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| **Management and Governance of a Plasma Biobank Framework** **Draft 27Mar2022***Prepared by the ISBT-TTID Workgroup/SRAP subsection* |
| **Introduction**A biobank is a collection of biological samples, such as blood, and associated information that can be an important part of performing medical research. Biobanks may collaborate with academic or institutional researchers, public health agencies, and industry for their use. Blood centers and similar institutions that collect blood from human donors can provide a unique population to study. As examples, some blood facility biobanks provide blood samples and data for surveillance monitoring during a pandemic outbreak, e.g. SARS-CoV-2; monitoring for certain diseases; or providing blood components and data for other types of research. The decision to establish a biobank as a service requires careful consideration. It really depends on how well a biobank fits as a service within the blood facility’s infrastructure and culture. Once the decision has been made to establish a biobank, there are several publications available that address the development of a biobank, including the [2012 International Society for Biological and Environmental Repositories (ISBER) Best Practices for Repositories](https://www.isber.org/page/BPR). This publication identifies best practices for the collection, storage, retrieval and distribution of biological materials for research. Other general considerations for developing a biobank include:• The type of service the biobank will provide. A biobank may provide samples and data, testing, special recruitment of specific types of samples or blood products depending on the researcher’s needs. • Required resources will need to be identified to develop, maintain and administer the biobank service and database of information. • A biobank governance committee should be created to provide oversite of the biobank. The oversite and management of the biobank may be different depending if it is created for public health use or academic or industry use. • Define any public health partners - these may be local, national or even international public health agencies. In addition, there may be consent nuances regarding the use of the biobank for emergency surveillance in a pandemic situation. • Donor participant considerations will require a broad informed consent where donors are willing to be health research participants. This may include subsequent information requests, consent requests, etc. Another consideration is how the relationship may change from a donor to a health research participant and what that process entails including communication, maintenance of trust, expectations, etc. Consider if participant feedback or community engagement will be included in the process. • Define the data that will be collected. Examples include age, gender, ethnicity, address or postal codes for linkage to a socioeconomic strata; risk factor data collected during the blood collection interview; specialized data requested by public health possibly for an emerging pathogen or public health concern, (e.g., Zika and pregnancy, HEV or biochemical marker studies and diet, travel and Lyme, etc.)• Considerations for specimen provision include the type of specimen in the biobank, e.g. whole blood, plasma, serum, etc. This includes how the material will be stored and where, energy requirements, the number of samples to be stored, and the stability of the samples in storage. There should be strict limits on the usage and access of specimens, including one-time aliquots provided to public health collaborators.• Other items to consider are privacy, ethics and the legal use of donor blood; security and safety of personal data and specimens; regulatory requirements; and safeguards against secondary access. Define the degree of personal identifiers that will be included, will the identifiers be anonymized or pseudo anonymized. Determine if the data will be provided as aggregate or individual data, and if researchers will be allowed to contact individual participants to obtain additional information.• Some other ethical considerations may include the use of biobank material for commercial purposes, such as method development and/or assay evaluation of emerging pathogens, underutilization of biobanks, or equitable access between low and middle-income countries vs high-income countries.• A process will need to be developed for the researcher to request blood and data from the Biobank. The Biobank governance committee should work with the researcher making the request for blood specimens and data. Considerations are how a request is made, how it is approved, what are the ethical considerations, the use of blood and data and if the data provided is aggregate or individual, timelines for maintaining the data, etc.Each facility that decides to establish a biobank may have its own specific requirements and needs. Below is an *example* of a framework for establishing and managing a biobank that can be modified to fit the needs of the individual Biobank. The example is based on the “**Management and Governance Framework for the Plasma Donor Biobank – Héma-Québec”** located at [www.hema-quebec.qc.ca](http://www.hema-quebec.qc.ca). |

