Margaret Cancer Centre, Toronto  * Clinical Trial Support Unit * Drug Development Program * Medical Oncology & hematology * Radiation oncology * Surgical oncology * Medical Imaging * UHN – TGH * UHN - TWH |
| **OCREB:** | Aurora de Borja, Cindy Sandel, Richard Sugarman (Chair), Alison van Nie, | |

**REGRETS**

|  |  |  |
| --- | --- | --- |
| **Sites:** | 1. Cambridge Memorial Hospital 2. Grand River Hospital 3. Hospital for Sick Children, Toronto 4. Humber River Hospital, Toronto London Health Sciences Centre  * Lawson * LRCP * Children’s Hospital * Other (DSO, URO, HEM)  1. Markham Stouffville 2. Michael Garron Hospital, Toronto 3. North York General Hospital | 1. Royal Victoria (Barrie) 2. St. Joseph’s Healthcare (Hamilton) 3. St. Joseph’s Health Centre (Toronto) 4. St. Michael’s Hospital, Toronto 5. Sinai Health System, Toronto 6. Thunder Bay Regional Health Sciences Centre 7. William Osler Health Centre, Brampton 8. Windsor Regional Hospital   Women’s College Hospital, Toronto |
| **OCREB:** | Beren Avci, Janet Manzo | |

*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**

**Session Roll-Call**

To save time, we will no longer be doing a roll call at the beginning of each meeting. Thank you to those who sent emails to Alison to let her know you attended the November session. However, we have discovered an easier way to track attendance. If you join the session over the web and phone, your name/affiliation will appear in the web report, so please do NOT send Alison a notice of attendance. If you join by phone ONLY, we have no way of determining your attendance, so please send Alison an email to let her know you attended by phone. Thanks for your patience!

**OCREB Office Staffing Changes**

Kathie Zeman has taken an offer she couldn’t refuse at a pharma company. Her last day at OICR was December 5th. Her position has been posted at: <https://www.recruitingsite.com/csbsites/oicr/JobDescription.asp?JobNumber=834446>.

Please pass on the job posting to colleagues.

**November 28, 2018 - position at OCREB**

OCREB is seeking a full-time Research Ethics Coordinator (REC). The REC serves as the primary liaison between OCREB and the research teams, and is integral to the operations of OCREB.

For more information and to apply, go to: <https://www.recruitingsite.com/csbsites/oicr/JobDescription.asp?JobNumber=834446>

**Updates to Annotated PIA**

OCREB guidance text was added to two questions in the PIA:

* Q1.8: the Sponsor name should be entered into the sponsor contact organization field even if the contact person does not work directly with the Sponsor so that the correct sponsor appears in listings and letters;
* Q1.12: the question refers to any scientific reviews (independent or not)

**CTO Stream Update**

CTO Stream is pleased to announce that they will be releasing a new update to the system on December 13, 2018. This update will include a new feature which allows an existing Provincial or Centre Reportable Event form to be updated with new information and re-submitted to the REB. Please note that this feature normally should only be used with AEs. Other RE submissions generally do not require updating.

This update also includes changes to the application-specific information contained within some Review tiles in the system. The addition of ‘application type’ to the review tiles will allow users to sort/filter the applications within these tiles by application type.

REB users can find more information about this update here: <https://apply.ctostream.ca/Personalisation/DownloadTemplate/27>

Additional information for Applicants can be found here:

<https://apply.ctostream.ca/Personalisation/DownloadTemplate/28>

A Quick Guide for applicants to use the new feature is available in the Help Menu of CTO Stream here:

<https://apply.ctostream.ca/Personalisation/DowloadTemplate/25>

**REMINDERS**

**Participant Withdrawal Guidelines**

In follow-up to the November session, a revised template will be posted on the OCREB website. The document serves to guide the discussion and documentation when a participant withdraws from a study.

**January Meeting Deadline**

All 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.

**New ICF Template**

It is anticipated that the new consent template will be released early in 2019.

