Management and Governance Framework for the Plasma Donor Biobank – Héma-Québec

Tracking Plasma Donors – Impact on the Immune Response from the Vaccination against SARS-CoV-2 that Causes COVID-19 – Building a Longitudinal Cohort

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EXTERNAL COLLABORATORS:

COVID-19 IMMUNITY TASK FORCE

PUBLIC HEALTH AGENCY OF CANADA

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PREAMBLE

This Management Framework sets out the operating rules and procedures for the Plasma Donor Biobank – Héma-Québec. This Biobank was established during the health emergency declared on March 14, 2020, during the COVID-19 pandemic, in order to quickly create a provincial resource for banking Samples and Data representative of the Quebec population, to be able to help the scientific and medical community better understand and combat COVID-19.

1. Description of the Biobank

1.1. Background – Héma-Québec

Héma-Québec is a non-profit corporation that is not an agent of the Crown and is independent of other structures in the Quebec health care system and is separate from the Canadian Blood Services (CBS). Its primary mission is to provide Quebec's health and social services institutions and the public with a safe and adequate supply of blood, blood products and components, and other human-derived biological products. Its vision is to become a strategic partner serving the Quebec health care system. Over the past year, Héma-Québec has collected donations from over 254,193 Donors and distributed more than 818,500 human-derived biological products (blood, plasma, stem cells, human tissues, and breast milk).

Since the beginning of the COVID-19 pandemic, Héma-Québec has been playing a support role to the Quebec and Canadian health care networks by conducting SARS-CoV-2 seroprevalence studies among blood Donors (REC #2020-06 and 2021-001). The Biobank and the studies arising from it will become part of the continuation of this collaboration. Héma-Québec provides a unique context for supporting this type of study, including ongoing access to regular Donors, a proven system for collecting and managing Samples, and the contribution of highly qualified scientific and technical individuals.

For the purpose of the above-mentioned seroprevalence studies, there are a number of advantages to studying the Donors, in particular because of their representation of the Quebec population and how frequently they donate. Also, the context of the frequent plasma collecting that Héma-Québec does is particularly well suited to the prospective cohort studies; whereas it is usually quite complex and expensive to build cohorts of subjects with the aim of repeatedly collecting samples over a long period of time. This bank of Samples will be able to be used for studying matters pertaining to the spread of the COVID-19 pandemic caused by SARS-CoV-2 and the effect of the vaccination campaigns on the population.

1.2. Definitions

The following definitions apply to this Management Framework:

- **Biobank**: An orderly, searchable collection of Samples taken in keeping with this Management and Associated Data Framework, collected from Donors for research purposes.
- **Biobank's Activities**: Collecting Samples and Data, creating and opening the Biobank to requests for access to the Samples and Data.
- **Centre**: Héma-Québec's operation centre where Samples are collected from Donors.
- **Data**: Information about the Donor, his/her Sample(s) and any information arising from analysis of his/her Sample(s).
- **Depersonalized Information**: Information coded and stripped of any Personal Information that could directly identify the individual in question such as last name, first name, date of birth, address and postal code, but is not anonymized.
- **Donor**: An individual who provides one or more Samples and Data in the context of the Biobank's Activities.
- **eProgesa Software**: Héma-Québec's blood donation management software.
- **External Researcher**: A researcher not employed by Héma-Québec.
- **Intellectual Property Asset**: Any creation resulting from the Biobank's Activities and likely to be subject to one or more Intellectual Property Rights.
- **Intellectual Property Rights**: Copyright, trademarks, patents, industrial designs, integrated circuit topographies, and trade secrets.
- **Internal Researcher**: A researcher employed by Héma-Québec.
- **Management Framework**: Management and governance framework for the Plasma Donor Biobank developed by Héma-Québec.
- **Personal Information**: Information that pertains to and identifies an individual, including but not limited to last name, first name, date of birth, address and postal code.
- **PLASCOV**: The administrative designation of the Biobank project.
- **REC**: Héma-Québec's Research Ethics Committee.
- **Sample**: A plasma specimen taken from a Donor's plasma donation in keeping with this Management Framework.
- **SAS Software**: Software used by Héma-Québec for analyzing and managing the Data.
- **Scientific Committee:** Committee responsible for assessing the scientific quality and relevance of Biobank-related projects. The Governance Committee for Projects by Medical Affairs and Innovation (the "GoPAMI" Committee), responsible for evaluating all research projects at Héma-Québec, acts as the Scientific Committee for the Biobank.

1.3. Description of the Biobank, objectives and timelines

1.3.1. Description

An expedited COVID-19 vaccination program by the government was introduced in March 2021 in the context of the health emergency in Quebec and aims to immunize the majority of the Quebec population as soon as possible. The speed of immunizing the Quebec population prompted Héma-Québec to quickly recruit a cohort of its frequent plasma Donors and accumulate Samples, before approval of this Management Framework required by Héma-Québec's internal governance. The quick start of the Sample collecting was authorized by the REC on February 5, 2021. On June 4, 2021, the REC approved the Biobank in principle, but that approval remained conditional upon final approval of the Management Framework. The Management Framework was approved by the REC on July 7th, 2021.

The Biobank consists of 3-mL plasma Samples collected during each donation from plasma Donors; those donations are normally dedicated to fractionation. The recruiting of Donors is guided by the recruiting plan provided in Appendix 1.

The collecting of Samples began on March 22, 2021, as part of a pilot project at the *Salon des donneurs de plasma – Plasmavie Sherbrooke*. Given the success of that pilot project, the project was rolled out to all Héma-Québec's Donation Centres starting April 5, 2021.

A controlled document was developed and approved in keeping with Héma-Québec's quality requirements system to allow the collecting of Samples specifically dedicated to the Biobank, as part of the procedures in effect for the plasma donation process. The procedures for collecting and managing the Biobank's Samples and Data are described in Appendix 2.

The ten (10) Centres that collect Biobank-dedicated Samples from plasma Donors are Héma-Québec's Donation Centres, namely: Saguenay, Lebourgneuf, Sainte-Foy, Trois-Rivières, Sherbrooke, Laval, Montreal, Kirkland, Brossard, and Gatineau (see Figure 1).

In the event that a new Centre opens during the term of the Biobank project, that Centre will be deemed to be part of the list of the above-mentioned Sample collection Centres for the purpose of standardizing the processes at the operational level for the Biobank project.

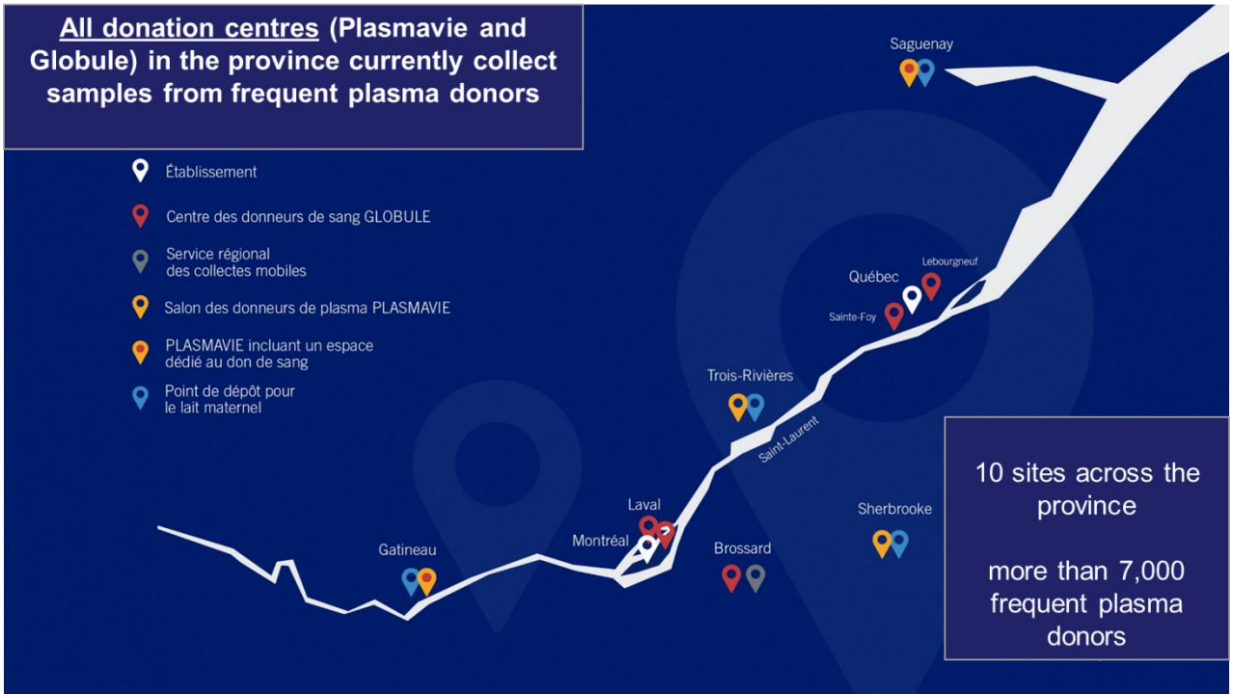

Figure 1. Geographic distribution of the Centres

1.3.2. Objectives

The Biobank's objectives are:

1) To build a cohort of frequent plasma Donors who consent to participating in studies in the pre- and post-COVID-19 vaccination context;
2) To systematically collect and store plasma Samples obtained from the Biobank's Donors;
3) To develop a Database that will contain certain information pertaining to the Biobank's Donors;
4) To allow Internal or External Researchers to have access to the Biobank's Samples and Data for the purpose of conducting studies in connection with COVID-19;
5) To ensure diligent management of the Biobank, compliance with the confidentiality rules, and the robustness of the process for assessing the scientific quality of projects.

Any Internal or External Researcher wishing to have access to the Biobank's Samples and Data will first have to submit a research protocol for approval from the Scientific Committee and then from the REC. After reviewing the research protocol, the REC will be able to authorize access to Biobank's Samples and Data under the research protocol submitted. To determine whether to authorize access, the Scientific Committee and the REC will assess the relevance, scientific quality, and ethical acceptability of the research protocol, as set out in Section 3 of the Management Framework.

All of the Biobank's Activities, from the recruiting of Donors for the cohort to the access process for Internal and External Researchers, are governed by the Management Framework and the procedures in the appendices.

1.3.3. Time frame

The Biobank project began on February 23, 2021. Figure 2 shows the major milestones of the Sample collection project. Only the studies already planned are included in it, but it is possible that other projects will be added. The Biobank's final analyses milestone involves the Biobank's portrait (number of Samples, number of Donors included, cohort profile, etc.).

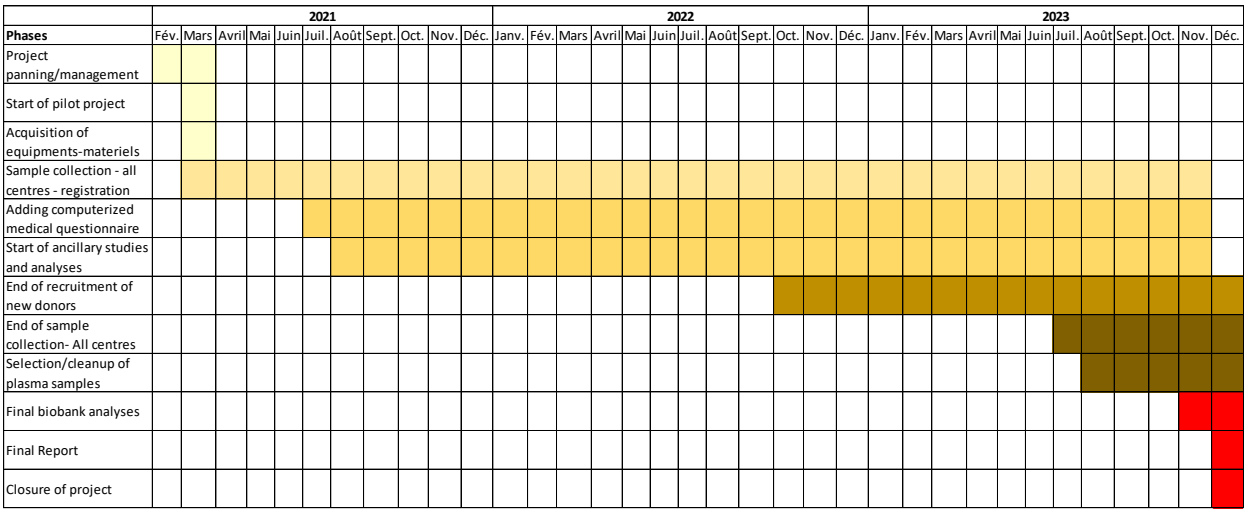

Figure 2. Major milestones

2. Governance and management structure

For the purpose of this section and of the Management Framework, the image below provides an overview of the Biobank's governance and management structure for reference (figure 3).

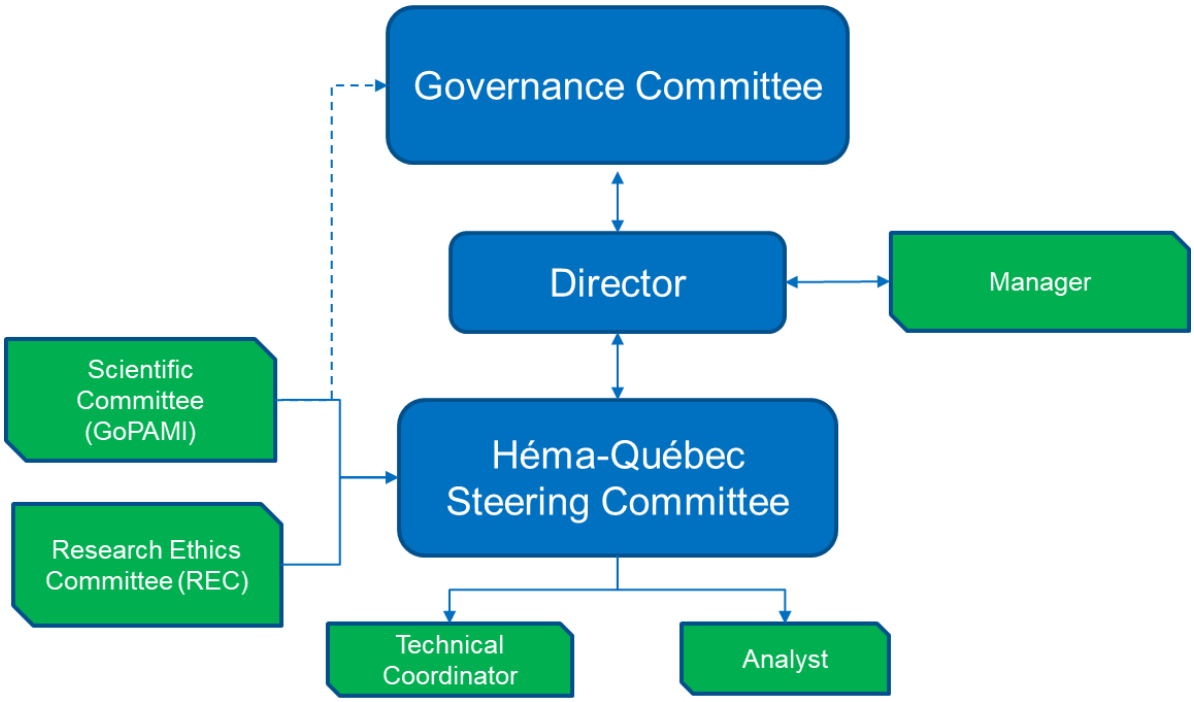

Figure 3. Biobank's governance and management structure

2.1 . People responsible

2.1.1. The Director and the Steering Committee

Under the responsibility of the Biobank's Director, MARC GERMAIN M.D., PH.D., the Steering Committee consists of the following members:

Members	Title at Héma-Québec
MARC GERMAIN M.D., PH.D.	Vice-President, Medical Affairs and Innovation **Biobank Director**
RENÉE BAZIN PH.D.	Scientific Director and Researcher
CHRISTIAN RENAUD M.D.	Medical Director of Microbiology, Epidemiology, and Researcher
ANTOINE LEWIN PH.D.	Chief of Epidemiology, Biological Risk Monitoring and Management, and Researcher; **Analyst**
MÉLANIE DIEUDÉ PH. D.	Director, Research Operations
NAHALIE SIMARD,M.Sc.	Biobank and Studies Specialist - Biobank Manager

Héma-Québec's Vice-President of Medical Affairs and Innovation is automatically the Biobank Director. The Biobank Director, in cooperation with the members of the Steering Committee, is responsible for ensuring that there is the infrastructure needed for ensuring the establishing and operational management of the Biobank. Specifically, he ensures that the Biobank's Activities are carried out properly, that the use of the Samples and Data is respected, and that confidentiality is protected in keeping with the administrative, legal and ethical requirements applicable to Héma-Québec.

