

CANADIAN BLOOD SERVICES RESEARCH ETHICS BOARD

NETCAD BLOOD4RESEARCH APPLICATION GUIDELINES

2017-10-19

The completed netCAD Blood4Research Product Application Form should provide all relevant information to allow for review and authorization by Canadian Blood Services staff. The form should include the scientific, technical, procedural and ethics information necessary for Research Ethics Board (REB) members to evaluate both the ethics of the proposal and whether the subject information and consent material accurately represent the project to potential participants.

The REB's decision to approve the aspects related to the ethics of a research project depends on the information submitted. Any new knowledge that significantly changes the information on which the REB's approval was based may invalidate that approval. The REB must be informed about any changes/amendments to the project. Please contact Sylvia Torrance, Policy Research and Leading Practices, Canadian Blood Services (CBSREB@blood.ca), for other research authorizations or for further information.

Please read the following two sections before submitting your application - **Involvement of Human Participants at netCAD Blood4Research Donor Clinic (page 2)** and the **netCAD Blood4Research Consent Form (page 4)**. The text in these sections has been approved by the Canadian Blood Services REB. Applications for research use must adhere to these guidelines; any necessary deviations must be explained in the application form.

INVOLVEMENT OF HUMAN PARTICIPANTS AT CANADIAN BLOOD SERVICES netCAD BLOOD4RESEARCH DONOR CLINIC

Blood components will be obtained from healthy donors who have registered with our netCAD Blood4Research Donor Clinic specifically to donate blood for research or other needs with which our netCAD Blood4Research Facility is associated, including provision of blood for teaching purposes. For certain projects, products that would otherwise be discarded from the regular Canadian Blood Services clinics will be provided.

Recruitment of donors to the netCAD Blood4Research Donor Clinic

NetCAD Blood4Research donors are typically members of the general public who want to give blood for research, often because they have been “deferred” by Canadian Blood Services for reasons such as travel or living abroad, body piercings, tattoos, *etc.*

Potential donors to our netCAD Blood4Research Donor Clinic are made aware of the opportunity to donate for research through a variety of means, including information at or after the donor clinic where individuals are informed of their deferred status, word of mouth, advertisements or notices, or www.blood.ca. Approximately 1,000 volunteers are listed in our donor database, which is maintained on Canadian Blood Services IT infrastructure.

Informed consent of netCAD Blood4Research donors

netCAD Blood4Research Donor Clinic staff will contact potential donors to schedule an appointment for blood donations. Once the donors arrive at our netCAD Blood4Research donor clinic, they will be informed of the current need for blood or blood components and invited to sign the netCAD Blood4Research Consent Form (page 4). They will be required to read the donor pamphlets “*What You Must Know to Give Plasma or Platelets*” or “*What You Must Know to Give Blood*” which clearly describes the procedure and associated risks for their donation. The consent forms are kept in secure donor files at our Blood4Research facility.

Collecting the blood

Donors will be bled as per Canadian Blood Services Standard Operating Procedures; the blood will be processed according to current Canadian Blood Services methods with modifications as required by the project.

Involvement of donors after the donation

The use of the blood donation for research or teaching has no requirement for any further links to the donor. Donors have no involvement after the donation except where routine testing of their blood for transmissible diseases makes this mandatory, or in the very rare cases in which a research study reveals an incidental finding (*refer to new CBS Policy*) that might be important for the health of the donor and about which the donor should be informed.

Potential harms

The risks of donation are identical to those involved in blood, plasma or platelet donations at Canadian Blood Services clinics. They are set out in the netCAD Blood4Research Consent Form (page 4).

Potential benefits

There are no direct benefits to donors.

Privacy and confidentiality

All donor information is stored securely on Canadian Blood Services IT infrastructure. netCAD Blood4Research donor information systems are separate from the nation-wide Canadian Blood Services system to ensure that permanently deferred donors are not mistakenly placed back on the active clinical donation list.

Each donation is identified with a donation number, which is used to track all subsequent processes and tests. This is the same procedure as is used for all blood donations to Canadian Blood Services. This donation number is linked to the donor and only Canadian Blood Services personnel who have signed confidentiality agreements and require access in the course of their Canadian Blood Services duties can access the system to link samples with individuals.