**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 November 28, 2018

**NEW STUDIES**

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **CTO ID** | **REV** | **Sponsor** | **Study ID** | **PA** | **Org** | **PIA Contact** |
| 1627 | Cindy | Tesaro | 3000-03-005/ENGOT-OV44 (FIRST) | Allan Covens | SHSC | Amanda Fonseca |
| 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 |
| 1669 | Aurora | Merck | MK-3475-495 (Keynote-495) | Mark Doherty | SHSC | Ilda Carvalhana |
| 1692 | Aurora | Esperas | ESPS-001(h) | Hal Hirte | HHS | Yvonne Kinrade |
| 1697 | Cindy | IIS | SABR-COMET 10 | David Palma | LHRI | Mary Beth Husson |
| 1698 | Cindy | ISOFOL | ISO-CC-007 | Derek Jonker | TOH | Lisa Turriff |
| 1701 | Beren | Karyopharm | KCP-330-024 / BGOG-EN5 / ENGOT-EN5 / SIENDO | Amit Oza | UHN | Bonnie Kwan |
| 1706 | Beren | AMGEN | 20170543 | Scott Laurie | TOH | Lisa Turriff |
| 1714 | Aurora | Merck | MK-5618-001 | Aaron Hansen | UHN | Mohammad Ahmad |
| 1718 | Aurora | Merck | MK-3475-756-00 (KEYNOTE-756) | Dave Cescon | UHN | Kaitlyn Zammit |
| 1722 | Cindy | AZ | ACE-CL-311 (D8221C00001) | David Spaner | SHSC | Arlene Mete |
| 1725 | Aurora | IIS | PET NET Registry | Ur Metser | UHN | Nanthini Tharahan |
| 1728 | Cindy | Incyte | INCMGA 0012-201 | Teresa Petrella | SHSC | Carolyn Lim |

**Other Potential New Studies:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Project 1721 - CA045001 | Elaine McWhirter | JCC | Yvonne K |
| COG | AGCT1532 |  | HSC |  |
| NRG | GU-005 |  | WRH |  |
| Merck | MK7902-002 | Jennifer Knox | UHN |  |
| CCTG | REC.4 / ECOG-ACRIN 8143 |  |  |  |
| AZ |  |  | TOH | Amy H. |

**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 December 11 deadline for the January 11, 2019 meeting, and December 17 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 January 11, 2019 Meeting**

For studies **expiring January 11 to February 7, 2019, inclusive**, provincial and centre continuing review applications are due by the December 11, 2018 deadline for the January 11, 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 Office for Human Research Protections (OHRP) is announcing the availability of a draft guidance document that relates to three burden-reducing provisions in the revised Common Rule that institutions may choose to implement during the delay period (July 19, 2018 through January 20, 2019) for general compliance with the revised Common Rule. The draft guidance document is titled, “Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements.” The draft guidance document can be accessed at <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html>. – to address the delays… in implementation of the final rule
* **FDA Issues Proposed Rule on IRB Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations**

In today’s edition of the *Federal Register*, the Food and Drug Administration (FDA) issued a Notice of Proposed Rulemaking entitled "Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations."   The proposed rule, if finalized, would permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

The proposed rule can be accessed on FDA’s [web site](http://app.info.fda.gov/e/er?utm_campaign=IRB%20Waiver%20or%20Alteration%20of%20Informed%20Consent%20For%20Minimal%20Risk%20Studies%20NPRM&utm_medium=email&utm_source=Eloqua&s=2027422842&lid=5519&elqTrackId=07C024CA69AAFA3A6AE6BC89A86E296F&elq=89ca0b51a0554c04b0c149b87ab2191f&elqaid=5831&elqat=1).  Comments on the proposed rule may be submitted at [https://www.regulations.gov](http://app.info.fda.gov/e/er?utm_campaign=IRB%20Waiver%20or%20Alteration%20of%20Informed%20Consent%20For%20Minimal%20Risk%20Studies%20NPRM&utm_medium=email&utm_source=Eloqua&s=2027422842&lid=683&elqTrackId=0B458A5035D2E20EDB46774F621395CD&elq=89ca0b51a0554c04b0c149b87ab2191f&elqaid=5831&elqat=1)

* CTTI released [new recommendations](https://www.ctti-clinicaltrials.org/sites/www.ctti-clinicaltrials.org/files/investigatorqualification-recommendations_112618_final.pdf) proposing a new approach for **investigator qualification**. This approach goes beyond repetitive one-size-fits-all training and includes individual experience and protocol-specific preparation. November 2018  
  + **ACRP in the News.** [ACRP Developing Competence Standards for PIs](https://www.acrpnet.org/2018/11/05/acrp-developing-competence-standards-for-pis/)

The Association of Clinical Research Professionals (ACRP) on November 5, 2018 announced a groundbreaking new **initiative to develop competence standards for Principal Investigators (PIs).**

“By focusing on the competence of the Principal Investigators (PIs), who are ultimately accountable for clinical trial conduct, ACRP and its partners are taking a major step to promote excellence in clinical research.”

