VOLUME 2, OCTOBER 2019

BC CANCER
Provincial Health Services Authority

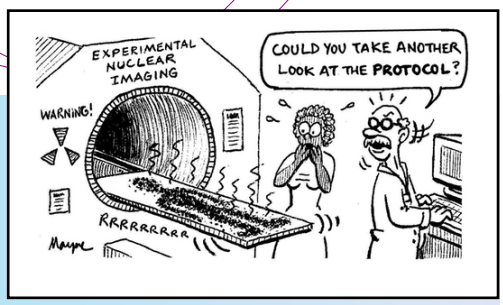
ETHICS & ELEMENTS

A NEWSLETTER

BC CANCER RESEARCH ETHICS

WHAT YOU'LL FIND

WHAT'S NEW!



NEW GUIDANCE: (because we all need guidance!)

- Health Canada Special Access
- BC Cancer REB Guidance for Chart Reviews

These can also be found on our website:

Http://www.bccancer.bc.ca/our-research/ethics-oversight/research-ethics-board/policies-procedures-guidance

IMPORTANT!! TCPS2 REVISED + Material Incidental Findings

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition 'TCPS2 (2018)' replaces TCPS2 (2014) as the official human research ethics policy of the federal research granting agencies. Revisions are summarized at Highlights of Changes

IMPORTANT: revisions included a new document: How to Address Material Incidental Findings - Guidance in Applying TCPS 2 (2018) Article 3.4. We've provided some key points below, but please refer directly to the guidance for further information.

Incidental Finding – An "incidental finding" is a discovery about research participants or prospective participants that is made in the course of research, but is outside the objectives of the research study.

Material Incidental Finding (MIF): incidental findings are "material" if they are reasonably determined to have significant welfare implications for the participant or prospective participant. MIFs can be discovered at any time, stage, or type of research (even in chart reviews).

There are three determinants of materiality: analytical validity, significance, and actionability

What do you need to do:

Where material incidental findings are reasonably foreseeable, researchers should develop a management plan for review by the REB. For **genetic research**, researchers are **required** to develop a plan for managing information that may be revealed through their research, and **submit the plan for REB review**. (TCPS 2, Application of Article 3.4)

There are three key considerations in developing a management plan: likelihood of discovery, management, and consent. Management may be compromised by resources but this does not exclude the ethical need to make a plan and to try and identify barriers to following the recommendations.

In addition:

- When MIFs are discovered (either foreseeable or unexpected) – it **MUST** be reported to the REB
- Any changes to the management plan or departures from consent (i.e. to disclose or not to disclose) – consult the REB and approval **MUST** be obtained from REB before implementing

If you have any questions, please contact us.

NEW OPTIONAL CONSENT FORM TEMPLATE

Last edition we mentioned that there were a couple of other consent form templates in the works! The Optional Consent Form Template is ready for use and can be found on the website:

BC Cancer Optional Study Information and Consent Form

RCR CORNER with Dr. Kristie Westerlaken

We decided to dedicate a section to the Responsible Conduct of Research or "RCR" (not to be confused with Resorts of the Canadian Rockies or Royal Canadian Regiment!) In each issue, we will highlight topics such as researcher misconduct, authorship, plagiarism, conflicts of interest, etc. In this first corner, we'll look at researcher responsibilities, including research integrity, two key documents that guide researchers, and a recent court case, Stirrett v Cheema, that sets out a researcher's fiduciary duty to their participant.

What are your responsibilities as a researcher?

It's important to recognize that research integrity underpins all responsibilities as a researcher. Research integrity is "the coherent and consistent application of values and principles essential to encouraging and achieving excellence in the search for, and dissemination of, knowledge. These values include honesty, fairness, trust, accountability, and openness" (see Honesty, Accountability and Trust: Fostering Research Integrity in Canada)

The values and principles of research integrity are embedded within two key documents that all BC Cancer researchers should familiarize themselves with: the Tri-Agency Framework: Responsible Conduct of Research (2016) and UBC Policy No. LR9 - Research Involving Human Participants – "Human Research Policy" (formerly Policy 89: Research and Other Studies Involving Human Subjects)

The Tri-Agency Framework states that, at a minimum, researchers are responsible for the following:

- Rigour
- Record Keeping
- Accurate referencing
- Authorship
- Acknowledgement
- Conflict of Interest Management

UBC's Human Research Policy, states that researchers **MUST**:

1.1.1: be familiar with all University policies relating to research, including without limitation the Human Research Policy, these Procedures, and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

AND

1.1.4: if there is any doubt as to whether such research project constitutes Research Involving Human Participants, consult the appropriate REB to obtain a determination as to whether such research project requires research ethics review.

Stirrett v Cheema, 2018 ONCSC 2595 ('thank you' to our legal representative Julie Gibson for this summary)

This recent Ontario judgment highlights the need for researchers to be aware of their responsibilities. The court found that the Principal Investigator breached his fiduciary duty to the participant (Mr Stirrett) because the PI failed to update the informed consent form, failed to submit the protocol amendments to the REB for review and approval, and failed to pass on the study changes to Mr. Stirrett. The changes that had occurred were:

- the study might close;
- enrolment numbers had changed; and
- the Data Safety Monitoring Board had not been set up.

The court stated that the patient-researcher relationship is subject to a strict duty where the subject of medical research is entitled to full and frank disclosure of all facts, probabilities and opinions that a reasonable person might be expected to consider before giving consent. The participant must rely upon the special skill, knowledge and experience of the investigator, who was placed in a fiduciary position.

It did not matter whether Mr. Stirrett would have decided to continue in the study if informed of the changes. It also did not matter if the new information was "significant" or whether it would have changed the risk of harm to the participating. That was not for the PI to decide.

As you can see, the court's reasoning is underpinned by research integrity values and principles - honesty, fairness, trust, accountability, and openness.

In closing, if you are involved in research at BC Cancer, you need to familiarize yourself with all your responsibilities as we don't want to see you in court!

In each edition, we are going to set out some of the untrue 'myths' that we hear:

A minimal risk project does not require ethics review or consent.

- False and False. Research involving humans (which can also encompass data and/or biospecimens) requires review. In addition, Articles 3.1 to 3.5 of TCPS2 (2018) set out the "default requirements for seeking the consent of individuals to participate in research". Of course, there are always exceptions to this, but just remember that consent is the default and any request to alter or waive consent must be reviewed/approved by the REB.

- **I'm only doing lab work, I don't need ethics approval.**
  - Inaccurate! Presuming the samples being worked on in the lab once belonged to humans, ethics approval (and possibly prior consent), is required. Please refer to TCPS2 (2018) Chapter 12, Section B

- **It's just a pilot study so I don't need to submit it for ethics review**
  - Untrue: Pilot studies fall within Article 2.1 of TCPS2 (2018's) definition of research requiring ethics review.

- **It's student research or it's just research on students so I don't need ethics review**
  - Research undertaken **by** students most likely requires ethics review, and, because students are considered to be humans, not only would you need ethics approval to do research **on** students, you would *also* need their consent.

    References:
    - https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes
    - Http://www.bccancer.bc.ca/our-research/ethics-oversight/research-ethics-board/policies-procedures-guidance

- **It's just a chart review, I don't need ethics approval or consent**
  - Faulty. Ethics review is required for chart reviews **and** consent may be required.

    Reference: BC Cancer REB Guidance for Chart Reviews

- **I am getting data and/or tissue from somewhere else (e.g. another institution, province, country, commercial entity, etc.) so I don't need ethics approval.**
  - Mistaken. Humans are humans no matter where they came from. And again, research involving humans (which can also encompass data and/or biospecimens, e.g. tissue, blood, cells, etc.) requires review.

