##### Data Request for Research

|  |
| --- |
| **General Instructions:*** A copy of research ethics board approval from a TCPS-compliant institution must be submitted with this request. If research ethics approval has not been obtained, a full application for the Canadian Blood Services Research Ethics Board must be completed.
* Once the request is approved, a Data Use Agreement will need to be completed if:
	+ The Principal Investigator is not a Canadian Blood Services employee or
	+ The Principal Investigator is a Canadian Blood Services employee but information will be shared with a third party outside Canadian Blood Services.
* For any questions, please contact Canadian Blood Services at: CBSREB@blood.ca
 |

1. **Date Submitted** (yyyy-mm-dd):
2. **Project Title** (max 10 words):
3. **Principal Investigator**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |
| Title/Position |  |
| Principal Organization |  |
| Address |  |
| Phone |  |
| Email |  |

Is the principal investigator a Canadian Blood Services employee?

[ ] Yes [ ] No

1. **Authorized Persons**

List co-investigators of the study and all persons who will have access to the data for research:

|  |  |  |  |
| --- | --- | --- | --- |
| Name  | Position/Organization | Province, Country | Co-Investigator? |
|  |  |  | [ ] Yes [ ] No |
|  |  |  | [ ] Yes [ ] No |
|  |  |  | [ ] Yes [ ] No |

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 what questions you are trying to answer, your hypothesis, how you plan to answer these questions, and how your discoveries will help your research field, specifically in the areas of donation, transfusion or transplantation.

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.

|  |
| --- |
|  |

1. **Ethics Review**

A copy of the research ethics submission and letter of approval from a TCPS-compliant REB must be submitted with this application.

Has the project materially changed in design since the original submission to the Research Ethics Board?

[ ]  Yes [ ]  No

If **Yes**, indicate changes:

|  |
| --- |
|  |

1. **Funding Support** [ ]  None

|  |  |
| --- | --- |
| Funding agency | Type of funding |
|  | [ ]  Peer reviewed [ ]  Non-peer reviewed |
|  | [ ]  Peer reviewed [ ]  Non-peer reviewed |
|  | [ ]  Peer reviewed [ ]  Non-peer reviewed |

1. **Data Requested**
2. This request is for:

[ ]  Aggregate data

[ ]  De-identified record-level data

[ ]  Identifiable record-level data

1. If identifiable record-level data is being requested, explain why the research cannot reasonably be accomplished without 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?

|  |
| --- |
|  |

1. Provide a brief description of the scope of the required data, e.g., target population, inclusion and exclusion criteria, geographical location:

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

[ ]  Yes [ ]  No

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

|  |
| --- |
|  |

1. Will any data be stored outside of Canada?

[ ]  Yes [ ]  No

If **Yes**, describe where:

|  |
| --- |
|  |

1. **Data Security**
2. 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 approach |

1. For **AGGREGATE DATA: go to step 11.**
2. For **RECORD-LEVEL DATA:** the following are the minimum data security requirements for devices storing or accessing, the provided record-level data. Check all conditions that will be met.

|  |  |
| --- | --- |
| 1. 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.
 | [ ] Yes [ ] No[ ] Not applicable |
| 1. Data stored on laptops, workstations and/or storage devices will be encrypted at the device level or file level.
 | [ ] Yes [ ] No[ ] Not applicable |
| 1. Data stored on cloud storage services will be:
	* Corporate governed or assigned
	* Hosted in Canada
	* Compliant with applicable privacy legislation
 | [ ] Yes [ ] No[ ] Not applicable |
| 1. Transporting data:
	* Data in transit (via a mobile device or over a network transmission) will be encrypted.
 | [ ] Yes [ ] No[ ] Not applicable |
| 1. Paper copies of data will be:
* Located in a physically secure location with restricted access to authorized personnel
* Transported by bonded courier services (for record-level data)
 | [ ] Yes [ ] No[ ] Not applicable |

1. 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?

|  |
| --- |
|  |

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

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Organization |  |
| Address |  |
| Phone |  |
| Email |  |

1. **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.

I declare that the computer facility and equipment associated with the research study that are used to handle, manipulate and store the requested data, are in compliance with security standards as described in this document.

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