Today’s news follows recent announcements by ACRP of competence standards for both Clinical Research Coordinators ([details](http://ACRP.informz.net/z/cjUucD9taT0yNDYyNjI4JnA9MSZ1PTM3NTk1ODM0NSZsaT0xNjIxMjM3Nw/index.html)) and Clinical Research Associates ([details](http://ACRP.informz.net/z/cjUucD9taT0yNDYyNjI4JnA9MSZ1PTM3NTk1ODM0NSZsaT0xNjIxMjM3OA/index.html)).

The PI competence initiative will be led by ACRP’s Workforce Innovation Steering Committee (WISC), whose membership includes global representation from a broad group of private and public stakeholders in clinical research ([details](http://ACRP.informz.net/z/cjUucD9taT0yNDYyNjI4JnA9MSZ1PTM3NTk1ODM0NSZsaT0xNjIxMjM3OQ/index.html)).

ACRP since 2001 has been validating the competence on PIs through its Certified Principal Investigator (CPI®) certification program, and ACRP Certification has been directly tied to lower protocol deviations and higher enrollment rates in clinical trials ([details](http://ACRP.informz.net/z/cjUucD9taT0yNDYyNjI4JnA9MSZ1PTM3NTk1ODM0NSZsaT0xNjIxMjM4MA/index.html)). To date, more than 1,200 PIs have earned the CPI® designation from ACRP.

“**Certification is only one piece of the competency puzzle. By developing consensus on PI competence standards, and continuing to validate competence in the workforce through independent and accredited certification programs, ACRP is continuing to raise clinical research standards and improve study outcomes**.

* + **ACRP in the News.** [Research Projects Show Credentialed Principal Investigators and CRCs Perform Better](https://www.acrpnet.org/2018/07/03/research-projects-show-credentialed-principal-investigators-and-crcs-perform-better/?utm_campaign=News&utm_medium=email&utm_source=internal&utm_content=PICompetence-PressRelease-10312018&utm_term=text-details&_zs=PIrCX&_zl=mL5P1)
* **CBC News**: [When scientists want their data fudged and why you should care](https://urldefense.proofpoint.com/v2/url?u=https-3A__www.cbc.ca_news_health_second-2Dopinion-2Dscientists-2Ddata-2Dfudging-2D1.4861556&d=DwMGaQ&c=0hCx1u36-XAMUG1zdNEI2VR5Zeej6Q9MkDa5wSI1xHs&r=KKbAYTtDmGbOSk8PNTAYbpTmX7RuUg-PESaUf2K6pLk&m=HUD4XIPSPUamEpOwFHAlp8y4Bk3rYFXbRshvV_pNcdY&s=YSoxbWUzZEhLS64ifBTsJtVF7gtfcjN5WiJmf7dzu9E&e=) – this is because there is reliance on outcomes and actions taken. Researchers may request changes to the statistical analysis not always due to a desire to act unethically but also because of lack of knowledge, etc.
* **Outsourcing Pharm.com:** [Watchdog files lawsuit against FDA to revamp informed consent, citing 150 deaths](https://www.outsourcing-pharma.com/Article/2018/11/01/Watchdog-files-lawsuit-against-FDA-to-revamp-informed-consent-citing-150-deaths) – ensuring participants are informed of the uncertainty of outcomes/adverse events.
* **Time:** [Researchers Want Cancer Patients To Share Their Medical Information In Search of Cures](http://time.com/5427807/count-me-in-cancer-research/)

A new non-profit project from several leading health organizations that launched Thursday, called Count Me In, lets cancer patients send their medical information directly to researchers who are searching for cures – democratic data collection.

Count Me In allows cancer patients to send their medical information — including blood, saliva and tumor samples — to a public database that any researcher can access. The tumor samples and blood samples are genetically sequenced, and that data, along with the patient’s medical history (including which treatments patients received and how well they worked), is then translated into an anonymous database.