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| **Acknowledgement**We thank Dr. Marc Germain and Héma-Québec for permission to use the “**Management and Governance Framework for the Plasma Donor Biobank – Héma-Québec”** as the basis for developing this template.  |
| **Selected References:*** Rigas et al. [2016](https://doi.org/10.1111/voxs.12231) ISBT Science Series provides an excellent example on the requirements, including handling and storage facility, experienced staff committed to biobank operation, information platform, including a secure mechanism for sharing of data with public health and health research participants.
* Williams et al. [2009](http://doi:10.1186/1742-4690-6-98) Retrovirology. Researchers wishing to use biobank samples are provided with an information pack and must obtain a positive ethical opinion and project approval by the governance committee.
* Peeling et al. [2020](https://doi.org/10.1016/S1473-3099%2820%2930461-8). Lancet Infect Dis. Discusses use of biobank material to develop diagnostic methods and/or assay evaluation of emerging pathogens.
* Singh et al. [2022](http://dx.doi.org/10.1136/medethics-2020-106858). J Med Ethics. Concerns regarding inequitable transfer among Low and Middle income countries and High income countries; and underutilization of biobank resources as a common problem and a source of ethical concern for biobankers.
* Management and Governance Framework for the Plasma Donor Biobank – [2021](https://www.hema-quebec.qc.ca/userfiles/file/media/francais/rd/Governance_Framework_Plasma_Donor_Biobank_HQ.pdf), Héma-Québec
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| **Management and Governance of a Plasma Donor Biobank** |
| *Title page***Management and Governance of the Plasma Biobank of XYZ Institution**Anywhere, City, Country*May include key contacts on this page or on a separate page. Examples:*

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| Biobank Responsible Head/Medical Director | *Name and title* |
| Biobank Technical Director/Manager | *Name and title* |
| Biobank Technical Coordinator | *Name and title* |
| Others *(optional)* | *Name and title* |
| External collaborators *(optional)* | *e.g. Public health agencies, tasks forces, etc.* |

 *(May wish to include primary contact name and information, e.g. email, phone)***For further information contact:**Name and title of primary contact AddressPhone and/or email |

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| **Document History**

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| Version Number | Effective Date | Approval |
| Original/ Version 1 |  |  |
| Version 2 |  |  |
| Summary of change/s |
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| Version 3 |  |  |
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|  | Summary of change/s |  |
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| **Definitions** *(Add definitions as they pertain to this document and your organization)* |
| Biobank | An orderly, searchable collection of Samples taken in keeping with this Framework, collected from Donors for research purposes. |
| Biobank activities | Collecting of Samples and Data, creating and opening the Biobank to requests for access to the Samples and Data. |
| Blood Center | Blood center where Samples are collected from the Donor. |
| Data | Information about the Donor, Donor Sample(s) and any information arising from analysis of the Donor Sample(s). |
| Pseudonymised data | 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. |
| External researcher | A researcher not employed by the Blood Center. |
| 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 the Blood Center. |
| Management framework | Management and governance framework for the Donor Biobank developed by the Blood Center |
| 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. |
| Sample | A biological specimen taken from a Donor’s donation in keeping with this Management Framework. |
| SOP | Standard operating procedures |
| Scientific Committee | Committee responsible for assessing the scientific quality and relevance of Biobank-related projects. |