The Biobank Director is assisted by a Manager responsible for the smooth running of the Biobank's day-to-day operations. Héma-Québec's Studies and Projects Specialist acts as Biobank Manager.

The Technical Coordinator, under the supervision of the Steering Committee, is responsible for receiving, storing, categorizing and handling the Samples. Héma-Québec's Research Services Supervisor acts as the Biobank's Technical Coordinator.

The Analyst is responsible for managing and analyzing Donors' Data, under the supervision of the Steering Committee. The Chief of Epidemiology, Biological Risk Monitoring and Management acts as the Biobank Analyst. The Analyst can delegate some of his/her duties to Héma-Québec's statistical and epidemiological specialists.

2.1.2. The Governance Committee

The Governance Committee's role is to ensure that the Biobank's Activities are carried out in a manner consistent with its objectives (see Section 1.3.2.) including proper management of the Biobank, compliance with the confidentiality rules, and the robustness of the process for assessing the scientific quality of projects.

The Governance Committee consists of members from Héma-Québec and representatives from the external organizations indicated below.

The members from Héma-Québec are:

- Marc Germain, Vice-President of Medical Affairs and Innovation
- Renée Bazin, Scientific Director
- Sébastien Gignac, Vice-President of the Executive Secretariat, Risks and Audits

The organizations represented on the Governance Committee are:

- The COVID-19 Immunity Task Force (CITF)
- The Public Health Agency of Canada (PHAC)

In addition to these organizations represented, the Governance Committee could ask for other representatives of related organizations to increase the representativeness of the various structures working in the health and research sectors. The goal is to have the opportunity to enrich the Governance Committee with various expertise that will help achieve the objectives of the Biobank.

2.1.3. The Scientific Committee (GoPAMI)

The Scientific Committee is responsible for reviewing research project requests for obtaining access to the Biobank's Data and Samples. The Scientific Committee assesses the project's alignment with the Biobank's mission and objectives. The research projects submitted to the Scientific Committee are then

evaluated on the basis of their scientific validity and relevance, feasibility, and risk level. Submitting a project to the Scientific Committee is a mandatory step in obtaining authorization to start a new research project using the Biobank's Data and Samples.

The group of experts on the Scientific Committee can consist of physicians, nurses, an epidemiologist, a biostatistician, Héma-Québec researchers and specialists, and the Director of Research and Development. External evaluators can be called upon if the required expertise is not available internally. There must be at least three Héma-Québec representatives on it and at least one external representative if specific expertise proves necessary.

2.1.4. Research Ethics Committee (REC)

The REC is responsible for the reviewing and ethical approval of all research projects and Biobanks conducted at Héma-Québec that involve either the participation of human subjects or the use of human-derived biological products. The REC reports to Héma-Québec's Board of Directors. Therefore, the REC plays a major role in the research project approval process, including ethical assessment of research protocols seeking access to the Samples and Data in the Biobank.

2.2. Reports and renewals

The Steering Committee must obtain a renewal of the REC's approval of the Biobank on an annual basis. The next request for approval renewal will have to be made on or around February 5, 2022, and annually thereafter.

The Steering Committee must attach a report on the Biobank's Activities to the renewal request submitted to the REC. That report will have to describe the Biobank's status and provide an update on its progress regarding such things as: total number of Samples in the Biobank; number of Samples added since the last annual report; number of Donors withdrawn; the list of research projects calling upon the Biobank. The report will also have to report and describe any specific events that occurred during the reporting period.

For any renewal request, the Steering Committee is responsible for ensuring that it has sufficient funding to continue the administrative and operational management of the Biobank for the renewal period.

3. Research project approval process

Any Internal or External Researcher who wishes to have access to the Biobank's Samples and Data must submit a research project to the Scientific Committee in the format set out in Appendix 3. The appendix to be completed for an external researcher are Appendix 3-5-6 and 7. Those for the internal researcher are Appendix 3 and 8. Appendix 8 must be signed by all Héma-Québec staff members who work with the Samples and / or Data from the Biobank.

Given that the Biobank was established to enable research on immunity to SARS-CoV-2, it is understood that the themes of the projects submitted will be able to differ from Héma-Québec's usual priorities.

The anticipated use of the Biobank's Samples and Data by Internal or External Researchers must, at all times and without exception, comply with:

- this Management Framework;
- the Biobank's objectives (Section 1.3.2.);
- the consent given by the Donors.

After the Scientific Committee approves a research project, it is submitted to the REC for final approval. The criteria considered by the Scientific Committee and the REC when assessing projects are described in Appendix 3.

The Biobank Director or his/her delegate responsible for access must document the REC's decisions.

External Researchers are responsible for obtaining any additional approvals required by the organization that they are affiliated with (including the ethics committee). External Researchers also undertake to comply with the ethical rules governing their external research activities and with Héma-Québec's rules of ethics. The Biobank Director must also retain evidence of the ethical approvals obtained by External Researchers.

4. Funding source

The Biobank project is made possible through financial support from the Public Health Agency of Canada (PHAC) (see Appendix 4) and from the COVID-19 Immunity Task Force (CITF). Héma-Québec also supports this project through its existing infrastructure and staff.

It is important to remember that the Biobank is a non-profit project.

5. Collecting, retaining and using the Biobank's Samples and Data

5.1. Collecting Samples and Data

5.1.1. Donor consent

Starting when the pilot project was introduced on March 22, 2021, the REC-approved consent process (REC-2021-003) made it possible to directly document Donors' consent in the eProgesa Software. Consent was entered by the nursing staff during the donation selection interview process in a section of the Donor's medical record. The Donor's signature on the general consent to donate blood also stipulates that the Donor gives express consent to participate in the Biobank and acts as the official signature for participation in the Biobank (see SPE-00939 available on request and for details about the consent documentation and the fact sheet referenced in Appendix 2, and documents PUB-00095(1) and PUB-00096(1) in SMART at the following link: https://www.hema-quebec.qc.ca/userfiles/file/media/anglais/rd/PLASCOV-AM-21-01-en.pdf).

Starting October 2, 2022, the above-mentioned REC-approved fact sheet (2021-003) will continue to be available for consultation but will no longer be used to recruit new Donors. Donors' explicit consent for the purpose of the Biobank project will already have been entered right on that questionnaire, in the section on Biobank participation. The signature for consenting to donate constitutes the official signature for participating in the Biobank.

The wording of the consent to participate in the Biobank reads as follows: *I have read and understood the content of the leaflet on the research project: Plasma donors follow up and specimen banking in order to study the impact of vaccination on the immune response against SARS-CoV-2 causing COVID-19, and I agree to participate in this research project.*

If a Donor withdraw his consent or for all new Donors post October 2, 2022, a Sample will still be collected due to operational constraints, however that Sample will be destroyed in conformity with the procedure described in Appendix 2 and will not be stored in the Biobank.

Refusals are entered and the Samples destroyed in keeping with the procedure described in Appendix 2.

5.1.2. Withdrawal of consent or death of a Donor

A Donor can decide at any time, simply by giving verbal notice, to withdraw his/her consent for the use of his/her Samples and Data. Héma-Québec has established an opt-out procedure that involves notifying the Biobank Manager by phone via the Collection Coordinator, whose contact information is indicated on the consent sheet and on Héma-Québec's website.

The information is then entered into the SAS Software as a refusal. If there are previous Samples, they will be destroyed in keeping with the procedure described in Appendix 2, and all future Samples collected for that Donor will be destroyed in keeping with that procedure.

The Data used by a study will not be destroyed until after the required retention period following the end of the study, in order to preserve the scientific integrity of the research in question.

In the event of the death of a Donor, the Samples and Data collected will continue to be used. However, no subsequent requests will be made to that Donor's family for obtaining additional information.

5.1.3. Sample and Data collection procedure

Once consent to participate in the Biobank is obtained, a plasma Sample is collected in keeping with the procedure described in Appendix 2. The Data collected at the time of the plasma donation are listed in Appendix 2.

In addition to the Data listed in Appendix 2, the Biobank Director will be able to enter into agreements with agencies under the Quebec Ministry of Health and Social Services for obtaining relevant information about Donors, including in connection with the COVID-19 vaccination. Those agreements will be listed in the register provided for this purpose in Appendix 2.

Finally, the consent to participate in the Biobank (Appendix 2) sets out the possibility of using targeted questionnaires as part of studies accepted by the Biobank's Scientific Committee and the REC.

In the event that Donors may be contacted, only Héma-Québec is authorized to do so.

5.2. Retention and use of Samples and Data

5.2.1. Sample and Data matching and retention

The Samples and Data collected are kept confidential and secure. To this end, the following measures are adopted and put in place:

- The Data are coded. A unique code number is assigned to each Donor prior to his/her Samples and Data being put into the Biobank. The key to the code is kept by the Analyst, who is responsible for protecting that information by using, among other things, a secure separate file. When Samples and Data are sent to an Internal or External Researcher, a new code is assigned (double coding) and no Personal Information is sent. The Samples and Data are encrypted before being sent to an External Researcher.

- Only the Analyst will have access to the Database that contains Donors' Personal Information; access to the Database is protected by a user ID and password; Héma-Québec's authorized staff assigned to the monitoring, administration and management of the Biobank will have access only to Depersonalized Information.

- The physical locations where the Samples are stored are locked with access restricted to Héma-Québec's authorized staff assigned to the monitoring, administration and management of the Biobank. Also, the freezers that the Samples are kept in are plugged into emergency outlets to ensure that an adequate temperature is maintained for preserving the Samples.

- Once the research project is approved and all required undertaking forms have been signed, the Analyst extracts the Data requested by the Internal or External Researcher; Personal Information cannot be sent as part of such a request.

- As for access to the Samples, the Biobank Manager, in cooperation with the Technical Coordinator, coordinates the selecting and shipping of the Samples to the Internal or External

Researcher once his/her research project is approved and the agreement between the Internal or External Researcher and the Biobank Manager is signed.

- A confidentiality agreement must be signed by any Internal or External Researcher and by any other individual who may have access to the Samples and the Data.

- Only Héma-Québec can do the matching of the Data with the Personal Information of the Donors participating in an approved research project.

Héma-Québec undertakes to maintain access to the Biobank's Samples and Data for at least two (2) years starting February 23, 2021.

At the time of the annual request for renewal by the REC for the Biobank project (REC 2021-003), the REC also assesses the relevance of continuing to retain the Samples, as well as the future retention period. That re-assessment is based on the potential future use of the Biobank, factoring in such things as the retention standards set out in the *Act respecting access to documents held by public bodies and the protection of personal information* (CQLR, c. A-2.1).

Likewise, at the end of the Biobank's Activities, Héma-Québec will assess the duration for and relevance of retaining the Samples and Data.

5.2.2. Use of the Samples and Data

Any individual authorized to access the Biobank's Samples and/or Data must give a written undertaking that he/she will respect the confidentiality of the Data, the Management Framework, and use the Samples and/or Data in a manner consistent with the Biobank's objectives (Appendices 5, 6, 7 et 8).

Even though they in no way have access to Donors' Personal Information, Internal and External Researchers undertake to ensure that the Data and research results derived directly or indirectly from the Biobank's Data is released, published or communicated only in a format that prevents the Donors from being directly or indirectly identified.

When required by an approved research project, Héma-Québec will send the required Samples to an external laboratory. Prior to the Samples being transferred, the external laboratory will have to undertake to comply with Héma-Québec's quality, operating and integrity standards. The transporting of Samples to other external laboratories must adhere to the rules in effect for transporting human-derived biological materials. Financial compensation will be required from the External Researchers for processing the Samples and transporting them to the analysis laboratory.

6. Management of incidental findings and communication with Donors

The Data collected for establishing and managing the Biobank are not intended for providing medical or health care information to Donors. Therefore, they cannot be used to make a clinical decision. Donors are informed of this. Even so, if incidental findings arise, Héma-Québec has a structure and procedures already in place for following up with Donors. Héma-Québec's Medical Affairs Department is then mandated to do the necessary follow up with Donors or their attending physician.

External Researchers' research protocols submitted for evaluation will have to factor in the possibility of incidental findings and will need to set out a procedure for notifying Héma-Québec of incidental findings pertaining to Donors.

In view of the confidentiality rules and the depersonalization of the Data sent to Internal and External Researchers, it will be impossible for Internal or External Researchers with access to the Data sent for the purpose of their research project to send the research results to the Donors. General information about the scientific research conducted and the results from it will be available on Héma-Québec's website and in scientific publications. Information about the use of the Data will also be made available to the public in the Internal and External Researchers' academic publications and/or public reports.

7. Intellectual property and publication of results

The Steering Committee will assess the potential for using and the method for managing the Intellectual Property Assets that will be able to be produced or acquired during the Biobank's Activities. That analysis will factor in the principles and objectives set out in the *Cadre de gestion et de valorisation de la propriété intellectuelle*, prepared by the Government of Quebec (https://www.economie.gouv.qc.ca/fileadmin/contenu/publications/etudes_statistiques/innovation/dispositions.pdf).

To do so, the Steering Committee will have to:

- Identify the type of Intellectual Property Assets that will be produced or acquired as part of the Biobank's Activities;
- Determine the potential for making use of the Intellectual Property Assets identified.

In light of the Steering Committee's recommendations regarding the potential for using the Intellectual Property Assets, Héma-Québec will have to decide how to make use of the Intellectual Property Assets.

The Biobank Director will have to ensure that Héma-Québec's decisions regarding the use of the Intellectual Property Assets are the subject of agreements, when required. Any agreement that in whole or in part covers the use of Intellectual Property Assets must be in writing.

Finally, any publication by an Internal or External Researcher who directly or indirectly used the Biobank's Samples and/or Data must mention Héma-Québec's contribution regarding access to those Samples and/or Data, in the "Materials and Methods" section of that scientific publication. If applicable, the scientific contribution of Héma-Québec's staff will have to be acknowledged in keeping with the practices that apply in scientific publishing.

Publicly sharing the scientific data resulting from the Biobank is not authorized.

8. Procedures for modifying the Management Framework

Any modifications to this Management Framework, excluding the Appendices, must be approved by the REC. The tracking of modifications made to the Management Framework must appear on the first page of the document.

The content of the Appendices can be modified at any time by the Steering Committee, with no formalities, to ensure the smooth running of the Biobank's Activities and to reflect the objectives set out in the Management Framework. However, to the extent that the Steering Committee considers that modifying an Appendix could have a significant impact on the scope of the Management Framework or on the Biobank's objectives, the Steering Committee will request the REC's authorization before proceeding with that modification.

APPENDIX 1

Donor Recruiting Plan

1. Donor recruiting

All plasma Donors on a PCS2 (machine for collecting plasma by apheresis) have been invited to participate in the Biobank since March 22, 2021, at the *Salon des donneurs de plasma - Plasmavie* and at all Donation Centres since April 5, 2021. For information: to ensure the Biobank's objectives, as of the start date of plasma donations at the Donation Centres, the overall vaccination rate reported by Public Health was 20%. Therefore, a certain proportion of Samples from frequent Donors were banked before the mass vaccination.

As of the date that the first version of the Management Framework was submitted in late May 2021, over 98% of plasma Donors on a PCS2 had agreed to participate in the Biobank. Héma-Québec plans to seek out more than 12,000 Donors during the recruiting period, which is expected to last until fall 2022, in order to obtain a minimum of 5,000 frequent Donors (3 or more donations per year) with at least one Sample collected before vaccination (see protocol REC 2021-003). By May 2021, Héma-Québec had already recruited more than 7,000 Donors, which equates to over 18,000 Samples. By May 2021, the vaccination rate was 50% at that time.

Depending on the vaccination progress rate, Héma-Québec may be able to finish collecting Samples earlier than planned, if the objectives are met. Héma-Québec also reserves the option of temporarily interrupting the collecting of Samples, in order to avoid unnecessarily collecting a Sample from Donors who make donations close together over time.

2. Donor inclusion and exclusion criteria

All Donors eligible for donating plasma are also eligible to participate in the Biobank. Plasma Donors are recruited in a number of Quebec regions. Therefore, all plasma Donors who qualify for donating during the recruiting period are included in the Biobank if they give their consent in the manner provided for in Section 5.1 of the Management Framework.

The inclusion and exclusion criteria are the same as those used for qualifying blood Donors. Some of those criteria are available on Héma-Québec's website. The full list is found in the blood donation criteria manual (BDCM), which can be accessed at the following link: https://www.plasmavie.ca/donner/index.en.html.

Here is an overview of the main inclusion criteria *(see the full list in the Donor Selection Criteria Manuals (DSCM) for more details, available upon request):*

- Age 18 and +;
- In good health;
- Minimum weight/size for donating plasma: https://www.plasmavie.ca/userfiles/file/plasmavie/PUB-00028.pdf
- Childbirth 6+ months earlier;
- Breastfeeding woman if delivery date was 6+ months earlier;
- Diabetes if resolved or controlled by diet or medication (except insulin).

Here is an overview of the main exclusion criteria *(see the full list in the Donor Selection Criteria Manuals (DSCM) for more details, available on request):*

- Under 18 years of age;
- In poor health;
- Pregnant woman;
- Diabetes treated with insulin;
- Not eligible for donating if less than 50 kg, regardless of size: https://www.plasmavie.ca/userfiles/file/plasmavie/PUB-00028.pdf
- On certain medications (e.g. anticoagulant, immunoglobulin, see the DSCM for the full list: https://www.plasmavie.ca/donner/medicaments/medicaments-a-b-c.en.html
- Intravenous drug use;
- Treatment using needles that are not single-use (acupuncture or electrolysis or tattooing/piercing less than 3 months ago);
- A man who has had sex with a man if the last sexual contact was less than 3 months ago;
- Sore throat until symptoms disappear and, if you take antibiotics, until the treatment is finished;
- Tick bite.

APPENDIX 2

Procedures for Collecting and Managing the Biobank's Samples and Data

1. Location of the Biobank

1.1. Samples

The physical location of the samples is confidential. They are stored in cryogenic boxes in freezers set at -30°C.

Access is limited to Héma-Québec's authorized staff who handle the receiving and managing of Samples; access is controlled by the use of a magnetic card.

1.2. Data

The Data about Donors are extracted from the eProgesa Software and centralized in the SAS Software with limited access by the Analyst. The physical locations of the computer servers are confidential.

Héma-Québec's IT architecture is not accessible externally and cannot be specified in the Management Framework. This information will be provided only if necessary. The servers are located within Quebec. A laptop computer with a secure connection on RSA key is used. The computer hardware is password-protected and supported by Symantec Endpoint Protection.

2. Collecting and managing the Samples

2.1. Sample type and collection procedure

Every Sample put into the bank contains 3 mL of plasma collected by apheresis. The collection procedure calls for administration of an anticoagulant (250 mL of 4% sodium citrate) because the blood cells separate during collection, and red blood cell and other blood cells return cycles are expected during collection. Sodium citrate is incorporated during collection to enable the apheresis process and blood flow into the machine, thereby preventing clot formation during the procedure.

The Sample intended for the Biobank is taken right from the plasma bag at the end of the donation, in the Donor's presence, at the same time as collecting the tubes for the regulatory analyses needed for qualifying the donation. No additional amounts are collected from the Donor for the purpose of the Biobank project because the Sample is taken from his/her donation at the pre-established volume for the donation. Therefore, this collection involves no additional risk for the Donor.

Once the sample is collected, the tube is placed on a carrier designated for the project. The carrier is placed into a refrigerator, set at a controlled temperature between 4 to 6°C, on collection day, and kept cold until delivered to Héma-Québec's facilities in Quebec City within 72 hours. The Sample is then stored on Héma-Québec's Research and Development premises assigned to this project. Every Sample is scanned with its unique number into an inventory file intended for this purpose and then immediately frozen in freezers set at a temperature of -30°C. The procedure for managing the R&D Samples inventory is available on request.

The tube used for the sampling procedure is a Vacuette from Greiner Bio-One, no additives, with white cap, black ring. The supplier's insert is available on request. The original tube can be frozen at temperatures as low as -70°C if previously refrigerated as set out in the collection process in effect (See procedure SPE-01257, available on request). The Samples are stored in cryogenic boxes in freezers set at -30°C.

2.2. Deviation from the Sample collection and management process

Any deviation from the Sample collection and management process is documented by the Studies and Projects Specialist and by the research staff in a form provided for this purpose. Samples that do not go through the cold chain up to the receiving and freezing stage will have to be destroyed and documented in the same form. The reconciliation of compliant donations collected in the eProgesa Software and the received Samples file is also done on a regular basis in order to identify potential collection oversights or the time for transporting to the storage facilities.

Documentation example on the form for documenting deviations from the Sample collection and management protocol

DÉVIATIONS – Étude PLASCOV - AM-21-01

No. déviation	Prénom et nom de la personne qui	Prénom et nom de la personne qui a	Date de documentation	# de don(s) impacté(s):	Description de la déviation (cocher une case)	STATUT
1	Amélie Boivin	Christine Doucet	22/04/2021	C000721390556203	☒Volume insuffisant (code 217) L'agent n'a pas pris le troisième tube car le volume était de 146mL et serait devenu non conforme. ☐ Prélèvement du tube refusé par le donneur ☐ Autre (décrire) :	COMPLÉTÉ

3. Donor consent sheet

COVID-19

Plasma donors follow up – Impact of vaccination on the immune response against SARS-CoV-2 causing COVID-19

If you've previously read this leaflet, please disregard it

Dear Donor,

You are invited to participate in this study, but before agreeing to participate, please take the time to read this document and do not hesitate to ask a Héma-Québec staff member any questions you may have. You are free to accept or refuse to participate, and you can inform the nursing staff of your choice during the medical questionnaire review or when you complete the self-service questionnaire. Your decision will have no impact on your eligibility to donate plasma and **your participation will not prevent your plasma from being used for fractionation.**

Héma-Québec plans to conduct research related to the SARS-CoV-2 virus that is responsible for COVID-19. More specifically, **we want to measure the impact of vaccination or infection on the immune response.** It is important to understand that the purpose of this study is not to diagnose cases of COVID-19, but to study the immune response following vaccination and/or infection. To this end, **we will collect a 3 ml sample from your plasma bag today and during your subsequent donations.** Other scientific teams may also propose new studies and thus have access to your samples. Such studies, all related to COVID-19, will first be reviewed and approved by Héma-Québec and its research ethics committee. All information collected as part of this study will be treated confidentially by Héma-Québec and its research partners will never have access to your personal data. You will only be identified by a code number.

If you agree to participate in the study: During the selection interview, the nurse staff may ask you brief questions or you may be asked questions via another method (online questionnaire, etc.). For example, we will want to know if you have received the COVID-19 vaccine, if you have had the infection, and if you have had a diagnostic test for COVID-19. **By agreeing to participate in this study, you also authorize Héma-Québec to consult information about you in the provincial registries maintained by the ministère de la Santé et des Services Sociaux (MSSS)**, provided that the required authorizations from the relevant government authorities are obtained (such as the Commission d'accès à l'information du Québec and the Institut national de santé publique du Québec). **The following data could be obtained: result and date of positive screening for COVID-19 and SARS-CoV-2 vaccination received** (type of vaccine, date(s) and number of doses administered). These requests for information will be made in accordance with the rules of confidentiality, ethics and rights of access to information. Héma-Québec may contact you to offer you the possibility of participating in other studies or to ask you questions related to COVID-19. For example, we may ask you if you have had symptoms of COVID-19 and what may have caused your infection.

If you decline to participate in the study: For operational reasons, a sample will still be taken from each of your donations. However, please be assured that **your samples will not be banked; they will be destroyed.**

If you have any additional questions or problems related to the study, you can call the nurse in charge of collecting specimens at Héma-Québec: 514-832-5000, extension 3256 or 1-888-666-4362, extension 3256. Please note that you may withdraw from this study at any time by contacting the nurse in charge of collection. If you withdraw, all samples collected for this study that have not yet been used will be destroyed.

Héma-Québec thanks you for your participation.

HÉMA-QUÉBEC

PLASCOV AM-21-01

4. Managing refusals to participate and destruction of Samples

4.1. Recording information

The information regarding refusals is recorded as described in Section 5.1. of the Management Framework. The staff of Héma-Québec's Research Branch, who are responsible for receiving and storing the Samples, are in charge of destroying the Samples of Donors who refused to participate in the Biobank, once the Samples are received at Héma-Quebec's storage location in Quebec City.

The Samples to be destroyed are identified, once the Sample is stored or received, using a file extracted from the SAS Software that draws the information from the eProgesa Software containing Donors' consent information.

4.2. Procedure for destroying Samples

There are four reasons why destroying Samples is required:

1. The Donor refuses to participate in the Biobank;
2. The Donor withdraws his/her consent after previously consenting to participate in the Biobank;
3. The Donor's plasma donation tests positive in a virological analysis: HIV, HCV, HBV;
4. The Sample is no longer useful for the purpose for which it was collected, either because of the end or interruption of the Biobank's Activities or because the remaining Samples are not required or residual.

When any Sample is received, the donation number is documented in the "Inventory – PLASCOV Samples" file, which is found in the SAS Software. Likewise for residual Samples or aliquots.

When the Samples are discarded for the reasons mentioned above, the following information is entered into the same file:

- Sample number;
- Destruction date;
- Employee who did the destroying;
- Biohazard box number (biohazard waste bin);
- Reason for destruction.

See the R&D protocol for all documentation steps. The "Inventaire Échantillons PLASCOV " file is the only place where destruction information is recorded.

The Samples to be destroyed and the destruction of them, if applicable, are checked every week or at most every 2 weeks for reasons of physical access to the Samples.

5. Data collecting

5.1. Information about a COVID-19 infection

As of July 5, 2021, if a Donor agrees to participate in the study, the following question will automatically be added to the donation qualification medical questionnaire:

- *Have you been infected with the virus that causes COVID-19?*

If "YES", the following question will be added*:*

- *Have you tested positive for COVID-19?*

If the Donor answers "YES", an additional question will be added to the interview to determine the date of the test.

If the Donor answers "NO" to the infection question, that answer will not be carried over to the next donation because it can vary over time. It will be asked again during the selection interview at the time of subsequent donations.

If a positive answer to infection is received, the following additional questions will also be added to the selection interview:

- *What was the onset date of the COVID-19 signs and symptoms?*
- *What was the end date of the COVID-19 signs and symptoms?*

Héma-Québec is also in discussions with the Quebec Ministry of Health and Social Services to obtain access to the COVID-19 infection registry in order to supplement and enhance the information about infections that occurred among the Biobank's Donors. That information will obviously be subject to the same confidentiality rules and legal requirements that both parties (Héma-Québec and the Ministry of Health and Social Services) are subject to.

5.2. Vaccination information

Information about the COVID-19 vaccination will also be collected. As of July 5, 2021, Donors will be asked questions about vaccination in their medical questionnaire.

- *What vaccines have you received within the last 3 months?*

This last question is already asked for qualifying the donation. Consideration should be give to the fact that the COVID-19 vaccine is currently only marked as "acceptable vaccine in the Donor's record" because this vaccine is not grounds for inadmissibility of the plasma donation.

The following questions are new questions specifically added for the purpose of the Biobank project:

- *Is it a vaccine against COVID-19?*
- *Which vaccine(s) did you receive?*

The multi-selection list* of the following vaccines is available:

- *1- Pfizer / BioNTech*
- *2- Moderna*
- *3- AstraZeneca / Oxford (including COVISHIELD)*
- *4- Johnson & Johnson / Janssen*
- *5- Medicago / GSK*

- *6- Sanofi / GSK*
- *7- Novavax*
- *8- Don't know*

*Note that the multi-selection list lets select more than one vaccine.

- *How many doses have you received?*

  The following answers are available:

  - 1 dose
  - 2 doses
  - More than 2 doses

- *What is the date of the most recent dose?*

Héma-Québec is also in discussions with the Quebec Ministry of Health and Social Services to obtain access to the vaccination registry in order to supplement and enhance the information needed for future studies. That information will obviously be subject to the same confidentiality rules and legal requirements that both parties (Héma-Québec and the Ministry of Health and Social Services) are subject to.

5.3. Sociodemographic Data

Socio-demographic Data about Donors is provided to Internal and External Researchers who have access to the Biobank's Data. That additional Data is associated with the Sample and is depersonalized and coded. This Depersonalized Information is Data collected at the time of the donation. In the general consent to donate, the Donor consents to this information being made available for research purposes.

The Data collected is as follows:

- Age
- Sex
- Location (CLSC, RLS, RSS)
- Ethnicity
- Weight/height (body mass index)
- Certain health conditions or information about the Donor that does not identify him/her are not grounds for inadmissibility of the donation: high blood pressure/controlled diabetes/mild asthma, blood type, etc.

5.4. Other Data collected

Some Data accompanies each Sample, namely the collection date, the collection site, and the date, time and freezing date.

The consent-related sheet (Appendix 2) provides for the possibility of using targeted questionnaires as part of research projects accepted by the Scientific Committee and the REC (approvals required in keeping with the Biobank access process set out in the Management Framework).

6. Registry of Data-sharing agreements

Date of agreement	Organization(s) involved	Type(s) of shared data	Particularity(ies)
July 16th 2021	Ministère de la santé et des services sociaux (MSSS), Institut National de Santé Publique du Québec (INSPQ) et Héma-Québec (HQ)	Access rights granted to HQ by MSSS for phase III of the seroprevalence study using samples from the Biobank (CÉR-2021-10). Data from the SP-PMI vaccination and infection register via the Public Health Trajectory Information System (TSP).	Access to SI-PMI and TSP registers on vaccination / infection data from part of the cohort. However, these data can only be used in the context of the phase III seroprevalence study (REB-2021-10).
January 14th 2022	Ministère de la santé et des services sociaux (MSSS), Institut National de Santé Publique du Québec (INSPQ) et Héma-Québec (HQ)	Access rights granted to HQ by MSSS for phase III of the seroprevalence study using samples from the Biobank (CÉR-2021-20). Data from the SP-PMI vaccination and infection register via the Public Health Trajectory Information System (TSP).	Access to SI-PMI and TSP registers on vaccination / infection data from part of the cohort. However, these data can only be used in the context of the phase III seroprevalence study (REB-2021-20).

Future agreements will be documented in this table

APPENDIX 3

Submitting a Project Proposal to Héma-Québec's Scientific Committee and REC - ACCESS FORM TO PLASCOV BIOBANK SAMPLES (external researcher)

SECTION 1: GENERAL INFORMATION

Date submitted to the Scientific Committee	Click here to enter text.
Date accepted by the Scientific Committee	Click here to enter text.
Date submitted to the REC	Click here to enter text.

Title of the project (in French)

Click here to enter text.

Lead external researcher

Click here to enter text.

Organization and address

Click here to enter text.

Collaborators and affiliations

Click here to enter text.

If the proposed project is in response to a request from another area of the company, identify the requester, his/her line of business, and his/her level of involvement in the project
Click here to enter text.

SECTION 2: RESEARCH PROTOCOL

Part 1: Description of the project in which the requested samples will be used

A. Short summary of the project and its objectives (max. 250 words)

Click here to enter text.

B. Scientific quality / originality (background, relevant literature review, hypothesis, objectives, method, statistic analysis, experimental method, expected results)

Click here to enter text.

