Application Form Part B4: Other studies pertaining to Canadian Blood Services

Instructions for completing Part B4

Please review the Application Guidelines available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-program> prior to completing an application form. Note that Part A must be completed in addition to Part B4 for all studies which are not captured under the Cord Blood for Research Program (Part B1), the netCAD Blood4Research Program (Part B2), and Canadian Blood Services data sets (Part B3).

For any questions or for clarity as to which Part B to complete for your study, contact CBSREB@blood.ca.

Instructions for submitting an application including Part B4

Submit the completed Application Form Part A and Part B4 as separate word files (.docx) and all required supporting documents as separate files to CBSREB@blood.ca.

1. Study Lay Title

*Study lay title must match study lay title provided in Part A*

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1. Study Alignment to Canadian Blood Services Priorities

Of the following possible study outcomes, please indicate which best reflects the expected outcome for your study:

[ ]  Study outcomes may benefit transfusion medicine practices.

[ ]  Study outcomes may benefit organs and tissues transplantation medicine practices or hematopoietic progenitor cell transplantation practices.

[ ]  There is no direct benefit to either transplantation, or transfusion practices

1. Study Design

3.a. Study design and methodology

Describe in detail the study design and methodology. Explain how study participants – Canadian Blood Services participants (e.g., blood donors, Canadian Blood Services staff) and others – will be involved. Provide details about the nature of the participant populations, how participants will be identified and approached, how participants will be involved, and how samples and/or data will be collected and used. If this study involves multiple institutions, clearly outline how the study involves Canadian Blood Services.

Please attach your study protocol to support your response.
*Note: For example, provide details about whether participants are approached during a donation event or outside of a donation event (e.g., by email or telephone), whether biological materials will be collected as part of a normal donation or will require a separate collection, whether participant data will be retrieved from Canadian Blood Services records or collected using non-routine questionnaires or surveys.*

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**3.a.i.** Will this study include a Data Safety Monitoring Board/Committee (DSMB/C)?

 [ ]  Yes

 [ ]  No

 [ ]  Not Applicable

3.b. Study participant population

Identify the study participant population(s). Check all that apply.

[ ]  General population of Canadian Blood Services blood donors\*

[ ]  Specific population of Canadian Blood Services blood donors\* (e.g., blood group, aberrant test results, deferred donors)

[ ]  General population of Canadian Blood Services non-blood donors (e.g., stem cell donors)

[ ]  Specific population of Canadian Blood Services non-blood donors (e.g., adult stem cell donors)

[ ]  Other population linked to Canadian Blood Services (e.g., Canadian Blood Services staff, Canadian Blood Services volunteers)

[ ]  Other population NOT linked to Canadian Blood Services (e.g., general population)

*\* Blood donors includes whole blood, plasma, and platelet donors at Canadian Blood Services.*

**3.b.i. Study participant population details and involvement**

Provide details about all study participant population(s) including but not limited to why the population(s) identified is required for the study, the inclusion and exclusion criteria, and the number of participants required, etc. If preliminary discussions or engagement has occurred with the population and/or community, please explain.

*If the inclusion/exclusion criteria are on the basis of culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age,* ***a valid reason must be provided****. See* [TCPS2 Chapter 4](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter4-chapitre4.html)*.*

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3.c. Study participant recruitment

Describe how potential participants will be identified and invited to participate and by whom. Indicate if any reimbursements or payments will be provided to the participants. **Attach copies of recruitment material(s) to your application** (e.g. recruitment email, posters, etc.).

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3.d. Study participant consent

**3.d.i.** Will consent be sought directly from participants to participate in this research study?

 [ ]  **Yes**, consent to participate in this study will be sought from participants.

 [ ]  **No**, consent will not be sought directly from participants.

**3.d.ii.** If **Yes to 3.d.i.**, (a) describe the consent process and **attach a copy of the consent form/script for this study** to your application; (b) indicate who will seek consent and how consent will be sought/documented; and (c) indicate how much time will be given to participants to review the information prior to being asked to provide consent.

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**3.d.iii.** If **No to 3.d.i.**, justify why consent will not be sought.

*Note: Please justify any alteration to consent or secondary use as per* [*TCPS 2 Article 3.7A*](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html#7a)*,* [*Article 5.5*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#d) *or* [*Article 12.3*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html#c) *as applicable. If Canadian Blood Services processes or documents are applicable, such as a privacy notice, please explain.*

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**3.d.iv.** Explain the process for participants to withdraw consent including how they would also request withdrawal of their data or biological materials, as applicable. If there are any limitations to withdrawal, explain.

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3.e. Deception

Briefly describe the use of deception or partial disclosure (If not applicable enter N/A).

*Note: Deception or partial disclosure involves not providing the research participants with the true or full nature of the study and/or providing false information. Studies that use deception must justify this approach and the plans for debriefing participants. See* [*TCPS 2 Article 3.7*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#b)*.*

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3.f. Risk/benefit estimates

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| List potential benefits for participants. |
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| List potential risks/harms for participants and the plan for reducing or mitigating those risks.*Note: Please include details about any potential adverse events that may occur and the plan for handling such events.* |
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***Note: If during the course of the study, an adverse event occurs, the principal investigator is required to report serious adverse events immediately to the CBS REB and minor adverse events within 7 days*** *using the ‘*Adverse Event Report*’ form found on the* [*REP website*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program) *(*[*https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program)*) and sending to* *CBSREB@blood.ca* *. External researchers must also notify their institutional REB following their policies and processes.*

3.g. Incidental findings

**3.g.i.** Is there potential for reasonably foreseeable incidental findings?

*(Note: ‘Reasonably foreseeable’ means that the researcher anticipates that incidental findings may be found)*

 [ ]  **No,** proceed to [Section 4](#Section4).

 [ ]  **Yes**, proceed to 3.g.ii.

**3.g.ii.** Would the incidental findings be considered ‘material’?

*(Note: Incidental findings are considered ‘material’ if they are reasonably determined to have significant welfare implications for the participant. For more information on incidental findings and how to determine if they are ‘material’, refer to* [*Article 3.4*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html) *of the Tri-Council Policy Statement (TCPS2) and the* [*How to Address Material Incidental Findings*](https://ethics.gc.ca/eng/incidental_findings.html) *Guidance document)*

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| [ ]  **No**, provide rationale below.

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| [ ]  **Yes**, provide a description of the analytical validity, potential significance to the participant, and the actionability of the findings below. A management plan will be required as a support document.*(Note: Where there is potential for a reasonably foreseeable ‘material’ incidental finding, you will be required to provide a management plan as a support document. The plan should include a detailed description of the determination of the materiality of the findings including expertise/resources involved in making the assessment and relevant support documents as applicable, e.g. participant notification letter. See the ‘*[*How to Address Material Incidental Findings’*](https://ethics.gc.ca/eng/incidental_findings.html) *Guidance document for additional details on a management plan. External researchers should consult with their institutional REB for guidance on developing a management plan.)*

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***Note: If during the course of the study, a foreseeable or unexpected material incidental finding is discovered, the principal investigator is required to report the finding to the CBS REB within 7 days*** *using the ‘*Adverse Event Report*’ form found on the* [*REP website*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program) *(*[*https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program)*) and sending to* *CBSREB@blood.ca* *. External researchers must also notify their institutional REB following their policies and processes. A management plan for an unexpected material incidental finding must be developed promptly.*

3.h. Artificial Intelligence (AI)

Provide details about any AI tools that will be used during the study (e.g., ChatGPT, Microsoft Co-Pilot, Google Gemini, Perplexity, Promethean AI, Baidu Ernie etc.). If not applicable enter N/A.

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1. Biological Materials

Does this study involve the collection or use of biological materials?

 [ ]  **No**, proceed to [Section 5](#Section5).

 [ ]  **Yes**.

If yes, describe the biological materials required (e.g., type, amount) and how the materials will be collected or acquired by the research team.