Storage and disposal of blood products

The netCAD Blood4Research Facility may store blood products for up to 24 months for use in future research projects that have not yet been identified (as set out in the netCAD Blood4Research Consent Form, page 4).

The Principal Investigator of the project takes responsibility for appropriate disposal of any blood product distributed to them from the netCAD Blood4Research Facility.

Payments, and compensation for harm

No compensation or remuneration is offered to donors or participants, other than payment for their parking or public transit expenses during their time of donation. Some donors waive this option. Consent to donate to netCAD Blood4Research does not imply waiver of legal rights nor excuse netCAD Blood4Research or other personnel from their professional or official responsibilities.

Commercialization

It is the policy of Canadian Blood Services to protect and commercially exploit valuable intellectual property rights arising from its research activities. Any net income derived from such commercialization will be shared with the inventor(s) according to Canadian Blood Services policies, but with no benefit to the participants involved in the study.

netCAD Blood4Research Donor Clinic Consent Form

Signing this form indicates your understanding of the following:

1. You are being asked to donate up to ~500 mL whole blood or up to ~750mL apheresis (platelets and/or plasma).
2. Your blood will be used for research, training, or evaluating and improving Canadian Blood Services' (CBS) processes and products.
3. The risks associated with donation will depend on whether you are donating whole blood, plasma or platelets. Prior to each donation, you will be required to read the pamphlet "What You Must Know to Give Plasma or Platelets" or "What You Must Know to Give Blood" which describes the procedure and the associated risks.
4. Your blood donation will be labeled with a barcode number. Only authorized Canadian Blood Services personnel can link the barcode number to your name when required for the performance of their duties and are required to keep your information confidential. CBS will not release any information about you unless required to do so by law.
5. You may withdraw permission to use this donation up until the time when it has been used for its intended purposes.
6. Your decision to not donate or to withdraw your donation will have no negative effect on your relationship with Canadian Blood Services, our netCAD Blood4Research Clinic, or anyone associated with the project.
7. You will have no involvement after the donation except that you will be contacted by a CBS medical officer if routine testing of your blood for transmissible disease reveals an infection that must, by law, be reported to the health authorities or in the very rare cases in which a research study reveals an unexpected finding that might be important for your health.
8. On request, your parking or public transit expenses associated with the donation will be reimbursed.
9. Your blood may be provided to approved researchers on a cost recovery basis.
10. The current list of projects is available on request or on our website. You may choose for your donation to not be used for a specific project or for specific purposes.
11. You will not receive any financial benefit from this donation, even if Canadian Blood Services or its associates eventually derive commercial benefit from the research.
12. By signing this form, you do not waive any of your legal rights, nor excuse Canadian Blood Services or its employees from their legal or professional responsibilities.
13. Upon request, you may receive a copy of this consent form.
14. Canadian Blood Services requires its senior management and the Canadian Blood Services Research Ethics Board to approve any research use of netCAD Blood4Research donations. If you have any questions, you are invited to contact Janet McManus, netCAD Blood4Research Manager (604-221-5515 x4848; janet.mcmanus@blood.ca). You may also contact Dr. Dana Devine, Chief Medical and Scientific Officer, Canadian Blood Services (604-822-7270; Dana.Devine@blood.ca) if you have any concerns about the ethics of this research or how you have been treated.

- 15. You have taken the time that you need to consider this donation.
- 16. You have had the opportunity to ask questions, and these have been answered to your satisfaction.

I understand that I will be asked to sign this consent form on a yearly basis, on my next visit if it is more than 12 months from today, or if a new version of the consent form is in use. Until that time, netCAD Blood4Research may use my donation:

For any project on the list, or for future projects that have not yet been identified until the next consent form is signed. I understand that the netCAD Blood4Research facility stores unused donation products for these future projects.

For any project except: _____

Date: _____

Donor Name: _____

Donor Signature: _____

I have discussed this consent form with the donor and answered any questions to the best of my ability.

netCAD Blood4Research Staff Signature: _____