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| **1.0 Description of Biobank** |
| **1.1 Background of XYZ Blood Center** *(insert name of institution)*The XYZ Blood Center *(enter name of institution)* is the national blood center under the Ministry of Health *(fill-in type of institution, e.g. public or private institution, national blood system, hospital, etc.)* in the Country *(fill in name of country or location).* It was established in XXXX *(year)*, and serves a population of XXX *(fill in information)*. The primary mission of the XYZ Blood Center is to provide a safe and adequate supply of blood and blood components to support those patients in need of transfusions *(fill in your institution’s mission).*The XYZ Blood Center collects over XXX volunteer blood donations, including XXX whole blood and XXX apheresis donations *(customize to your institution)*. We serve XX hospitals in XX regions, distributing over XXX human-derived biological products, i.e., blood, plasma, stem cells, human tissues, and breast milk on an annual basis *(list types of biological products provided).*The services at XYZ blood center currently includes a scientific research institute focused on advancing blood safety *(Customize to your institution)*. The Biobank *(insert name of Biobank)* is an extension of that service and was established to support other scientific research by providing high-quality human biological materials from volunteer blood donors including serum, plasma and whole blood samples, etc. *(list offering)* for research purposes. *(Modify or add other information about the Biobank)* Blood donors provide a unique population to study for research purposes. Blood donors are a large cohort of healthy individuals who donate on a regular basis and are interested in helping further medical research. This group of volunteer donors are well suited for large prospective population health cohort studies. In addition, XYZ Blood Center has an existing infrastructure that allows for the recruitment, collection, preparation and testing of donor samples and associated demographic information that can be useful for research studies. *(Provide other information to support the biobank, the use of blood donors and blood center infrastructure for research purposes)*. |
| **1.2 Description of the Biobank and objectives** |
| **1.2.1 Description***(Describe the Biobank, e.g. samples collected, source of donors, geographic distribution, demographic and/or other available data)*The XYZ Biobank *(insert name of Biobank)* is located at XXX *(enter if same location or different location from Blood Center)* and maintains a repository of plasma samples. Samples are collected during each donation from volunteer blood donors. Each donor provides written permission to collect additional samples for research purposes and/or specifically dedicated to the Biobank. These donors include both whole blood and apheresis donors *(specify if plasma samples are collected from specific donors, e.g. plasma donors only)* that donate at our XX *(enter number)* collection centers. The collection centers are located in … *(add locations or names of collection centers).* Samples are collected in addition to those samples that are used for donor testing purposes *(Indicate if collection of samples is different)*. All donations are tested for evidence of infectious pathogens, i.e., HIV, HCV, HBV and syphilis, *(Add other infectious disease markers, as applicable)* and must be negative prior to their release as Biobank samples. Plasma samples consist of approximately X mL *(add volume)* and are stored frozen at -80°C *(enter temperature)*. Donor demographic and other personal information are stored on a secure server within the Blood Center. Data specific to fill Biobank requests are pseudoanonymized and maintained on a separate server at the Biobank location. Backed up data is store off-site *(Modify as necessary).*  |
| **1.2.2 Objectives**The objectives of the Biobank are:* To build a cohort of frequent donors *(modify if limited to plasma donors)* who consent to their blood samples being used in research studies.
* To systematically collect and store these samples in the Biobank repository.
* To develop and maintain a secure database that will contain certain information pertaining to the Biobank donors.
* To allow internal and external researchers to have access to the Biobank’s samples and data for conducting scientific studies as approved by the Biobank’s Steering Committee.
* To ensure diligent management of the Biobank, comply with all local, state/regional *(modify as applicable)* and national regulatory requirements, including privacy and confidentiality rules, and to ensure the robustness of the process for assessing the scientific quality of proposed studies/projects.
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| **2.0 Governance and Management Structure** |
| The Biobank’s governance and management structure consists of the following members:* Medical Director
* Steering Committee
* Governance Committee
* Scientific Committee
* Research Ethics Committee

*Can include a flow diagram to illustrate how each committee interacts with one another**The following section describe the roles and responsibilities of each*  |
| **2.1 Responsibilities***Describe each title, roles and responsibilities - can include individual’s name*  |
| **2.1.1 Medical Director**The medical director of the Biobank is *name, title* and chairs the Steering Committee. The role of the medical director is to provide oversight and ensure that the activities of the Biobank are carried out properly according the facility’s policies and procedures. These activities include the collection, storage and use of the Biobank samples and data, and that donor confidentiality is protected according to applicable regulatory, legal and ethical requirements. |
| **2.1.2 Steering Committee**Members of the Steering Committee include: *(The makeup of the membership is based on the Biobank structure)** *Add names and titles*

The Steering Committee is responsible for ensuring the establishment and operational management of the Biobank. The Biobank Manager is responsible for the day-to-day operations.The Technical Coordinator is responsible for receiving, storing, categorizing and handling the Biobank samples.The Analyst is responsible for managing and analyzing donor data. |

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| **2.1.3 Governance Committee**Members of the Governance Committee represent various expertise to help the Biobank achieve its objectives. The membership consists of: *(The makeup of the membership is based on the Biobank structure)** *Add names and titles, including any collaborating external organizations (e.g. Public health agency), as applicable.*

The Governance Committee’s role is to ensure that the Biobank activities are carried out in a manner consistent with its objectives, as stated in section 1.2.2., including proper management of the Biobank, legal and regulatory compliance for donor confidentiality, and the robustness of the process for assessing the scientific quality of projects. |
| **2.1.4 Scientific Committee**The Scientific Committee is responsible for reviewing and approving all research project requests for obtaining access to the Biobank samples and data.Members may vary according to a submitted project request and the level of expertise required for assessing a project request. Members may be physicians, nurses, epidemiologists, biostatistician, XYZ Blood Center researchers/scientists, specialist, etc. External expertise may be included. At least *X* number of members are required to review each project request, with the majority from XYZ Biobank/Blood Center. *(May include list of name, titles and expertise).*Approval of project requests are based on the following requirements:* Alignment to the Biobank’s mission and objectives.
* Scientific validity and relevance
* Feasibility and risk level
 |
| **2.1.5 Research Ethics Committee**The Research Ethics Committee is responsible for the review and ethical approval of all research projects involving the Biobank of XYZ Blood Center. The Research Ethics Committee reports to XYZ Board of Directors *(indicate to whom).* The Research Ethics Committee has a major role in the research approval process, including the ethical assessment of research project requests for Biobank samples and data. |

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| **2.2 Reports and renewals** *Indicate any requirements, if applicable (e.g. Research Ethics Committee, licenses, etc.)*The Steering Committee must obtain a renewal of the Research Ethics Committee approval of the XYZ Biobank on an *X (e.g. annual, bi-annual, etc.)* basis. The Steering Committee must attach a report of the Biobank’s activities to the renewal request. The report will include *(e.g., annual report)*: * Total number of samples in the Biobank
* Number of new samples since last report
* Number of samples withdrawn to fill project requests since the last report
* Number and list of project requests since the last report
* Any noteworthy events that occurred since the last report
* Statement/budget to illustrate sufficient funding to continue the administrative and operational management of the Biobank for the renewal period
 |
| **2.3 Funding source***Describe how Biobank is funded* |
| **2.4 Procedures for modifying the management framework***Describe any requirements, approvals needed when making modifications to this management framework. Include how revisions will be documented.* *Are there exceptions to revising the appendices?*From time-to-time, revisions may be required to the management framework for improving the activities of the Biobank and/or for regulatory or legal reasons. All modifications will follow the policies and procedures according to XYZ Blood Center Quality Management Systems for Document Control and Recordkeeping. Modifications will be approved by the Medical Director, Quality and the Research Ethics Committee.The content of the Appendices may be modified by the Steering Committee without approval by the Research Ethics Committee provided that the modifications do not have a significant impact on the scope of the Management Framework or the Biobank’s objectives. |

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| **3.0 Collecting, retaining and using the biobank’s samples and data** |
| * 1. **Collecting samples and data**
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| * + 1. **Donor eligibility**

At the time of donation, all eligible whole blood and plasma donors *(indicate if different)* are invited to participate in the Biobank. Minimum criteria include: *(list donor requirements)**Age**Weight**Hemoglobin**In good health as determined by XYZ Blood Center donor questionnaire and interview SOPs (Or may list minimum requirements)**Can also include main exclusion criteria, if desired*  |
| * + 1. **Donor consent**

*Describe how donor consent is obtained (signed consent form – separate or part of donor history record, electronic capture, etc.)**Provide an example of the consent in the appendices*At the time of donation, whole blood and plasma donors *(specify if different or only plasma donors)* donating at XYZ Blood Center(s) are provided information about the potential use of their blood samples for the research purposes on a voluntary basis. A pamphlet or fact sheet (Appendix 1) *(indicate what type of written information is provided to the donor)* is provided with information about the Biobank, if tubes of blood are collected, how the samples may be used for medical/scientific research, the sharing of anonymized data, and the option to participate in further studies. The donor will be provided the opportunity to verbally ask questions during the donor interview process. If the donor agrees for their samples to be used for research purposes, documentation of their consent (Appendix 2) will be captured by written signature on the donor record (donation card) and/or electronically in the donor management computer system *(enter name of electronic system) (indicate how consent is captured).*Refusals for the use of their blood to be used for research purposes will be documented electronically in the donor management computer system *(enter name of electronic system).* |
| * + 1. **Withdrawal of consent or death of donor**

