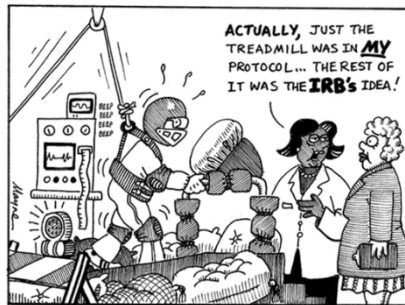


## WHAT YOU'LL FIND

- ❖ Meet the REB Admin Team and REB Chairs
- ❖ REB Admin drop-in times
- ❖ New BC Cancer ICF Template
- ❖ Five year renewal period
- ❖ Revised Phase I/II clinical trial application guidelines
- ❖ PREP launch
- ❖ Student Research



## WHY A NEWSLETTER?

Research Ethics is a constantly evolving area resulting in the need to regularly adapt to new regulations, policies, guidelines, and procedures. The BC Cancer Research Ethics Board is striving for new ways to improve communications about these changes, and thought a newsletter might be useful.

Within this inaugural edition, you will be introduced to the REB Admin team and Chairs; find information about recent policy and procedure changes; and get some general hints, tips, tricks, fun facts, and maybe even a cartoon or two, because people need more laughter in their lives!

Our plan is to do a quarterly newsletter, but we want to make sure that the content is valuable to you, so please e-mail us and let us know what you would like to see in upcoming issues of *Ethics & Elements*: [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca).

## MEET THE REBA TEAM

(aka Research Ethics Board Administration)

**Dr. Kristie Westerlaken, REB Manager.** Kristie comes to us from the land of OZ where she spent 15 years eagerly avoiding the huntsman spider and conducting her own research on the relationship between psychopaths and leaders. Which one are you? Feel free to ask her!

**Evani Goll, REB Coordinator.** Evani has spent the last 20 or so years in clinical research, working on all sides of the clinical research spectrum: clinical trial coordination, data management and industry. She enjoys humour and cake.

**Naama Rozen, REB Coordinator.** Naama is a pharmacist by trade, and has worked as a clinical trial coordinator in nephrology studies. Naama is also a previous restaurant owner and loves to bring in food for us. We love Naama.

**Jessica Gagliardi, REB Coordinator.** Jessica is very active: she plays hockey, ringette, goes to spin class and then rides her bike to work after spin class—but she never rubs it in. Her background is art and sculpting, but she has been a part of PHSA for the last 15 years because pension.

## REB ADMINISTRATION DROP-IN

If you have questions about research ethics, drafting your ethics application or consent forms, need help navigating RISE, etc., we will be starting drop-in times every **THURSDAY** between **10am and 12:00pm**.

Our office is located on the 13<sup>th</sup> floor of the Fairmont Medical Building (Suite 1315). No need to call or email first – just come on by!

AND, to start this off, we will be hosting a

### REBA MEET & GREET

**THURSDAY JUNE 6<sup>th</sup> between 10am & noon**  
 Fairmont building: **11<sup>th</sup> Floor Boardroom**  
 Drinks & snacks provided! See you there!

## MEET THE REB CHAIRS

**Dr. Karen Gelmon, REB Chair.** Karen does more before 8:00am than most of us do all day! A world-renowned researcher, clinician, sought-after speaker, she is a medical oncologist and Professor of Medicine. She has been active in research including chairing (at different times) the Canadian Clinical Trials Group (CCTG) New Drug (IND) committee and Co Chairing the Breast Site Committee. She has been on the Scientific Advisory Board of the Susan G Komen Foundation and Co Chair of the Ontario Institute of Cancer Research (OICR). She is a Fellow of the Canadian Academy of Health Sciences. She is also active in a number of community boards. She is busy.

