Research Ethics BC
British Columbia Academic Health Science Network

Pilot Model for Harmonization of Clinical Trials

Are you a researcher involved in clinical research / clinical research that involves more than one institution in BC?

Research Ethics BC is piloting a model for harmonized ethical review of multi-jurisdictional clinical research including clinical trials. This is an opportunity for you and your co-investigators in the other institutions to benefit from an efficient ethical review process.

What is the scope of this pilot?

The scope of the pilot applies to clinical trials conducted under the auspices of more than one Research Ethics BC (REBC) partner institution and includes:

a) Trials in which the lead Principal Investigator (PI)/sponsor is conducting the trial under the auspices of a REBC institution;
b) Minimal risk and above-minimal risk trials;
c) Health Canada regulated and non-regulated trials;
d) All clinical trial designs, including pilot & feasibility trials in which an intervention is administered; long-term extension studies are included; AND,
e) Interventions may include (but are not limited to) drug administration, medical devices, natural health product administration, surgical procedures, telehealth, non-invasive interventions and techniques including psychological, eHealth and rehabilitation interventions, imaging procedures, etc.

Excluded from this pilot are trials that are sponsored by a corporate/industry/for-profit entity, and/or where the trial data is sent to a corporate/industry/for-profit entity.

Where do you begin to be a part of the pilot?

The lead PI submits the initial research ethics application on the PREP/RISe system, ensuring that you identify the sites & Qualified Investigators (QIs)/Site PIs for each site in the trial.

What are my responsibilities in this process?

As the lead PI, you and your research team are the link between the ethical review process and the other sites. You will be responsible for working with the site PIs to ensure all the site-specific information is included in the initial ethics review application and working with the REB to address the provisos.

Once the study is approved and you receive the Certificate of Ethical Approval in RISe/PREP, you will need to ensure all site PIs receive copies of the Certificate of Approval if they do not have access to RISe/PREP.

After approval, you will be responsible for submissions to the REB including:

- All requests for acknowledgement
- Reporting safety events within **15 calendar days** of the investigator becoming aware of the problem(s). Fatal or life-threatening reportable local SAEs should be reported within **7 calendar days.**
- Amendment requests that affect the overall study. Site PI's may submit minor administrative amendments that do not impact study documentation (e.g. consent forms, recruitment posters, etc.)
- Adding sites as an amendment specifying all required site-specific information, including site PI/QI, co-investigators, study locations, anticipated number of participants recruited, and recruitment/consent/data management procedures (as necessary)
- Protocol deviations within **15 calendar days of discovery** may be reported by either the lead PI or Site PI**.** Deviations or changes form the protocol to eliminate immediate hazards to participants must be reported as soon as reasonably possible, but not more than within **5 days** of discovery.
- Annual renewal application
- Study closure application

Are there times when the site PI reports directly to the REB?

Any unanticipated serious adverse events occurring at one of the sites covered by the ethics approval should be submitted as a Local SAE, rather than an External/Non-Local SAE, by the site PI in RISe/PREP.

For site specific close-outs the site PI submits the site-specific close-out as an amendment.

Where can I get more information?

We have a Guidance Document available that describes the harmonized process in detail.

In addition, please contact your local REB or the REBC office for more information or a consultation. We can reached at pvidal@bcahsn.ca or tfleming@bcahsn.ca.