*Describe how donor can withdraw their consent to use their samples**Describes what happens in the event of a donor’s death**Include country specific requirements**Describe how is the request documented**Describe what happens with the samples and data** + - 1. **Withdrawal of consent**

A donor can decide at any time to withdraw their consent to participate in the collection of samples and data for the Biobank. The donor’s request will be documented on a XYZ Biobank Withdrawal form (Appendix 2) and captured electronically in the donor management computer system *(enter name of electronic system)*. The Collection staff *(indicate who will be responsible)* will notify the Biobank Manager where the refusal will be entered in the Biobank software system *(Indicate name of software)*. All existing samples associated with the donor will be destroyed. In the event that some of the previously collected samples and data associated with the donor are used in a study, the remaining samples and data will be retained until the end of the study. In such case, the Biobank will notify the donor (Appendix 2).**3.1.3.2 Donor death**In the event of the death of a donor, the samples and data can be used; however, no subsequent requests will be made of the donor’s family for obtaining additional information. |
| * + 1. **Sample and data collection procedure**

*Briefly describe and include the procedure in the appendices**Describe if the Biobank has any special arrangements with the Ministry of Health or other agency to collect additional relevant information abo*ut donors. *If any, may wish to include a copy of the agreement in the appendices**Describe if an special questionnaires or other tools are used to collect donor data*Once the donor consent has been obtained to participant in the Biobank, an extra tube of whole blood or plasma will be collected from the donor during the donation process. The standard procedures for sample and data collection will be followed (Appendix 2.2 and 2.5, respectively).Additional data may be obtained from the donor depending on special signed agreements between the Biobank and government agencies *(insert name, e.g. Ministry of Health).*Targeted questionnaires may also be used as part of studies that have been approved by the Biobank’s Scientific and Research Ethics Committees. |

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| * 1. **Retention and use of samples and data**
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| * + 1. **Sample and data matching and retention**

*Describe what measures are in place to ensure that the samples and data are kept confidential and secured.**Describe who has access (e.g., of database, physical location or hardcopy of records).**Describe how sample security is maintained, including emergency backup power systems, who has access or storage freezers, how long are samples retained.*Donor samples and data collected are kept confidential and secure.A unique (coded) number is assigned to each donor sample and associated data prior to storage. This information is maintained by the Analyst who is responsible for protecting the information. Once a project has been approved, a new code is assigned to the samples and data which are sent to the internal or external researcher *(This information is only true if the Biobank plans to double code the samples and data).* Samples and data are encrypted before being shared with an external researcher *(This information is only true if the Biobank plans to encrypt)*.No personal information is sent as part of the request. Only the Analyst and Biobank Manager will have access to the database that contains the donors’ personal information *(indicate who will have access)*. Access to the database is protected by user ID and password. All other Biobank personnel will have access only to depersonalized information.The physical location where samples are stored is in a restricted, locked area with access only to authorized staff. All sample storage freezers are connected to an electronic temperature monitoring system and to emergency backup power.The Technical Coordinator and Biobank Manager may coordinate the selection and shipping of samples to internal or external researchers once the project request has been approved. An agreement is signed between the researcher and the Biobank Manager. A confidentiality agreement (Appendix 3) must be signed by any internal or external researcher and by any other individual who may have access to the samples and data.Access to Biobank samples and data will be maintained for at least two years *(indicate length of time)*. The retention time will be re-evaluated each time during the renewal of the Biobank by the Research Ethics Committee or if the operation of the Biobank activities cease. |

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| **4.0 Responsibilities of Biobank Users** |
| **4.1 Research project approval process***Describe the process for a Researcher to access the Biobank’s samples and data**Describe if there are additional requirements with an External Researcher vs. an Internal Researcher**Describe if a confidentiality agreement is required. May include a copy in the appendices*Internal or External Researchers wishing to have access to the Biobank’s Samples and Data must submit a research protocol (Appendix 4) for approval from the Scientific Committee and the Research Ethics Committee. The Scientific Committee and the Research Ethics Committee will assess the alignment to the Biobanks mission and objectives, scientific validity and relevance, feasibility and ethical acceptability of the research protocol. External Researchers are responsible for obtaining any additional approvals as required by their organization. A copy of their organization’s ethics committee approval will be provided to the Biobank as part of the submission process.Upon approval of the proposal and prior to release of Biobank Samples and Data, the authorized responsible party for the research will be required to sign a confidentiality agreement. |
| * 1. **Use of samples and data**