**Dr. Vivien Bramwell, REB Vice-Chair.** Vivien is even more active than Jessica! When she's not providing her expertise for us, she is playing tennis, mountain biking, day-hiking and home renovating. Vivien was the Founder (1985) and National Coordinator of the Canadian Sarcoma Group, and Disease Site Chair for the Sarcoma Committee of the CCTG until 2013, a group of investigators that performs research in these rare soft tissue and bone tumors. In 2014, she received the Dr. Joseph Pater Award for Excellence in Clinical Trials Research at the CCTG Annual meeting.

## ★\*NEW\* BC CANCER CONSENT FORM TEMPLATE

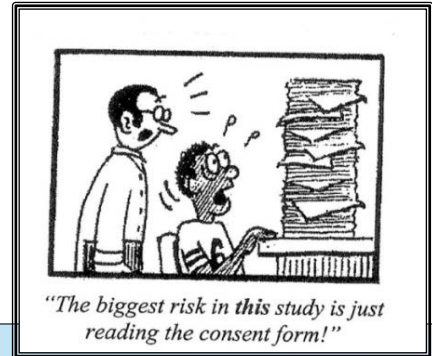
It's (finally) here!! BC Cancer's new Study Information and Consent Form is ready to use. The new template meets all current regulatory and ethical requirements, but was also developed to be concise and clear so as to ensure participants are actually informed about the study.

It has been posted on our website, along with a "How To" document.

★ **BC Cancer Study Information and Consent Form:** [BC Cancer ICF Template.docx](#)

★ **How to Use:** [BC Cancer ICF Template.Instructions.pdf](#)

This consent template will be required to be used for all studies submitted to the BC Cancer REB (e.g., industry sponsored, investigator initiated, etc). We are also currently working on finalizing an Optional Consent and Biobanking template. Stay tuned... (and remember to check [our website](#) for updates as these are "living" documents and subject to change).



## RISe APPLICATION FIVE YEAR RENEWAL PERIOD

We have implemented a 5-year renewal period for ongoing research projects to ensure we are compliant with changing ethics and regulatory requirements. Some of you may have already seen the proviso requesting that if your project is still ongoing one year from the date of the 5<sup>th</sup> annual renewal, a new ethics application will be required to be submitted at that time. All standard submission procedures apply to the new application and when submitting in this context, researchers should include information outlining the current status of the project and clearly indicate in the new application form which parts of the project have already been completed and which are still ongoing.

All study documents (e.g., protocols, informed consent forms, recruitment materials, study materials, etc.) will also need to be reviewed and updated.

Side note - according to UBC BC Cancer REB guidelines, studies may be closed when all data collection procedures as per the approved protocol have been completed. If you are unsure whether or not your project can be closed, please review the [UBC CREB guidelines](#) on study completion prior to completion and submission of your RISe PAA.

## DID YOU KNOW...?!?

- The **Phase I/II Clinical Trial Guidelines** have been revised. Please access this link: [BCC REB Guidelines for Combined Phase I and II Clinical Trials. May 2018.pdf](#)
- The **Provincial Research Ethics Platform (PREP) for Harmonized Ethical Reviews** was officially launched on September 1, 2018. This platform (using RISe) has been developed to assist with multi-jurisdictional reviews (when applicable/appropriate). For more information on the Research Ethics BC (REBC) harmonization initiative or the launch of PREP, please see <http://bcahsn.ca/network-development/research-ethics-bc/>. **Please note that harmonization is assessed on a case-by-case basis – if in doubt, seek help!**
- **1999** was the year that the NIH and OHRP required all people conducting or overseeing human subjects research to have some training in research ethics. (**Hint:** please ensure your ethics training has been updated in RISe!)

## STUDENT RESEARCH

We've developed the "BC Cancer Research Ethics Board Guidance for Student Research" and an accompanying flow chart to assist with navigating student research:

**Guidance for Student Research:** [BC Cancer REB Student Research Guidance.pdf](#)

**Student Research Flow Chart:** [BC Cancer REB Student Research Flow Chart.pdf](#)



**That's all for this addition and  
thank you for reading!**

Let us know what you would like to see in future editions: [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca)