**PROTOCOL TEMPLATE**

**FOR DATABANKS AND/OR BIOBANKS**

**Note for research teams:**

This document is made available to investigators at the Sainte-Justine UHC (SJUHC) as a template to guide them in the development of their protocols for databanks and/or biobanks. The template must be adapted to reflect the particular circumstances that pertain to each databank/biobank.

1. **Name of the Bank:**

(Please specify)

1. **Person in charge of the Bank**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, PhD, Investigator, Research Axis, SJUHC, is the Director of the Bank.

Contact Details: \_\_\_\_\_\_\_\_\_

* He has the required infrastructure to implement the Bank.
* He has developed expertise in the field of \_\_\_\_\_\_\_.
* He oversees and manages the Bank. Specifically, he ensures the proper functioning of the Bank’s activities and compliance with policies on the use of data and/or samples, including the protection of their confidentiality.
* He also ensures compliance with SJUHC’s applicable ethical and administrative requirements.

1. **Access Committee**

**An access committee is made up of:**

**(to be completed)**

Once ethical approval has been obtained, the project must be submitted to the databank/biobank access committee. The access committee is responsible for ensuring that:

* the requests it receives for the use of data and/or biological samples pertain to a project pre-approved by a qualified Research Ethics Board (REB);
* the proposed use of data and/or biological samples meets the objectives of the databank/biobank, its access policy and the consent given by its participants (or their legal representatives); and
* the project has scientific merit.

The access committee must document its decisions. It must also maintain evidence of the various ethical approvals obtained by the research teams.

1. **Source of funding**

**(Please specify)**

1. **Scientific objectives of the Bank**

Collect and store data and/or samples to facilitate research projects in the field of \_\_\_\_\_\_\_\_ and on \_\_\_\_\_\_\_\_ as well as their related pathologies and treatments.

1. **Economic entity**

The bank is a non-profit entity.

1. **Participants**

* **Inclusion criteria**
* (List the criteria)
* **Recruitment methods**

(Specify how, where and by whom they are approached)

1. **Type of data collected**

We will collect the following data:

(List the types of data)

Examples:

* socio-demographic data;
* clinical data: pertinent data from the participants’ medical records;
* clinical data on a child’s future follow-up. These data will be collected throughout the period during which a child is monitored at the SJUHC;
* data from the following questionnaires:
* imaging data (ex.: magnetic resonance, ultrasound) from the clinical database;
* genetic data;
* If a child takes part in other research projects at the SJUHC, the data gathered over the course of these projects will also be entered into the databank.

1. **Types of biological materials collected**

No biological materials were collected.

OR

Example:

Various types of biological materials (DNA, RNA, serum, plasma) from the children’s bone marrow, blood, urine and saliva.

1. **Storage location**

The Bank is located at the SJUHC in the \_\_\_\_\_\_\_\_\_\_\_ Department.

1. **Storage duration**

No date has been set for the end of the Bank’s activities. The data and/or samples will be kept for as long as the Director of the Bank is able to ensure their proper management, including compliance with administrative, ethical and scientific requirements.

1. **Privacy**

The data and/or biological materials collected are kept confidential. To this end, the following measures have been taken:

Examples:

* The data and biological materials are encoded. Each participant is given a unique code number before his data and/or biological samples are put in the databank and/or biobank. The key to the code will be stored safely under the responsibility of \_\_\_\_\_\_\_\_\_\_ in a secure separate file. When data or biological materials are sent to the investigator-user, no personally-identifiable information is provided. A new code is issued (double-coding).
* Access to the databank will be restricted to managers of the Bank and require a user code and password.
* A confidentiality agreement will be submitted to research assistants and investigators who use the Bank.
* The investigators agree to release, publish or announce the Bank’s data and findings only in a way that prevents the participants from being personally identified.

1. **Consent of the participants**

The consent of the participants’ legal representatives will be obtained before collecting and putting any data and/or biological materials in the Bank.

Should a participant (or his legal guardian) wish to withdraw from the study, he will specifically be asked whether he wants his data and/or biological materials that have already been collected to be destroyed. If so, these data and/or biological materials will be removed from the Bank.

1. **Access to the Bank by the research team**

Individuals given access to the Bank will include investigators, research assistants, students and research trainees (supervised by members of the research team).

These people must agree in writing to respect data confidentiality as well as the Bank’s management protocol and use the data and/or samples in accordance with the Bank’s objectives.

1. **Access to data and/or biological materials for research purposes by other investigators:**

* The data may be shared with investigators from the SJUHC or elsewhere;
* The project must first receive approval from a qualified REB;
* The project will then have to be authorized by the Bank’s access committee;
* All the above-mentioned individuals (investigators and research assistants) must sign an agreement to ensure the confidentiality of the information collected (commitment to maintain data confidentiality) and only use the data for previously approved research purposes.
* An agreement must be entered into for the transfer of data and/or biological materials when data and/or biological materials are shared with investigators from other institutions;
* No fees are connected with the use of the Bank’s data and/or biological samples;

OR

* The investigator-user will pay a fee that covers the costs of creating and maintaining the Bank.

1. **Feedback given to the participants on personal and general research findings**

* **Individual findings**

No individual findings will be announced to the participants (or their representatives).

OR

Individual findings could be sent to the participants (or their representatives). (And add what is planned to the information and consent form in this regard)

* **Overall findings**

General research results may be sent to the participants at their request (or that of their legal representatives).

These results will also be dealt with in articles, presentations, posters or general discussions.

1. **Commercialization**

New commercial products could be developed based on the data and/or biological samples and these products could generate profits. However, the participants will not have any right to share in any future profits.

1. **REB approval**

* The Bank’s protocol has been approved by the SJUHC REB.
* All of the projects that use data or biological materials from the Bank must be approved by a qualified REB.
* The REB of the SJUHC monitors the activities of the databank and/or biobank on an ongoing basis. A report that describes how the Bank is progressing and the requests that have been made to use data and/or biological samples will be submitted to the REB once a year.