*Describe what information is provided to the Researcher, e.g. anonymized only**Describe if any requirements for use of data for publications or other purposes*Request for access to the Biobank’s Samples and Data must include a written study proposal describing the research to be performed (Appendix 4). The proposal must address the confidentiality of the Data, use of the Samples and/or Data in a manner consistent with the Biobank’s objectives. Only anonymized data will be provided to the Researcher upon approval of the proposal request. In addition, the Researcher must 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.  |

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| **4.3 Management of incidental findings and communication with donors** |
| *Determine what constitutes an incidental finding (i.e., a condition that is treatable; a heritable condition/trait, etc.)**Describe how incidental findings from an External Research may be addressed**Describe the procedure that describes if/how a donor will be notified, how confidentiality is maintained, etc.**Include if a special consent is required for donors to provide/not provide this information, Include an example in the appendices*Data collected for establishing and managing the Biobank are not intended to provide medical or health information to the donors. Donors participating in the Biobank program are informed that the data collected cannot be used to make clinical decisions. General information about the scientific research conducted and the results will be available in scientific publications *(Include where else this information may be found, e.g. Blood Center website).*However, incidental findings from the research project may arise. An incidental finding is defined as observations, results, or other findings that may occur as a result of the research project, e.g. a condition that is treatable, a heritable condition or trait. Due to the confidentiality rules and anonymization of donor data provided to the researcher, the researcher would be unable to contact the donor. Therefore, the researcher must communicate notification of incidental findings to XYZ Blood Center *(Indicate who/where notification is given to at the Blood Center)*.The XYZ Blood Center has a process and procedures in place for donor follow-up. Follow-up by the XYZ Medical Department *(enter who does the follow-up)* is either with the donor and/or with their attending physician *(Enter how donor follow-up is addressed)*.External Researchers must include in their submitted proposals the possibility of incidental findings pertaining to the donors and the procedure for notifying the Blood Center. |

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| * 1. **Intellectual property and publication of results**

*Describe Researcher contract language that addresses intellectual property**Include language in the contract to address publications by Internal/External Researchers, e.g., if the Biobank and/or staff should be acknowledged with regards to access of the Samples and/or data*The Steering Committee is responsible for assessing 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. *(This may be related to local governmental requirements).*The assessment includes: * Identify the type of Intellectual Property Assets that will be produced or acquired as part of the Biobank’s Activities and
* Determine the potential for using the identified assets making use of the Intellectual Property Assets identified.

Based on the results of the assessment, XYZ Blood Center will decide how to use the Intellectual Property Assets. The decision made by XYZ Blood Center must be included in writing in all research agreements (Appendix 5, Section 5.1.4).Any publication by an Internal or External Researcher who directly or indirectly used the Biobank’s Samples and/or Data must mention XYZ Blood Center’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 XYZ Blood Center staff will be acknowledged in keeping with the practices that apply in scientific publishing.Publicly sharing the scientific data resulting from the Biobank is not authorized. |

**APPENDICES**

**APPENDIX 1. Donor information**

* 1. *Pamphlet or fact sheet with information about the Biobank*
	2. *Provide an overview of how donors are recruited*
	3. *Include any inclusion/exclusion criteria*

**APPENDIX 2. Procedure for collecting and managing the Biobank’s samples and data**

* 1. Location of Biobank
		1. *Describe sample storage location and how accessed*
		2. *Describe data storage and how confidentiality is maintained*
	2. Collecting and managing samples
		1. *Describe sample type and collection procedure*
		2. *Describe process for managing deviations from the sample collection and management (optional)*
			1. *Include example worksheet if tracking required (example below)*

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| **Sample Collection and Management Deviations** |
| **Date** | **Donor number** | **Description of deviation** | **Initials** |
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* 1. Donor consent sheet to participate in Biobank
		1. *Include example*
	2. Managing refusals to participate and destruction of samples – internal SOP
		1. *Biobank withdrawal form*
		2. *Describe how refusals are recorded/documented*
		3. *Describe procedure for destroying samples*
			1. *Include example of donor notification (for samples in current study)*
			2. *Include example worksheet if manual tracking required (example below)*

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| **Destruction of Samples** |
| **Date** | **Donor number** | **Reason for destruction** | **Initials** |
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* 1. Data collecting
		1. *Provide information on infectious disease screening and what tests are performed*
		2. *Vaccination information, if applicable, e.g. COVID-19 vaccine*
		3. *Include list of sociodemographic data available*
		4. *Other data collected pertaining to research needs, e.g. targeted questionnaire*
	2. Registry of Data-sharing agreements
		1. *Describe type of data shared, e.g. Ministry of Health*

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| **Date of agreement** | **Organization** | **Type data shared** | **Custom requests** |
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* 1. Biobank’s Financial support letter
		1. Provide a copy

**APPENDIX 3. Confidentiality agreement – Internal employees**

**Add your own institution’s confidentiality agreement for employees**

**APPENDIX 4. Submitting a project proposal template**

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| **1.0 Title page/General information** |
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| **Title of the project:** |
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| --- | --- |
| **Lead Researcher** | *Enter name and title* |
| **Organizational affiliation and address** | *Enter* |
| **Collaborators and affiliations** | *Enter* |
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| **INTERNAL USE ONLY** |
| **Action** | **Date** |
| Date submitted to the Scientific Committee |  |
| Date accepted by the Scientific Committee |  |
| Date submitted to the Research Ethics Committee |  |
| Date approved by the Research Ethics Committee |  |

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| 1. **Research Protocol**
 |
| **2.1 Description of project in which samples and data will be used** |
| **2.1.1 Summary of project and its objectives** *Enter a short description* |
| **2.1.2 Scientific quality/originality***Provide background, literature review, hypothesis, objectives, method, statistical analysis, experimental method, expected results* |
| **2.1.3 Project relevance, including the use of samples and data, in accordance with the Biobank’s objectives as described in the Management and Governance Framework (Section 1.2.1)***Indicate* |

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| **2.2 Anticipated Deliverables***Describe* |
| **2.3 References***List* |
| **3.0 Schedule and Required Samples** |
|  |
| **Project start date:** | *Enter projected start date* |
| **Duration of project:** | *Enter anticipated length of project* |

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| **Samples required:** |
| Total number required | *Enter number of sample requesting* |
| Volume for each sample | *Enter volume* |
| Profile of donor for whom samples are required | *Indicate:*[ ] single donor[ ] longitudinal samples[ ] sex [ ]M [ ] F[ ] age, indicate range[ ] region of origin[ ] other, describe |

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| **4.0 Information for Ethical Assessment** |
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| --- | --- |
| Laboratory/location where project will take place | *Enter location* |
| Total number of samples requested | *Enter from Section 3.0* |
| Data related to samples/donors required for project | *Indicate*[ ] single donor[ ] longitudinal samples[ ] sex [ ]M [ ] F[ ] age, indicate range[ ] region of origin[ ] other, describe |
| Justification of need for data: |
| Ethical approval of the Researcher’s institution.*Provide proof from the Researcher’s institution of the project approval for which the samples are requested.* |
| How is privacy and confidentiality of samples and data maintained in accordance with the objectives of the Biobank as stated in the Management and Governance Framework? Refer to Appendix 6 |
| List any analysis that will be performed as part of the project that may lead to any incidental findings? If so, include a sample letter that will be sent by XYZ Blood Center *(enter name)* to the participant in the event that a result may require donor follow-up. |
| Will the project include questionnaires? If yes, attach the questionnaire. |
| Sample preservation and destruction. Refer to Appendix 6*Describe the duration, place of preservation, method of tracking and destruction of samples.* |
| List any specific ethics related points that should be brought to the attention of the Biobank’s Research Ethics Committee: |
| *Attach proof of acceptance of the project by the Research Ethics Board of your institution.**Attach any other relevant documents.**Submit the word version and a pdf version for review with your application.* |
| **Researcher’s signature** |  |
| **Date** |  |

