**Are you creating a database? Are you consenting individuals to have some of their data included in this database? Will data in your database be used in future studies involving linkage to administrative health data? If the answer to these questions is yes, then this document lists MOH’s requirements for database creation.**

**Definitions - Study vs. database:**

**Study:** Specific time period. Data collected for use in one study only and is not expected to be re-used for future studies. (Templates to use: Behavioural Consent or Clinical Consent)

**Database:** Indefinite period of time. Database population is not and will not be expansive, compared to registries. Data collected for use in multiple studies/future research. A database may NOT include data from other administrative databases. **Only researcher collected data can be included in a database.** Linkage of database data to other databases will be reviewed on a per project basis. (Template to use: Database Consent Outline)

**Definitions – PIPA and FIPPA:**

FIPPA: Freedom of Information and Protection of Privacy Act. This governs use of information held by public bodies.

PIPA: Personal Information Protection Act. This governs use of information held by private organizations (e.g. private clinics not under a health authority)

**Database documentation requirements:**

1. Consent to build a database should be separate from the consent to use the data in the database for a specific project.
   1. Note: TCPS2 Article 5.5B: Secondary use of coded information may identify individuals in research projects where the researcher has access to the key that links the participants’ codes with their names. Consent to use the data for the particular research involving indentifiable information would be required in this situation. However, the same coded information may be assessed as non-identifiable in research projects where the researcher does not have access to the key. Consent would not be required in this situation. (Note: Check with your REB for consent requirements for use of data under PIPA)
2. Fulfillment of relevant requirements noted in FIPPA section 69 and/or PIPA
3. Information Sharing Agreement (ISA) with private third parties to include their data in the database as researcher collected data (e.g. collection of EMR data from a private physician’s office).
4. Documentation that researcher has sought the guidance of the Privacy Office of their Institution/Health Authority to ensure that the database has the appropriate governance structure.
5. Privacy Impact Assessment
6. Information Security Management/Systems Risk Assessment
7. List of Variables to be collected and stored in the database.
8. Funding agreement
9. Ethics certificate

**Database consent form Requirements:**

1. **GOVERNANCE:**
2. Clear and detailed description of the governance structure surrounding the database (ie. how data is collected, used and disclosed):
   1. Clear statement of the purpose of data collection and storage in the database
   2. Method of data collection - How will data be collected and under whose legal authority (FIPPA or PIPA)?
   3. A list of variables collected – A justification for each variable is necessary (\*the list can be on a separate sheet but should be referred to in the consent form)
   4. Statement of where database is located and where the data is stored
   5. Statement of steps taken to secure the data
   6. Information about the data steward (Who will be the data steward?)
   7. Information about data confidentiality (Who will hold the linkage file? Will this be separated from the data? Who will have access to this file? Where will this file be stored?)
   8. Information about access to database (Who can access the database data? What are the requirements/conditions for accessing the data? For what purposes? Will it be available for future research? Can it be accessed outside of Canada?)
   9. Information about governance (Who reviews and approves the applications to use data in the database?)
   10. Information about data destruction (How about data destruction? What if the database “ends” (e.g. PI moves on to a different position)? What will happen to the data?)
   11. Statement that each study using the database data will go through a separate application process and in cases of linkage studies, will get approval from each individual data steward.
3. **FUNDING:**
4. Funders – Who is the funder and what contractual agreement is in place with the funder? Note: The funding agreement will need to be provided during consent review.
5. **DATA LINKAGE: (perhaps have a separate check box and signature line to consent for data to be used in any future research (ie. research involving patient contact and data linkage type research or just research involving patient contact))**

1) Will future project potentially require data linkage?

2) What types of data can this project be linked to?

3) What identifiers will be sent out of the database for linkage purposes? Who will do the linkage?

4) Where will linked data be stored?

**D. WITHDRAWAL**

1) Specific note on withdrawal – what will happen to the database data? What will happen to database data once linked?

Include this note:

You may withdraw at any time and may choose between two types of withdrawal:

a) Withdraw but allow the database team to retain data already collected about you. No additional data will be collected about you

b) Withdraw and request all data already collected about you be destroyed. No additional data will be collected about you.

If you choose to withdraw all your data AFTER your data has been de-identified and merged with data from the other providers noted above, then the database team will inform PopData of your withdrawal. PopData will then give the database team information about you that would allow the database team to **identify all your records (including those from the agencies noted in this consent)** in the combined data. The database team will then remove the data collected by them within the combined data.

NOTE: Prior to project start, a copy of the consent form should be submitted to the Data Stewards via Population Data BC (PopData) for approval in order to ensure compliance with privacy legislation.Once data steward approval **has been received, the consent form, along with the ethics application, must be submitted to the REB for their review and approval.**