Canadian Blood Services

Frequently Asked Questions about Research Ethics Board approvals

Does my study need Canadian Blood Services Research Ethics Board approval?

The Canadian Blood Services Research Ethics Board (REB) reviews all research involving human participants conducted by or on behalf of Canadian Blood Services or involving personal information or biologic materials collected by Canadian Blood Services. This includes research using blood products from our Blood for Research facility in Vancouver and cord blood bank as well as blood products or data from donors.

Quality assurance or process improvements studies, as well as projects requiring blood products for educational purposes or proficiency panels do not need REB approval. If you are unsure whether your study is quality assurance or research, please contact us at cbsreb@blood.ca.

Which application form do I use?

Canadian Blood Services REB has four application forms:

- Requests for blood products/netCAD products for research
- Requests for cord blood for research
- Requests for data for research from Canadian Blood Services data holdings
- Regular application (for all other types of submissions)

In most cases, a copy of REB approval from your academic institution or hospital REB is also required. Please check the application form for a list of documents that need to be submitted.

What does the REB need to know about your research?

The REB requires evidence that three main issues have been addressed:

- 1. The REB must determine if the research is of sufficient value to warrant the inclusion of human participants. The REB wants to know about methodology, the state of existing evidence in the field of research, and the investigators' qualifications.
- 2. The REB is also concerned about the potential effects of the research on participants —the harms and benefits they may experience. The effects of research are not limited to physical effects but they also include psycho-social, legal, and other impacts including privacy, confidentiality, data security and trust in the integrity of the blood system.
- 3. The REB requires assurance that adequate provisions have been made for informed consent.

When do I need to obtain consent from research participants?

Consent for research is built into the blood for research and stem cell/cord blood donor processes and, as outlined by the Tri-Council Policy Statement, the REB may also approve research without consent if the research involves no more than minimal risk to participants, the welfare of participants will not likely be adversely affected, and/or it is impossible or impracticable to carry out the research otherwise.

However, most studies involving blood donors from clinics will require specific consent. If you are unsure, please contact us at cbsreb@blood.ca.

How long does approval take?

Please allow at least eight weeks to process your application. It can take longer if it is a complex study or if there are questions from the REB.

When does the REB meet?

The REB meets three times a year (fall, winter, and spring). However, the REB also handles applications electronically between meetings. You can email cbsreb@blood.ca to find out the date of the next REB meeting and when it is best to submit your application.

How long does my approval last?

REB approval is granted for one year. One month prior to your renewal date, you will receive an email reminder with a renewal form to complete and submit. Studies are limited to four renewals, i.e. five years in study length. If you want to continue your study after five years, you will need to submit a new application.

What if I want to make changes to my study after it is approved?

No change can be made without prior REB approval, except in an emergency when subject safety is in question. To request a change, submit an <u>amendment form</u> to <u>cbsreb@blood.ca</u>. Note that changes to the Principal Investigator of a study also require an amendment.

Who can I contact with questions?

All questions can be directed to cbsreb@blood.ca.