C. The project's relevance to the objectives of the Biobank mentioned in the Management and Governance framework (section 1.3.2.)

Click here to enter text.

SECTION 2: RESEARCH PROTOCOL

Part 2: Anticipated Deliverables

List/describe the anticipated deliverables here

Click here to enter text.

SECTION 2: RESEARCH PROTOCOL

Part 3: References

List of references cited

Click here to enter text.

SECTION 3: SCHEDULE AND SAMPLES REQUIRED

Projected start date of the project

Cliquez ici pour taper du texte.

Total planned duration (how long will the project last?)

Cliquez ici pour taper du texte.

Samples Required

Total number of samples required: Cliquez ici pour taper du texte.

Volume (maximum 0.5 mL subject to sample availability): Cliquez ici pour taper du texte.

Profile of donors for whom samples are required (e.g. single donor, vaccinated or unvaccinated, longitudinal samples, sex, age, region of origin, date or period covered by direct debits, no preferences, etc.): Cliquez ici pour taper du texte.

SECTION 4: INFORMATION PERTAINING TO THE PROJECT'S ETHICAL ASSESSMENT

a. Laboratory(s) / location where the project will be carried out

Click here to enter text.

Coordination centre (if different from where the project will be carried out)

Click here to enter text.

b. Total number of samples requested (refer to section 3 of the form for detailed information)

Click here to enter text.

c. Data related to samples / donors required for the project and justification of the need (for the list of available variables, see section 5 of the Biobank Management and Governance Framework)

Click here to enter text.

d. Ethical approval of the institution of the external researcher: Provide proof of acceptance of the project which will use the samples requested by the REB of the home institution of the external researcher. Mention additional information to the document (s) if necessary.

Click here to enter text.

e. Are there any analyzes performed as part of the project that could lead to an incidental finding? If so, attach a sample letter that will be sent by Héma-Québec to the participant in the event of a result that would require follow-up with the donor.

Click here to enter text.

f. Will there be questionnaires? If yes, attach the questionnaire (s) to the project submission. As described in the Management and Governance Framework, a researcher could request that HQ contact participants with additional questions.

Click here to enter text.

g. Preservation / destruction of samples (describe the duration and place of preservation; the method of tracking and destruction of the samples).

Click here to enter text.

ARE THERE ANY SPECIFIC ETHICS-RELATED POINTS YOU'D LIKE TO BRING TO THE REC'S ATTENTION?
Click here to enter text.

ATTACH PROOF OF ACCEPTANCE OF THE PROJECT BY THE REB OF YOUR ATTACHING INTSTITUTION AS WELL AS ANY OTHER DOCUMENT RELEVANT TO THE REQUEST.

SUBMIT THE WORD VERSION AND THE PDF VERSION FOR REVIEW OF YOUR APPLICATION.

SIGNATURE (FOR SUBMISSION TO THE REC)
Save the form in PDF format and sign electronically below.

For REC use only

☐ Submission approved

☐ Submission refused

☐ Request for clarification

☐ Request for modification

☐ Approval deferred

☐ Conditional approval

Date: _____

Aide-mémoire pour le dépôt d'un projet de recherche (v04-12-2019)

La soumission d'un projet au comité de gouvernance des projets (GoPAMI) et au comité d'éthique à la recherche (CÉR) n'est pas une formalité mais bien une démarche par laquelle un chercheur va obtenir l'autorisation de démarrer un nouveau projet. Il est donc de la responsabilité du chercheur de présenter une description de son projet suffisamment claire et complète pour permettre à un lecteur avisé (i.e. qui a de bonnes connaissances sur les produits et/ou opérations d'HQ) de pouvoir aisément en évaluer le bien-fondé, la pertinence et la faisabilité. Pour certains projets, il pourrait arriver qu'une évaluation externe (aux AMI ou même à HQ) soit demandée, d'où l'importance de bien présenter le contexte, les enjeux et objectifs visés par le projet. Le tableau ci-dessous présente les éléments à prendre en considération lors de la préparation d'une soumission et identifie les évaluateurs de ces éléments.

SECTION	CONTENU
1- **Renseignements généraux (GoPAMI et CÉR)**	**PARTIE 1 : Renseignements généraux** • Dates de soumission et d'acceptation • Titre du projet • Identification du chercheur responsable • Identification des chercheurs-collaborateurs (HQ ou externes à HQ; bien distinguer le rôle de chacune des personnes mentionnées) • Identification du demandeur (dans le cas où le projet répond à une demande venant d'un autre secteur de l'entreprise) et son degré d'implication dans le projet
2- **Protocole de recherche (GoPAMI)**	**PARTIE 1 : Description du projet** A. Court résumé du projet et des objectifs poursuivis • Utiliser un langage clair et compréhensible pour un lecteur qui ne possède pas nécessairement une expertise dans le domaine du projet proposé • Bien faire ressortir la question de recherche et son contexte immédiat B. Qualité scientifique / originalité • Le projet est articulé de façon adéquate: - La mise en situation permet d'apprécier facilement le contexte du projet ainsi que la problématique qui fera l'objet du projet - L'état de l'art et des connaissances actuelles en lien avec le projet proposé est présenté et supporté de façon adéquate par la revue de littérature - Lorsqu'approprié, une hypothèse est clairement formulée - Les objectifs spécifiques sont clairement énoncés - La méthodologie est suffisamment détaillée et claire pour permettre d'évaluer la faisabilité du projet - Une réflexion de la taille d'échantillon requise pour le projet est présentée • Lorsqu'applicable, des données préliminaires sont présentées • Les résultats attendus sont mentionnés ainsi que des mesures de mitigation dans les cas où des problématiques pouvant survenir durant la réalisation du projet pourraient survenir C. Pertinence du projet pour Héma-Québec (bien faire ressortir dans sa description que son projet touche à un ou quelques-uns des éléments suivants) • Le projet concerne une des lignes de produits ou activités de l'entreprise • Le projet vise à améliorer l'efficacité et/ou le rendement d'un produit ou procédé de l'entreprise • Le projet vise à générer de nouvelles connaissances qui ne pourraient pas être accessibles autrement, à apporter une meilleure compréhension quant aux propriétés et/ou mécanismes d'action d'un produit de l'entreprise • Le projet vise à développer un nouveau produit ou service qui pourrait s'inscrire dans le mandat de l'entreprise • Le projet est en support aux opérations courantes ou futures de l'entreprise • Le projet a le potentiel d'améliorer la sécurité/efficience d'un produit ou service (sécurité des donneurs ou des receveurs) • Le projet aura un impact positif sur la réalisation de notre vision de vouloir devenir un partenaire stratégique au service du système de santé québécois • Le projet aura la possibilité de générer de la propriété intellectuelle au bénéfice de l'entreprise • La réalisation va répondre à un besoin/questionnement opérationnel **PARTIE 2 : Livrables anticipés** • Développement ou optimisation d'un produit/essai/procédé • Encadrement d'un étudiant • Publication scientifique/rapport interne/revue de littérature/recommandation • Données préliminaires pour demande de financement externe

Pour le dépôt d'un projet multicentrique dont le CÉR évaluateur du projet n'est pas le CÉR de HQ	
Lettre de déclaration du CÉR évaluateur	Il s'agit de la lettre qui déclare que «Le Comité atteste avoir les compétences requises pour faire l'évaluation éthique du projet et accepte d'agir comme CÉR évaluateur pour l'ensemble des centres participants au Québec.»
Lettre d'approbation éthique du CÉR évaluateur	Il s'agit de la lettre qui vous informe que le projet est approuvé par le CÉR (autre que le CÉR d'Héma-Québec).

APPENDIX 4

Financial Support Letter – Public Health Agency of Canada

Public Health Agency of Canada / Agence de la santé publique du Canada

Le 21 mai, 2021

Marc Germain, *M.D., Ph. D., FRCPC*
Vice-président, affaires médicales et à innovation
Héma-Québec
1070, avenue des Sciences-de-la-Vie
Québec (QC)
G1V 5C3

Docteur Germain,

Titre du projet : Mise en place d'une cohorte de donneurs de plasma avec mise en banque d'échantillons en vue d'étudier l'impact de la vaccination contre la COVID-19

J'ai le plaisir de vous informer que votre projet *« Mise en place d'une cohorte de donneurs de plasma avec mise en banque d'échantillons en vue d'étudier l'impact de la vaccination contre la COVID-19»* a été approuvé dans le cadre du programme de sérosurveillance et recherche de la COVID-19.