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**4.a.** Will the biological material be identifiable or potentially identifiable to the research study team?

 [ ]  **Yes**.

 [ ]  **No**.

**4.a.i** If **Yes to 4.a.**, (a) explain why the research cannot reasonably be accomplished without identifiable biological material; and (b) indicate how long the biological will remain identifiable and explain why.

*Note: Direct collection of biological materials from the participant inherently requires that they are initially identifiable.*

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**4.a.ii** If **No to 4.a.**, provide details on how the biological material is not identifiable to the research team and the protections in place to prevent re-identification of the individual from whom it was collected.

*Note: Examples may include coded biological materials where the research team does not have access to the master list, etc.*

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**4.b.** Will the biological materials be linked with information about the participant?

[ ] **Yes**.

[ ] **No**.

1. Study Data

For the purposes of this section, the term ‘information’ means any data element, including but not limited to directly and indirectly identifying personal information, that is required for the purposes of the study.

5.a. Information Collected from Participants

**5.a.i.** Identify all information to be collected directly from participants during the study. Provide a rationale as to why the information will be collected. Use the table below and/or append a separate and clearly labelled document that identifies each data element and rationale for collection. For example, demographic information, survey, interview guide, etc.

*Note: Ensure that the data elements list is final. Any changes to the data elements list following approval of the study will need to be resubmitted as an amendment.*

**If you are not collecting information directly from participants, go to** [**Section 5.b**](#Section5b)**.**

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| **Data element** | **Rationale** |
| [ ]  The information to be collected directly from participants is attached as a separate document. |
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*Insert rows as needed.*

**5.a.ii.** Will identifiable or potentially identifiable personal information be collected, used, disclosed or retained as part of the research study?

*Note: Identifiable information can include directly identifiable information (e.g. full name) as well as information that collectively could potentially identify an individual (e.g. age + gender + full postal code).*

 [ ]  **Yes**.

 [ ]  **No**.

**5.a.iii.** If **Yes to 5.a.ii.**, (a) explain why the research cannot reasonably be accomplished without identifiable personal information; and (b) indicate how long the identifiable personal information will remain identifiable and explain why.

*Note: Identifiable information can be required for logistical aspects of the research (e.g. setting up interviews).*

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**5.a.iv.** If **No to 5.a.ii.**, provide details on how the information is not identifiable to the research team and the protections in place to prevent re-identification of the individual from whom it was collected.

*Note: Examples may include, an anonymous survey, the research team does not have access to the master list, etc.*

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5.b. Information Requested from Canadian Blood Services’ Existing Data Sets

**5.b.i.** Will any information be requested from Canadian Blood Services database(s) for the study?

[ ]  **Yes**, information will be requested from Canadian Blood Services database(s) for the study.

 [ ]  **No**, information will not be requested from Canadian Blood Services database(s) for the study. **Go to** [**Section 5.c**](#Section5c)**.**

**5.b.ii.** Indicate the type of information requested from Canadian Blood Services for the study.

[ ]  Anonymized data\*

[ ]  Coded record-level data#

[ ]  De-identified record-level data#

[ ]  Identifiable record-level data#

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| \*Anonymized data | Summed and/or categorized data that can answer research questions about populations or groups of organizations. The data has been compiled from record-level data to a level where the identities of individuals cannot be determined and that individual records cannot be reconstructed. |
| Coded/ pseudonymized record-level data | Data that has direct identifiers removed from the information and is replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants. |
| De-identified record-level data | Data that identifies an individual has been removed and modified so that there is no reasonable expectation of re-identification if combined with other available information. |
| Identifiable record-level data | Information that can reasonably be expected to identify an individual, when used alone or combined with other available information. |
| #Record-level data | Data in which each record is related to a single individual. Record-level data can be ***identifiable*** or ***de-identified*** . |

**5.b.iii.** If **requesting** **identifiable record-level data**, explain (a) why the study cannot reasonably be accomplished without identifiable record-level data and (b) indicate how long the information will remain identifiable and explain why.

