**Research Ethics Board Application**

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| --- | --- |
| This form should be used for applications to the Canadian Blood Services Research Ethics Board (REB). Submit application to: CBSREB@blood.ca  | **Centre for Innovation use**Protocol #:Date received (yyyy-mm-dd): |

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# Section A: General

1. **Project Title (max 10 words):**
2. **Principal Investigator (PI)**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |
| Position |  |
| Organization |  |
| Address |  |
| Phone |  |
| Email |  |

Is the principal investigator a Canadian Blood Services employed scientist (part or all of salary paid directly by Canadian Blood Services)?

[ ]  Yes [ ]  No

1. **Co-Investigators or Trainees (T) involved in the project**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**  | **Position/Institution** | **Phone** | **Email** |
|  |  |  |  |
|  |  |  |  |

1. **Contact Person**

In addition to the Principal Investigator, who should receive correspondence related to this submission?

|  |  |  |
| --- | --- | --- |
| **Name**  | **Phone** | **Email** |
|  |  |  |

1. **Funding Support** [ ]  Not Applicable

List all sources of funding for this project.

|  |  |  |  |
| --- | --- | --- | --- |
| **Source and Amount/Year** | **Investigator and Funding Application Title** | **Period** | **Type** |
|  |  |  | [ ]  Peer reviewed [ ]  Non-peer reviewed |
|  |  |  | [ ]  Peer reviewed [ ]  Non-peer reviewed |

Will any investigator receive direct personal payments from the research funding?

[ ]  Yes [ ]  No

|  |
| --- |
| If yes, describe payments to be made: |

1. **Potential Conflict of Interest**

|  |
| --- |
| Disclose all contracts and any conflicts of interest (actual, apparent, perceived or potential) relating to this project: |

1. **Study Period**

Expected start date (yyyy-mm-dd):

Expected end date (yyyy-mm-dd):

1. **Project Summary** (max 200 words)

Summarize the study in lay terms. Indicate the rationale for this study, the hypothesis, or research question, the significance of the study (e.g. overall anticipated public and/or scientific benefit); describe the primary outcomes/goals of the study and explain the relevance of this project to Canadian Blood Services’ mandate.

Please note that if the study is approved, this lay summary may be published on Canadian Blood Services’ website to inform donors and the public about research that is supported by Canadian Blood Services.

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1. **Research Design**

Describe the design and methodology. Briefly explain how research participants will be involved; from how they will be approached to how data will be used.

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1. **Publication/Dissemination of Results**

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| Indicate how the results will be communicated to participants and other stakeholders (e.g. advocacy groups, scientific community): |

# Section B: Involvement of Human Participants

1. **Subject Population and Involvement**

Identify the nature of the subject population and links with Canadian Blood Services.Check all that apply.

|  |  |  |
| --- | --- | --- |
| **Participants required** | **When approached** | **Subject involvement** |
|[ ]  General population of Canadian Blood Services donors |[ ]  At time of normal clinic donation |[ ]  Use of all or part of clinic donations |
|[ ]  “Failed” clinic donors, e.g., deferred, small volume, screened out |[ ]  Outside donation time, e.g., by mail/ telephone  |[ ]  Collect blood from special donations made outside normal donor clinics |
|[ ]  Specific clinic donors e.g., blood group, aberrant test results |[ ]  No consent to be sought |[ ]  Use of personal data from Canadian Blood Services records |
|[ ]  Other |[ ]  Other |[ ]  Collection of personal data from non-routine questionnaires, surveys etc. |
|  |  |  |  |[ ]  Other |

Provide details (why the population identified is needed, inclusion and exclusion criteria, number of participants required, etc.); explain “Other” responses.

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| --- |
|  |

**Risk / Benefit Estimates**

|  |
| --- |
| List potential benefits for participants: |
| List potential risks / harms: |

**Incidental Findings**

Provide details below if there is potential for data to be generated from this study that would be meaningful to the health of the individual donor, and/or the study results in data that would be required to be reported to the public health system.

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|  |

1. **Recruitment and Consent**

Describe how potential participants will be identified, invited to participate, and by whom. Indicate if any reimbursements or payments will be provided to the participant. **Attach copies of written material.**

|  |
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Will consent be sought to participate in the research?

|  |  |
| --- | --- |
| [ ]  Yes | Describe the consent process. Indicate who will seek consent and how consent will be served. Indicate how much time will be given to participants to review the information before being asked to give consent: |
| [ ]  No | If no consent is to be sought, justify: |

1. **Data Collection**

Does the research require the ability to identify the participants?

|  |  |
| --- | --- |
| [ ]  No | Provide details on how the data / samples will be de-identified and the protections in place to prevent their re-identification. |
| [ ]  Yes | Explain why the research cannot reasonably be accomplished without identifiable data. Indicate how long the personal information will remain identifiable and explain why.  |

List all personal information to be obtained and the source of the data, e.g., directly from the participant or from an existing database. If obtaining from an existing database, indicate the system and the organization (e.g., PROGESA, Canadian Blood Services).