Selon l'analyse des renseignements que vous avez fournis avec votre demande, l'organisme que vous représentez, Héma-Québec, doit se conformer aux dispositions applicables de la *Loi sur le ministère du Conseil exécutif* (loi M-30) avant qu'un accord pour le projet mentionné ci-dessus puisse être signé avec l'Agence de la santé publique du Canada (ASPC). Pour de plus amples renseignements sur la loi M-30, veuillez consulter le site Web du Secrétariat du Québec aux relations canadiennes (SQRC):

https://www.sqrc.gouv.qc.ca/relations-canadiennes/ententes-intergouvernementales/processus-approbation-autorisation.asp

L'ASPC enverra l'Accord de subventions et les documents connexes au ministère du gouvernement du Québec responsable de l'application de la loi M-30. Nous vous informerons lorsque le processus a été finalisé. Si vous avez besoin de plus amples renseignements, veuillez contacter **Martin Boulianne**, votre agent responsable des opérations du Centre de subventions et de contributions (CSC), par courriel à martin.boulianne@canada.ca ou par téléphone au 514-239-1426.

Nous vous prions d'agréer nos salutations les meilleures.

Dr Pascal Michel, DMV, IPSAV, MPVM, PhD
Conseiller scientifique en chef
Bureau du conseiller scientifique en chef
Agence de santé publique du Canada

cc : Martin Boulianne, agent responsable des opérations du CSC, ASPC
Dr Margaret Neuspiel, chef de programme, Bureau du conseiller scientifique en chef

Canada

APPENDIX 5

Undertaking regarding the Management and Use of the Biobank by an External Researcher

Planned content:

- Ethical undertakings
  - To adhere to HQ's rules of ethics and the Management Framework;
  - To adhere to your institution's rules of ethics and provide copies of any ethical approvals required by its research project.

- Undertakings regarding the use of Samples and Data
  - To cover the costs of transporting the Samples and Data;
  - To respect confidentiality;
  - To obtain a written undertaking of confidentiality from every employee or individual that it authorizes to access the Samples and Data as part of the research;
  - To use for research purposes only;
  - Under no circumstances are the data to be used by the Researchers to attempt to identify or contact the Donors;
  - To ensure the security of the Samples and Data through secure and adequate storage processes and technology;
  - In the event of a security incident involving the Samples and Data, to notify HQ immediately;
  - To destroy the Data and Samples in keeping with the Project-related destruction schedule and confirm the destruction to Héma-Québec (form to be sent to HQ);
  - Prohibited from surrendering, transferring or otherwise disposing of the Samples and Data other than for research purposes;
  - To follow the procedure for transferring the Samples and Data to third parties under contract (have a confidentiality agreement signed, use for research purposes only, inform HQ of the transfer and of the subcontractor's identity, with proof that the subcontractor is committed to the management framework and management undertaking).

- Undertakings regarding incidental findings
  - To set out a procedure in the research protocol for handling incidental findings;
  - To inform HQ of incidental findings pertaining to Donors.

- Undertaking regarding intellectual property
  - Waiver of Intellectual Property Rights (scope of the clause to be determined further to the analysis of identifying the Intellectual Property Assets);
  - To notify Héma-Québec of the filing of patents arising from the use of the Samples and Data.

- Undertakings regarding publishing of the research results
  - To mention HQ's contribution;
  - To respect the confidentiality of the Samples and Data;
  - To inform HQ of any publication arising from the use of the Data.

- End of the agreement
    - Termination clause for the benefit of HQ in the event that the researcher fails to fulfil his/her obligations;
    - When the research project is completed: to return the Samples to HQ at its own expense and provide an attestation of destruction of the Data.

- General clauses
    - Prohibited from using HQ's advertising material or logo;
    - The agreement does not create an employment relationship or a corporation, mandate, joint venture, etc. between the parties;
    - The Researcher undertakes to indemnify HQ against any claim arising from its use of the Samples and Data;
    - Modifications to the agreement must be made in writing and signed by the parties;
    - Agreement governed by the laws of Quebec;
    - Judicial district with jurisdiction to hear any application: Quebec.

APPENDIX 6

External Researcher's Undertaking: Data Management Form

Describe the medium and method for transmitting the Data

Specify the medium/media used by the holder(s) of the Data that will be conveyed to you:

☐ Paper CD

☐ DVD USB Key

☐ Removable medium

☐ Secure link

☐ Others,

specify:_____

_____

_____

Specify the method for sending the medium:

☐ Registered mail

☐ Email

☐ FTP/RTSS

Is the transmitted information encrypted:

☐ Yes ☐ No

If yes: Encryption method

_____

_____

_____

Describe the security measures for the handling and retention of the Data

Indicate where (premises, offices) the information will be retained:

_____

_____

Please identify the security measures in place for protecting access:

- On the premises: ☐ magnetic card ☐ key
- At the work station(s): ☐ password ☐Other, specify _____
- ☐ On-site security officer
- ☐ Other,
  specify_____
  _____
  _____

Describe the method for storing the Data for the duration of its use:

☐ server (network)

☐ stand-alone laptop computer

☐ stand-alone desktop computer

☐ removable medium (USB key, external disk, etc.)

☐ other,

specify_____

_____

_____

Describe the main workstation:

☐ Desktop computer

☐ Laptop computer

Specify whether the computer used is equipped with protective equipment (e.g. firewalls, antivirus, etc.):_____

_____

_____

Attach hereto the list of all individuals who will have access and the reason (Appendix 5 must also be completed and Appendix 7 if applicable).

Describe the procedure for retention and destruction of the *Samples and/or Data*:

_____

_____

_____

_____

_____

APPENDIX 7

External Researcher's Undertaking – Sub-contractor – Form Content

Form to be prepared and sent to the researcher by Héma-Québec and through which the Researcher's subcontractor undertakes:

- *to respect the confidentiality of the Data;*
- *to adhere to the Management Framework; and*
- *to use the Samples and/or Data in a manner consistent with the Biobank's objectives (1.3.2. of the Management Framework).*

That form will be signed by the subcontractor and sent to Héma-Québec before the Samples and/or Data are transmitted to the subcontractor.

APPENDIX 8

Confidentiality agreement - Héma-Québec staff

1. I acknowledge having read and agree to respect the **Management and Governance Framework for the Plasma Donor Biobank – Héma-Québec**.

2. I acknowledge that I will have access, within the general framework of my work, and more specifically while engaged in direct and indirect activities in connection with the Biobank, to confidential information, including the Samples, Data, Personal Information, and Depersonalized information that could be acquired directly or indirectly within the Biobank's activities, and that the protection of such confidential information is an ongoing concern for Héma-Québec.

3. To that regard, while being employed or following the end of my employment, regardless of the cause, I agree to:

    a. Respect and conform to the procedures established by Héma-Québec and take the necessary measures to preserve the confidential nature of the information to which I will have access over the course of my employment;

    b. Withhold from communicating or disclosing any confidential information to unauthorized persons, or to use this information other then for the accomplishment of my work, when required to;

    c. Refrain from copying or withholding copies of documents and confidential information, or removing documents and confidential information from my workplace, unless authorized by Héma-Québec;

    d. Return to Héma-Québec, on demand of Héma-Québec or at the termination of my employment, regardless of the cause, all documents or confidential information to which I had access over my work term;

4. In addition, I confirm having read the **Code of ethics for Héma-Québec's employees** and **Héma-Québec's Politics on intellectual property**, and abide to continue to respect them, without limitations, within the framework of my tasks tied directly or indirectly to the Activities of the Biobanque.

In WITNESS WHEREOF, I have signed on [**DATE**] in [**PLACE**]**:**

HÉMA-QUÉBEC	**EMPLOYEE**
Par: _____	_____
REPRÉSENTANT D'HÉMA-QUÉBEC	**EMPLOYEE**