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**5.b.iv**. Identify the information requested from Canadian Blood Services and provide rationale as to why each data element is required for the study. Use the table below or append a separate and clearly labelled document.
*Note: Ensure that the data elements list is final. Any changes to the data elements list following approval of the study will need to be submitted as an amendment, prior to the release of data.*

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| **Data element** | **Rationale** | **Special instructions** | **Indicate Canadian Blood Services data sources, if known** |
| *Example: Donor age* | *Example: For calculating age adjusted incidence rates* | *Example: Include donors 20 – 30 years old inclusive* | *Example: eProgesa* |
| [ ]  The requested information is attached as a separate document. |
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*Insert rows as needed.*

**5.b.v.** Indicate the timeframe for which information is requested.
*Note that this may be different than the study start and end dates.*

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| From (YYYY-MM-DD)  |   |
| To (YYYY-MM-DD) |   |

**5.b.vi.** Indicate the requested frequency of information transfer.

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| Single transfer |  [ ]  |
| Multiple transfers |  [ ]  |
| Requested frequency (e.g. weekly, monthly) |  |

**5.b.vii.** Indicate the preferred format in which information be provided (e.g., SAS data cut, tab delimited text file).

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**5.b.viii.** Provide contact details for the individual to whom Canadian Blood Services will send information.

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| First Name  |   |
| Last Name  |   |
| Title/Position  |   |
| Organization  |   |
| Department |  |
| Address  |   |
| City, Province, Postal Code |  |
| Phone (**not** a personal phone number) |  |
| Email (**not** a personal email) |   |

5.c. Additional Details about Study Information

**5.c.i.** In terms of contextual sensitivities or foreseeable harms, is there any potential for results to be generated that would identify, stigmatize, or harm any person, group, or institution?

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**5.c.ii.** Will the study result in reporting of any individual physicians, hospitals or institutions?

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**5.c.iii.** Will the information collected from participants or obtained from Canadian Blood Services be linked to any other data, database, or registry?

[ ]  Yes [ ]  No

If **Yes**, describe the data elements that will be linked, how linkages will be performed, and why the linkages are required.

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**5.c.iv.** Will any information collected from participants or obtained from Canadian Blood Services be transferred, processed or stored outside of Canada?

[ ]  Yes [ ]  No

If **Yes**, describe where the information will be transferred, processed and stored.

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1. Information Security and Safeguards

Identify all locations where information will be stored and confirm that the following minimum information security requirements for devices storing or accessing the record-level data.

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| **Storage on workstations or fixed storage devices** |
| Data will be stored on workstations or fixed storage devices (e.g., desktop or laptop computers, servers, and database systems). | [ ]  Yes[ ]  No |
| If **data will be stored on fixed workstations/storage devices**, the following data security requirements will be met.* Only computing devices connected to a secure, trusted network will be used to store or access data.
* The network will employ up-to-date firewalls and antivirus software, and the antivirus software will automatically check for updates on a weekly basis, at minimum.
* Devices will employ logical access controls (strong passwords) at the file, device, and network level, with an automatic screen lock-out after no more than 15 minutes of inactivity.
* Users will have individual accounts (no shared accounts), and data access by users will be tracked and logged.
* Fixed devices will be located in a physically secure location with restricted access to authorized personnel.
 | [ ]  Yes[ ]  No |
| **Storage on mobile storage devices** |
| Data will be stored on mobile workstations (e.g., mobile phones, tablets) and/or storage devices (e.g., USB keys, CDs, DVDs). | [ ]  Yes[ ]  No |
| If **data will be stored on mobile workstations/storage devices**, the following data security requirements will be met.* Data will be encrypted at the file or device level.
 | [ ]  Yes[ ]  No |
| **Storage on cloud storage services** |
| Data will be stored on cloud storage services. | [ ]  Yes[ ]  No |
| If **data will be stored on cloud storage services**, the following data security requirements will be met.* Cloud storage services will be corporately managed.
* Cloud storage services will be hosted in Canada.
* Cloud storage services will be compliant with applicable privacy legislation.
 | [ ]  Yes[ ]  No |
| If **data will be stored on cloud storage services**, specify the service. |
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| **Data in transit** |
| Data in transit via a mobile device or a network transmission will be encrypted. | [ ]  Yes[ ]  No [ ]  N/A |
| **Storage as paper copies** |
| Paper copies of data will be stored. | [ ]  Yes[ ]  No |
| If **paper copies of data will be stored**, the following data security requirements will be met.* Paper files will be located in a physically secure location with restricted access to authorized personnel.
* Paper files will be transported by bonded courier services.
 | [ ]  Yes[ ]  No  |
| **Other approaches to storage** |
| Other approaches will be used to store data | [ ]  Yes[ ]  No  |
| If **other approaches will be used to store data**, provide details and indicate the safeguards used to protect the confidentiality and security of the personal information throughout the research (during recruitment, data collection, analysis and publication). |
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1. Information storage after project completion

