

**Hi! We're your Research Ethics team at BC Cancer. You may have seen us show up on your RISE applications and post-approval activity (PAA) submissions. As part of the REB Admin Team, our job is to ensure that your studies are aligning with Health Canada's regulations for human research and the Tri-Council Policy Statement (TCPS). To qualify for CIHR, NSERC and SSHRC (Tri-Council) grants, it is our responsibility to ensure that all academic research being done here at BC Cancer complies with the TCPS. Sometimes it may be confusing or frustrating why we issue certain provisos. RISE serves as our official documentation tool, and it is very important to ensure proper and consistent documentation of your study and our ethical review. To help out with this, we have made a table of the most common provisos we issue that can be easily avoided!**

Submission	What we look for	Issue/Proviso	Reason/Purpose
<b>Initial submission</b>	Patients paying out of pocket to cover for expenses incurred from study participation	If participants will have to pay for research-related expenses (e.g. parking, meals), allocate funds to reimburse	Patients are donating their time, and perhaps had to take time off work, to participate in your study. Partially/fully covering these costs may help financially insecure participants ( <a href="#">TCPS2 Article 3.2[j]</a> )
	Requesting patient information outside of the scope of the research question	Either justify why this information is needed for the research question or remove it.	Research should collect data with a purpose. The purpose of data collection needs to be directly explained to participants in order to get informed consent. Requesting unjustified information is an invasion of privacy, can propagate stigma and contribute to undue harm.
	Collection of personal information while ensuring privacy	Requests for both gender and sex of participants	Requesting both gender and sex can infringe on patient privacy for people who are gender diverse. These two factors mean different things; is your study more interested in gender identity or biological sex?
	Inclusivity for non-English speakers	Only enrolling English-speaking participants	To ensure equal opportunity to all patients (and diversity/representativeness in your study), we ask that you seek use of a <u>certified PHSA interpreter</u> ( <a href="#">TCPS 2 Article 4.1</a> )
<b>Amendment - Updated Documents</b>	Consistencies between information on PAA coversheet vs application	Inconsistent labeling of document, application and PAA coversheet	We must ensure that the <u>name, date and version</u> of the document is exactly the same on the document, coversheet, and application for rigorous record keeping^
		Changes made in the study documents (IB, protocol, etc) do not match what is listed on the application	We must ensure that the application reflects the most current study information because this is our main reference document for your study^
	Outdated versions of the revised documents	Only include the most current study documents (e.g. protocol/consent form)	To maintain a clear study file, we ensure that only the most up-to-date working documents are included on your application^
<b>Amendment - Addition of team members</b>	Adding graduate students to study team	Indicate if the intention is to allow the graduate student to conduct research related to their studies under the ethics application and if so, attach the student's research proposal	Since the nature of graduate research can expand upon ongoing research, we ensure that the bounds of the graduate research project is within the scope of the approved ethics application. Otherwise, the student will need to submit an ethics application for their own research. Guidance on student research can be found at BC Cancer REB website

<b>Amendment - Addition of Funding</b>	An attached funding package	How does the newly funded research align with the approved ethics application?	We ensure that the research purpose of the funding matches the scope of the research on the ethics application (and of course - congratulations!)
<b>Annual Renewal</b>	Complete study status update	A breakdown of total patients consented and treatment status (ie total number screened, enrolled, on treatment, on follow up, deceased) or charts reviewed	We need to know the progress of your study to determine if it needs the Chair/full board review - plus we've invested a lot of time into reviewing your study, and we're interested to see how it's going!
	Enrollment goal numbers listed on PAA coversheet and application	Inconsistent enrollment and recruitment goal, number screen failed, etc on PAA vs application	This is very commonly written incorrectly or misunderstood - <u>the recruitment goal on the PAA coversheet should match exactly to what has been approved on the application</u> . The enrollment should be the <u>total number of patients enrolled to date</u> . If the recruitment goal has changed, this needs to be submitted as a study amendment
	Chart review dates between PAA coversheet and application	Inconsistent dates for chart reviews	The dates on the coversheet should match what has been approved on the application. If the date ranged should change, this can be submitted as a study amendment
<b>Request for Acknowledgement - Privacy breach</b>	All privacy breaches have been meticulously and concisely explained	Missing information on whether participants have been informed of privacy breaches, their response to this notification and efforts to rectify the situation	We understand that mistakes happen, however they need to be properly dealt with and documented. It is important that any privacy breaches are reported to the <u>PHSA privacy office</u> and <u>the participant is notified of the situation and whether or not they wish to continue with the study</u> . All efforts to rectify the situation should have been taken and listed (ie. study team has been re-trained and privacy office notified)
<b>Request for Acknowledgement - Study Deviation</b>	All study deviations have been meticulously and concisely explained	Missing information on whether participants have been informed of changes to the study that affects them, their response to this notification and if all efforts to rectify the situation have been taken (ie. study team has been re-trained)	We understand that mistakes happen, however they need to be properly dealt with and documented. It is important that any significant study deviations are reported and the participant is notified of the situation and whether or not they wish to or are eligible to continue with the study
<b>Request for Acknowledgement - Safety Updates</b>	Summary of line listings on the PAA coversheet	The SUSAR documents are attached, but the summary of the conclusion is not explained.	In order to evaluate the impact of a product update (ie. safety line listing, etc), it expedites your application to state the conclusion of the update in the PAA coversheet

^ICH GCP guidelines section 4.9: [https://database.ich.org/sites/default/files/E6\\_R2\\_Addendum.pdf](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)