This information is invaluable to scientists who can use it to see patterns that might eventually lead to new understanding of how cancer works — and more importantly, to new drugs for treating it. The project is a collaboration among the Emerson Collective, an organization focused on innovative solutions for social change that was founded by Laurene Powell Jobs, who is Apple founder Steve Jobs’ widow, the Broad Institute of MIT and Harvard, the Biden Cancer Initiative and the Dana Farber Cancer Institute. The Broad, a leading genetics institute, performs the sequencing and for now will store the samples patients send in. People in the U.S. and Canada can send their medical records and samples by signing an online consent form on Count Me In’s website. After signing up, they receive a kit by mail for providing a saliva sample; Count Me In contacts their hospitals to collect medical records and blood and tumor samples. Since it’s not a commercial business, Count Me In’s patient database will not be sold to other entities like pharmaceutical companies, and the project will be funded mainly through philanthropy. [we reviewed similar project called Driver last month which provided a service for a fee – matching data and tissue with recommendations, trials, etc.]

* GDPR: Germany's first fine under the GDPR offers enforcement insights: On Nov. 21, the State Commissioner for Data Protection and Freedom of Information for Baden-Wuerttemberg imposed the first fine under the GDPR in Germany. The fine was imposed on a social media company for a violation of its data security obligations. This is not the first GDPR-related fine in Europe that has become publicly known: **The Austrian DPA imposed a 4,800 euros fine for illegal video surveillance activities, and a 400,000 euros fine was imposed in Portugal on a hospital after staff members illicitly accessed patient data.** However, the current example from Germany provides further insights into how DPAs intend to use their new, heightened fining powers under GDPR. Oliver Schmidt reports.
* **NY Times:** [The Results of Your Genetic Test Are Reassuring. But That Can Change](https://www.nytimes.com/2018/10/16/health/genetic-testing-mutations.html)

While a person’s genome doesn’t change, the research linking particular bits of DNA to disease is very much in flux. Geneticists and testing labs constantly receive new information that leads them to reassess genetic mutations.

As a result, a mutation seen as benign today may be found dangerous tomorrow. And vice versa. But there is no good way to get the new information to doctors and patients.

GDPR: Germany's first fine under the GDPR offers enforcement insights: On Nov. 21, the State Commissioner for Data Protection and Freedom of Information for Baden-Wuerttemberg imposed the first fine under the GDPR in Germany. The fine was imposed on a social media company for a violation of its data security obligations. This is not the first GDPR-related fine in Europe that has become publicly known: **The Austrian DPA imposed a 4,800 euros fine for illegal video surveillance activities, and a 400,000 euros fine was imposed in Portugal on a hospital after staff members illicitly accessed patient data.** However, the current example from Germany provides further insights into how DPAs intend to use their new, heightened fining powers under GDPR. Oliver Schmidt reports.

* In a [September 2018 article](http://r20.rs6.net/tn.jsp?f=001uivy7gDPV_wG-TxUYsRScmI57gaTQGMa_uGjExNRN1SaF_4iIV_X957J-wV-fmjwLuxrghqxQH9GI87F-56F3ZbvVB-C3GbgVnVBux-P_gK-T3GuHpGBw14DYrXlp2JNss25V44dyQAjELoY_pxVToO0VMkWZTVskvAvTbLZjRSCwyzJVp9fIcVgnyhQ-EtDthKwJwBuS-HBD4nUUZAQiKeMzk1_cXDErNGicCGYa-PBr3SruNpsTw==&c=zVe1Ayyrl7-1Xz_8fxs9gZVR_kMl4JM8VOwdrZB_o9XLPju8OpnKlw==&ch=w0Ys7vNjlEvVd2gqdoEikiJ_cT0QLyg5p5aXuqQHpjZD4LWFbsuG-Q==) in **PLOS ONE**, the Clinical Trials Transformation Initiative (CTTI) shares recommendations on planning for pregnancy testing in clinical trials.

* [Portal to access world’s largest database of pediatric genomic data goes live](https://news.oicr.on.ca/2018/09/portal-to-access-worlds-largest-database-of-pediatric-genomic-data-goes-live/)  
  OICR’s Genome Informatics team plays key role in development of the Gabriella Miller Kids First Data Resource Portal. The Gabriella Miller Kids First Data Resource Center (DRC) at the Children’s Hospital of Philadelphia has launched the Kids First Data Resource Portal, which will advance personalized medicine for the detection, therapy, and management of childhood cancer and structural birth defects. As the Kids First DRC’s chief outward-facing tool, the Kids First Data Resource Portal serves the needs of a diverse group of patients, researchers, and clinicians partnering to create the world’s largest database of pediatric genomic data, and provides the necessary tools and computational resources for their analysis and interpretation.

**Next Web/Teleconference Session**

We will not be holding a session on January 4, 2019. The next session will be: **February 1, 2019 @ 9am**