**7.a.** Please identify how record-level data used for analysis will be stored after completion of the project. Provide details about storage location, the duration of time for storage, and how the record-level data will be destroyed or disposed of.

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**7.b.** Please identify how publication data and analyzed study results will be stored after completion of the project. Provide details about storage location, the duration of time for storage, and how the analyzed study results will be destroyed or disposed of?

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**7.c.** If record-level data used for analysis will not be destroyed after completion of the project, please provide a rationale.

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1. Supporting Documents Checklist

Please indicate all supporting documents submitted with this application.

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| **8.a. Academic institutional or commercial REB documentation (see Part A)***If the application is for a* ***research*** *study and it is an external Principal Investigator, they must secure approval from their academic institutional REB or a commercial REB.* |
| Institutional REB Application Included | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Institutional REB Approval letter included | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.b. CCAC accredited animal care committee documentation (see Part A)** |
| Approval letter | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.c. Study Design documents (see Part B4, Section 3: Study Design)**  |
| Study protocol  | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Recruitment documents | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Consent documents | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.d. Data elements to be collected (see Part B4, Section 5a: Study Data)** |
| Table of data elements to be collected | [ ]  Table included in Section 5a[ ]  Table appended to application[ ]  Not Applicable |
| **8.e. Data elements requested (see Part B4, Section 5b: Study Data)** |
| Table of data elements requested | [ ]  Table included in Section 5b[ ]  Table appended to application[ ]  Not Applicable |
| **8.f. Other supporting documents** |
| List any other supporting document(s) (e.g., survey, interview guide). If not applicable, enter “N/A”. | Click or tap here to enter text. |
| **8.g.** If **No** to **8.a., 8.b.,** and/or **8.c.,** provide details as to why documentation is not provided. |
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1. Principal Investigator Signature

*Note: The individual signing Part B4 must be the Principal Investigator identified in Part A.*

[ ]  By ticking this box, I declare that to my knowledge, no researchers involved in this study are affiliated with, or in receipt of funding or in-kind support, from an organization included on the Government of Canada’s ‘[Named Research Organizations](https://science.gc.ca/site/science/en/safeguarding-your-research/guidelines-and-tools-implement-research-security/sensitive-technology-research-and-affiliations-concern/named-research-organizations)’ list.

By typing my name and the date below, and submitting this application, I, the Principal Investigator on this study, declare that all of the information provided in Part A and Part B4 of this application is accurate and complete and I agree to accept responsibility for the conduct of the proposed study. I am aware that a study may not begin until all required approvals are in place. Ensuring all approvals are in place is the responsibility of the Principal Investigator (PI).

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| First, Last Name  |   |
| Date (YYYY-MM-DD) |   |

Instructions for submitting an application including Part B4

Submit the completed Application Form Part A and Part B4 as separate word files (.docx) and all required supporting documents as separate files to CBSREB@blood.ca.

If your application package includes more than one Part B, submit the completed application package to CBSREB@blood.ca .