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BC CANCER
Provincial Health Services Authority

ETHICS & ELEMENTS
A NEWSLETTER
BC CANCER RESEARCH ETHICS

WHAT'S NEW(ISH)!

WHAT YOU'LL FIND

SPECIAL POINTS OF INTEREST:

- New team member
- Is E-Consent the way of our future?
- Do YOU know the difference between Compliance and Ethics?
- Administrative Provisos are a thing, and you need to know!

WE'RE BAAACK! We had a brief hiatus as we got sidetracked with a global pandemic–did you hear about that?! But, we thought we'd try and get on board with this new normal stuff and ease our way into it with a bit of newish/oldish research ethics stuff so here goes:

CONTACTING US: As we are WFH (for the non-hipsters, that's Working From Home) it's best to contact us at reb@bccancer.bc.ca and we can set up a phone call or videoconference. We will also continue to specifically set aside our former Thurs 10-12 'drop in' time slot to schedule distance consultations. When in doubt and need help, shout out!! Zoom, Zoom.

WE'RE HIRING/WE'VE HIRED: Evani Goll abandoned us on March 13th (clearly, she had insider information about COVID and wisely fled before the onslaught of curtailments, exemptions, amendments, RFAs, resumptions, etc.) Seriously though, we want to thank Evani for all of her contributions over the years and wish her all the best in her new adventures! We will miss her and her sense of humour! (and, you may too, as she usually wrote the funny bits in this newsletter so if it's a bit 'meh', it's all her fault...)

Alanna Dyck started with us on August 5, and is still here which we think is a good sign given it definitely hasn't been a traditional job start. Alanna has a BA & MA in Philosophy and has worked at UBC BREB, PHC REB, and SFU's REB. Yes, she's got experience in research ethics (& RISe = bonus!), but the real reason we hired her was because she mentioned implementing a 'chocolate' table in the office. Welcome Alanna - we look forward to sharing chocolate in person at some point (of course, from an appropriate distance & while wearing masks) and hope you've found your forever home with us!

NEW GUIDANCE: Use of interpreters and translated documents: The use of interpreters and translated documents for the consent of persons for research studies is guided by the principles of non-discrimination and fairness. It is important to not discriminate in the enrolment of persons in research studies based on their language or reading ability. The ICF is a critical document for the participant to have in their possession and be able to read in their language and refer to at their discretion, particularly for information relating to risks and/or side effects. Please refer to the full guidance document on our website and don't hesitate to contact us with any questions.

NEW (& updated) CONSENT FORM TEMPLATES: New BC Cancer Template Consent forms for: Biobanking and Non-Interventional Studies, and updates to the Clinical–main & optional ICFs (on our website).

FEE INCREASES:
Effective April 1, 2020 the initial application & annual renewal fees were increased. Please see BC Cancer Research Ethics Fees.pdf for full details.

ELECTRONIC CONSENT (E-CONSENT)

The research community at Provincial Health Services Authority (PHSA) provides opportunities for patients to access important studies across a wide range of health domains but participation is often limited to those who can attend a face-to-face meeting and sign a paper-based consent form. In the past, researchers have attempted to overcome this participation barrier by asking participants to email, scan, mail, or fax signed consent forms but these methods are cumbersome and less than ideal from a privacy and security perspective. To resolve this issue, the BC Children's Hospital (BCCH) Research Data Management Team is now offering electronic-consent (e-consent) to researchers across the PHSA, including BC Cancer researchers.

E-consent is a platform for consenting research participants either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap platform at BCCH is a pre-approved tool that is available to all PHSA researchers and has undergone extensive security and privacy review. When using the BCCH instance of REDCap, the consent form data are stored on a private, relational MySQL database at the data centre which is located on-site at BC Children's Hospital in Vancouver, BC. Research studies that use this tool are captured under the current privacy impact assessment and security review and are not required to undergo any additional reviews after Research Ethics Board (REB) review and approval is secured.

The BCCH Research Data Management Team has already published E-Consent Tips and Tricks on its website (https://hub.bcchr.ca/pages/viewpage.action?pageId=82673891), and BC Cancer Research Ethics Guidance on E-Consent can be found on our website. It is important to note that we have not investigated if e-consent would be acceptable for regulated clinical trials.

> **"...email, scan, mail or fax signed consent forms...are cumbersome and less than ideal from a privacy and security perspective."**

TOP 10 ADMINISTRATIVE PROVISOS (for enquiring minds...and in no particular order...)

Do ANY of these sound familiar?

1. In the PAA coversheet, please confirm that the newly added study team members have completed TCPS 2 Core Tutorial or CITI equivalent.
2. Please remove previous versions of the protocol, and other relevant documents as required.
3. Please update the relevant sections of RISe with the revisions per this amendment.
4. Please include a version date within the documents. Please ensure the dates in the documents match what is listed in RISe.
5. Please ensure tracked-changed versions of documents are attached so they can easily be reviewed.
6. Please attach a copy of the grant/funding application for the additional funding to Section 9.8 of the RISe application for REB review
7. For ease of readability, please ensure the font type and size is consistent throughout the document
8. Please remove the newly included wording as this has already been stated on page xx.
9. Thank you for your submission however no changes to the application form can be seen. Please edit as outlined in the PAA coversheet/Proviso response and resubmit for REB review.
10. In section 3.3 it states that only 50 patients were enrolled but last annual renewal it stated that 400 were enrolled. Please reconcile.

If the answer is "YES" to any of the above, please ensure the RISe application and/or PAA submission has been reviewed for completeness prior to being submitted.