**Note: If Canadian Blood Services data is being requested, Appendix A must also be completed.**

|  |  |
| --- | --- |
| Data Element: | Data source (system/roganization): |
| [ ]  Name |  |
| [ ]  Address |  |
| [ ]  Telephone |  |
| [ ]  Email address |  |
| [ ]  Date of birth |  |
| [ ]  Donor identification number |  |
| [ ]  Blood type |  |
| [ ]  TD test results (specify): |  |
| [ ]  Other information (specify): |  |
|  |  |

Will the data be linked to any other data, database or registry?

[ ]  Yes [ ]  No [ ]  Not applicable

If yes, describe the data that will be linked, how linkages will be done and why this is required:

|  |
| --- |
|  |

Will any data be stored outside of Canada?

[ ]  Yes [ ]  No [ ]  Not applicable

Ifyes, describe where:

|  |
| --- |
|  |

1. **Data Security**

Data will be stored on the following (Check all that apply):

|  |  |
| --- | --- |
| [ ]   | Fixed workstations/storage devices (e.g., desktop computers, servers and database systems) |
| [ ]   | Mobile workstations (e.g., laptop computers, mobile phones, portable tablets) |
| [ ]   | Mobile storage devices (e.g., USB keys, CDs, DVDs) |
| [ ]   | Cloud storage services (specify): |
| [ ]   | Paper |
| [ ]  | Other: |

Indicate below the safeguards used to protect the confidentiality and security of the personal information throughout the research (during recruitment, data collection, analysis and publication). Check all conditions that 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 the network level, with an automatic screen lock-out after no more than 15 minutes of inactivity. |
| [ ]  | Data access can be tracked to individual users (no shared accounts) and information of data access will be automatically tracked and logged. |
| [ ]  | Fixed devices will be located in a physically secure location with restricted access to authorized personnel.  |
| [ ]  | Data stored on laptops, workstations and/or storage devices will be encrypted at the device level or file level. |
| [ ]  | Data stored on cloud storage services will be Corporate governed or assigned, hosted in Canada and compliant with applicable privacy legislation. |
| [ ]  | Data in transit (via a mobile device or over a network transmission) will be encrypted. |
| [ ]  | Paper copies of data will be located in a physically secure location with restricted access to authorized personnel and transported by bonded courier services (for record-level data) |
| [ ]  | Other: |

Indicate what will happen to the data at the completion of the study: How long will this data be stored after the project is complete? Where will it be stored? When and how will it be destroyed?

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# Section C: Other Ethics Review

1. **Ethics Review**

Has this project been submitted elsewhere for ethics review?

[ ]  Yes [ ]  No

**If yes, include a copy of the research ethics submission and letter of approval with this application.** Identify below if there have been any material changes in the study since the original submission to the other REB.

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1. **Animal Care**

Does this project involve the use of animals?

[ ]  Yes [ ]  No

If yes, please identify:

|  |
| --- |
| Canadian Council on Animal Care accredited Animal Care Committee that will oversee this use of animals: |
| CCAC approval # and date approved: |

# Principal Investigator Signature

**Principal Investigator**

I declare that all of the information provided in this application is accurate and complete to the best of my knowledge and I agree to accept responsibility for the scientific conduct of the proposed research study.

|  |
| --- |
| Name: |
| Signature: | Date: (yyyy-mm-dd) |

# Appendix A: Request for Canadian Blood Services Data

1. This request is for:

[ ]  Aggregate data

[ ]  De-identified record-level data

[ ]  Identifiable record-level data

1. In terms of contextual sensitivities or foreseeable harms, is there any potential for data to be generated that would identify, stigmatize or harm any person, group or institution? Will the project result in reporting of any individual physicians, hospitals or institutions?

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|  |

1. Indicate any preference regarding the format in which data are prepared (SAS data cut, tab delimited text file, etc.).

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|  |

1. Data timeframe: From yyyy-mm-dd to yyyy-mm-dd
2. Data transfer frequency:

[ ]  One-time

[ ]  Multiple (specify, e.g. monthly, weekly):

1. Provide data elements required. Use the table below or append a separate and clearly labelled document. To finalize specifications, consult with Canadian Blood Services program area staff.

|  |  |  |
| --- | --- | --- |
| **Data Elements**  | **Rationale** | **Special Instructions** |
| Example: Donor age | Example: For calculating age/gender adjusted incidence rates | Example: Include donors 20 – 30 years old inclusive, and 55 – 65 years old inclusive |
|  |  |  |

1. Indicate the person/data contact to whom the data will be sent:

|  |  |
| --- | --- |
| Name |  |
| Position/ Organization |  |
| Address |  |
| Phone |  |
| Email |  |