

Items necessary to create a **management framework** for a database or a biobank created for research purposes

Description of databank	<ul style="list-style-type: none"> • the name given to the bank • define the type of research data that will be collected and stored in the bank, specify which data will be collected (ex: sociodemographic, social, medical, etc.) • identify the scientific purpose/goal of the bank (why the research databank is necessary)
Administrative procedure to manage the bank	<ul style="list-style-type: none"> • An organizational structure should be clearly defined to encompass at a minimum the following roles and elements; leadership (need to identify the person who will be accountable), management of operations including access processes of the personnel who will be working with the research databank. • qualification required of the personnel working with the bank data • funding source for creating and operating the bank • process to document voluntary and informed consent to collect or use data (secondary analysis) was secured. • management of request to access the bank • Initial and ongoing evaluation process to obtain Hôpital Montfort's REB approval without conditions and to maintain approval for the bank : <ul style="list-style-type: none"> ○ creating and maintaining the bank and all its amendments ○ as well as for the research project using the data for their project
Data and samples that will be deposited in the bank	<ul style="list-style-type: none"> • process describing how <i>data will be stored once collected</i> • process to confirm that data collected have been authorized by an informed consent form approved by the Hôpital Montfort's REB including when appropriate the possibility to re-establish contact with participants. • the format in which the data will be stored (e.g. individually identifiable, re-identifiable or non-identifiable)
Data protection	<ul style="list-style-type: none"> • process to control access to the local (physical environment) -where the bank will be located • process to request access and to transfer data to another bank or researcher
Protecting privacy and confidentiality	<ul style="list-style-type: none"> • security measures in place to ensure the protection as well as the confidentiality of data from the time it has been collected until it will be destroyed. • identify conditions to be met to approve coupling of data
Management of the collection of data and its storage in the bank	<ul style="list-style-type: none"> • the format in which the collected data will be stored • chosen process to protect the data being collected for the projected duration of their storage • process to manage data and specimen when they are sent back • process to manage a request to withdraw a participant with and without their collected data • process to validate the quality of the c • collected and stored data (ex. Standard Operating Procedures) in the bank • date when data bank end (retention period) • destruction (disposal) process of the data at the end of their retention period
Commercialization and intellectual property	<ul style="list-style-type: none"> • agreements for commercialization and intellectual property • the method selected to securely disseminate the research outcome
Templates and forms	<ul style="list-style-type: none"> • management framework • recruitment <ul style="list-style-type: none"> ○ consent form ○ withdrawal data form • annual report (bank activities) • data disposal confirmation form • data or material transfer agreement