- **The data/tissue that I am analyzing is anonymous, so…**
  - Iffy. Talk to us first – there are many misunderstandings about the definition of anonymous and anonymized, de-identified, re-identified, identifiable, coded, and on and on…

- **They are my patients so I don't need ethics approval or consent to talk to them or access their charts for my own research**
  - Oh dear. **Code Grey!** (for those of us who don't know, Code Grey means system failure, **or** natural disaster.) Call us immediately (and you may wish to remain anonymous…)

In summary, TCPS2 (2018) Article 2.1 states that the following requires ethics review and approval by an REB before the research commences. Research involving:

- living human participants;
- human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

When in doubt about the applicability of this Policy to a particular research project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exemption from research ethics review.

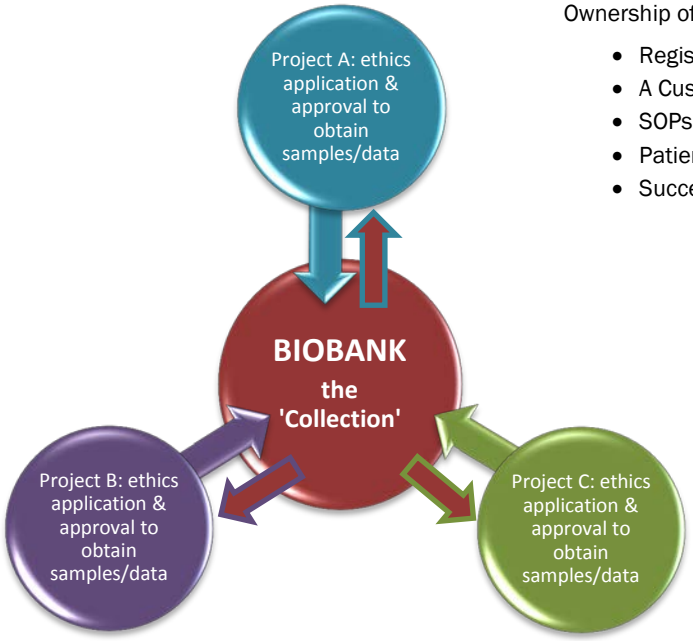
In addition, Chapter 3: The Consent Process states that subject to exceptions set out in this Policy, consent must be obtained from participants prior to the conduct of research.

Where elements of the consent process may need to be adapted to the requirements of a particular research project, the REB can play an educational and consultative role in determining the appropriate process for seeking and maintaining consent. REBs must consider whether the requested alterations are justified or whether another approach would make it possible, practicable and appropriate to follow the normal consent requirements.

SAY HELLO TO BIOBANKING

A Biobank is exactly the same idea as a money bank where you make one transaction to deposit your money, and if you need to take out money each time you wanted to buy a different shiny thing, you would have to fill out a withdrawal slip (this is an old style bank, not like e-transfer…). The samples/data are deposited into a single savings account (the "collection") using a single ethics application, and each time you have a new project and need to withdraw some samples/data, you need to fill out and submit a new ethics application for review and approval.

Now, imagine you are the manager of the money bank. Could you walk in, open up the safe, and take out all the money whenever you felt like it? Well, you could, but that would be unethical! (and, likely, illegal…) Biobanks are the same. You cannot be a manager (i.e. a "custodian") or be a team member on a biobank and do whatever you want/whenever you want with the samples/data collected. Like any other bank customer, you must submit an ethics application for review and approval prior to withdrawal for each new project.



Ownership of a biobank also requires the following:

- Registration with CTRNET (ctrnet.ca)
- A Custodian
- SOPs
- Patient Consent
- Succession Plan

Still confused?!
We get that – so please feel free to contact us!

UPCOMING EVENTS AND REMINDERS

SAVE THE DATE

TUESDAY, DECEMBER 3, 2019 AT 12:15 PM

NOON ROUNDS: Topics of discussion include research ethics and responsible conduct in research

JOHN JAMBOR AUDITORIUM

(there may or may not be food; come and find out!)

HAPPY HALLOWEEN!

REMINDER:

Research Ethics Administration has drop-in sessions **every Thursday from 10:00am to noon**. #1315, 750 West Broadway

(and, we like coffee and chocolate)

The 2020 REB Full Board Meeting Dates are now posted on the website!

That's all for this edition and thank you for reading!

Let us know what you would like to see in future editions: reb@bccancer.bc.ca