RCR CORNER with Dr. Kristie Westerlaken

(how we envision we are thought of sometimes…)

What is research ethics? Before we tell you what it is, let's tell you what it isn't!
Research ethics is NOT:

a. the Informed Consent Form;
b. the RISe application;
c. compliance (see Mythbusters for more info!);
d. someone else's problem;
e. the sole responsibility of the Research Ethics Board;
f. a painful, soul destroying process.

Well, if we're honest, it can sometimes be 'f' (and, we know that you've probably used words that start with 'f' when dealing with research ethics – like research ethics is 'FUN', 'FABULOUS', and 'FULFILLING', right?!)

Let's start with a definition of ethics. Ethics is the study of morality and application of ethical reasoning to determine principles and practices relating to right or wrong in any given situation regardless of what the laws, rules, and regulations say. Research ethics is concerned with ethical conduct and decision making in undertakings intended to extend knowledge through a disciplined inquiry and/or systematic investigation (TCPS2, 2018). When designing research, we need to be thinking about the principles of ethical conduct (and these are what research ethics reviewers are considering when reviewing projects):

- **Merit & Integrity** – research shouldn't be done just because it is interesting – there needs to be a purpose, and the purpose is determined by identifying gaps in the existing research. Research should also be undertaken by someone who has appropriate expertise, and there needs to be sufficient resources (eg financial, human, infrastructure, etc) available to support the project.
- **Respect for Persons** – we need to ensure that we treat our participants with due regard. Respecting our participants also includes the core concepts of autonomy and informed consent. This means that participation in research is voluntary, and the decision to participate (or not) can be reached by potential participants by having ongoing discussions with them about who's involved, what's involved, benefits, risks, etc – this is 'informed consent'. It's important to note that the informed consent process does not end as soon as the consent form is signed – the discussion with participants needs to continue until the research is completed.
- **Concern for Welfare** (beneficence and non-maleficence) – we need to think about acting in ways to benefit the participant while trying to avoid/reduce the causing of harm. This is about balancing risks and benefits (proportionality). We need to think about negating or minimizing harms as much as possible.
- **Justice** – when thinking about whether a project is just, we consider whether the benefits and risks are distributed fairly and equitably across the participant pool.

"Researchers do not have an inalienable right to pursue research with human subjects" (Oakes, 2002)

In sum, while the principles of research ethics can be defined, there is not a 'one size fits all' approach to implementation. The nature and contextual specifics of EACH research project will impact how the above ethical principles are applied, as well as the weight given to each. Research ethics requires a continuing dialogue throughout the life of the project and amongst all the key players (researchers, participants, and the research ethics team). It's complicated!

FALSE!

In this issue, there is only one Mythbuster, and it's a doozie...

Compliance and ethics is the same thing.

- **Wrong! Wrong! Wrong!**

Compliance is about following laws, rules, regulations, or policies (international, federal, provincial, or local). These laws, rules, regulations, or policies are usually codified and accessible so that everyone operating within the jurisdiction(s) to which these laws, rules, regulations or policies apply, can readily review them and ensure that they follow them. Compliance is reactive – it's doing something because someone told you to.

Ethics (and ethical research conduct) follows a set of values based core principles. It is about what is 'right' and what is 'wrong' regardless of what the laws, rules, and regulations say. Ethical conduct is more subject to variation, and we can be more proactive in developing and applying ethical principles.

We can use our new Guidance on the Use of Interpreters and Translated Documents to illustrate the difference between compliance and ethics. In relation to US FDA regulated trials, a non-English speaking participant MUST be provided with a copy of the informed consent document (in its entirety) in the language understandable to them, in order to meet the requirements of 21 CFR 50.20. Therefore, we have no choice but to get ICFs translated in all FDA trials because the regulations tell us we have to do this (and so does everyone else who is conducting FDA trials) – we must 'comply'.

Health Canada does not have this same requirement and there is no written law, rule, regulation, or policy that says we have to do this. However, BC Cancer Research Ethics believes that when non-English speaking participants are encountered, the ICF should still be translated to the language understandable to them because it is the 'right thing to do' based on the ethical principles of respect, fairness, and concern for welfare. It is important to not discriminate in the enrolment of persons in research studies based on their language or reading ability; and, importantly, the informed consent form is a critical document for the participant to have in their possession and be able to read in their language and refer to at their discretion, particularly for information relating to risks and/or side effects. So, while Health Canada is not explicitly telling us that ICFs must be translated (ie a compliance-based approach), and other organizations may not require their researchers to do this, BC Cancer Research Ethics is proactively taking the approach that ICFs should be translated into the language understandable to the participant because we believe it's the right thing to do (ie an ethics-based approach).

WHO CAN BE A PI FOR A BC CANCER RESEARCH PROJECT?

****IMPORTANT****
Review your RISe profile to ensure it's up to date!!!

Requirements to obtain Principal Investigator ("PI") status for a BC Cancer research project are:

- ◊ MUST have a formal affiliation with BC Cancer (eg be currently employed by BC Cancer); and
- ◊ be qualified by education, training, and experience to fulfill the role. Please note, the PI can delegate duties required to conduct a study to other team members but CANNOT delegate the responsibility.

For clinical trials that are regulated by Health Canada, the PI is referred to as a Qualified Investigator, defined below, and who meets the criteria specified below:

The person responsible to the sponsor for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is

- in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and
- in any other case a physician and a member in good standing of a professional medical association (see Food and Drug Regulations, CRC, c 870)...

For the full document, please see our 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