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| **FOR XYZ RESEARCH ETHICS COMMITTEE USE ONLY:** |
| **Decision** | **Date** |
| [ ] Submission approved |  |
| [ ] Submission refused\* |  |
| [ ] Request for clarification\* |  |
| [ ] Request for modification\* |  |
| [ ] Approval deferred\* |  |
| [ ] Conditional approval\* |  |
| \*Provide explanation to decision, if applicable |
| Signature of Ethics Committee Representative and title |  |

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| **APPENDIX 5 Management and Use of the Biobank by an External Research** |
| **5.1 Researcher’s agreement**Approval of the Biobank’s Samples and Data require the Researcher to abide by the following requirements. |
| **5.1.1 Ethics*** Adhere to XYZ Blood Center’s *(fill in name)* rules of ethics and the Management Framework
* Adhere to the Researcher’s own institution’s rules of ethics
* Provide a copy of the Researcher’s own institutions ethics approval required by the research project
 |
| **5.1.2 Use of Samples and Data*** To maintain confidentiality, including
* Obtaining written agreement of confidentiality of all employees with access to the Samples and Data as part of the research project
* Under no circumstances are the data to be used by the Researchers to attempt to identify or contact the Donors
* To use the Samples and Data for research purposes only
* To cover the cost of transporting the Samples and Data from the Biobank
* To ensure the security of the Samples and Data through adequate storage processes and technology
* In the event of a security breech involving the Samples and/or Data, to notify XYZ Blood Center *(fill in name)*  immediately
* To destroy the Samples and Data in keeping with the Project-related destruction schedule and confirm in writing the destruction to XYZ Blood Center *(fill in name)*
* Samples and Data are prohibited from being transferred or used for non-research purposes
* To follow the procedure for transferring Samples and Data to third parties under contract, including:
	+ A signed confidentiality agreement
	+ Use for research purposes only
	+ Inform XYZ Blood Center *(fill in name)* of the transfer, including identity of the subcontractor
	+ Proof that the subcontractor is committed to the Management framework and the requirements as outlined in Appendix 6 and 7
 |

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| **5.1.3 Incidental Findings*** A procedure for the handling of incidental findings will be included in the research protocol
* To inform XYZ Blood Center *(fill in name)* of incidental findings pertaining to Donors.
 |
| **5.1.4 Intellectual property*** The biobank 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 research project
* Waiver of Intellectual Property Rights based on an analysis of identifying the Intellectual Property Assets
* To notify XYZ Blood Center *(fill in name)* of the filing of patents arising from the use of the Samples and Data
 |
| **5.1.5 Publication of research results*** To mention XYZ Blood Center’s *(fill in name)* contribution
* To respect the confidentiality of the Samples and Data
* To inform XYZ Blood Center *(fill in name)* of any publication arising from the use of the Data
 |
| **5.1.6 End of the agreement*** Termination clause for the benefit of XYZ Blood Center *(fill in name)* in the event that the Researcher fails to fulfill his/her obligations
* When the research project is completed, to return Samples to XYZ Blood Center *(fill in name)* if xx mL volume is remaining,at its own expense and provide a written attestation of destruction of the Data
 |
| **5.1.7 General*** Prohibited from using XYZ Blood Center *(fill in name)* 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 XYZ Blood Center *(fill in name)* against any claim arising from its use of the Samples and Data
* Modifications to the agreement must be made in writing and signed by both parties (Researcher and XYZ Blood Center *(fill in name)*)
* Agreement is governed by the laws of *state country*
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| I have read the above list of requirements and understand my responsibilities as they pertain to the use of the Samples and Data for my research project.  |
| **Research signature** | **Date** |
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| **APPENDIX 6. External Researcher’s Data Management** |
| **6.1 Transmitting of data***Describe the type of media to be used to transfer Data to the Researcher.*[ ] DVD USB Key[ ] Removable medium[ ] Secure link[ ] Other, specify:  |
| **6.1 Method for sending the medium**[ ] Registered mail[ ] Email[ ] FTP/RTSSIs the transmitted information encrypted?[ ] No[ ] Yes, describe: |
| **6.2 Security measures*** Describe the security measures for handling and retention of the Data. Include the location (premises, offices, etc.) where the information will be retained.
* Identify the security measures in place for protecting access to data:

[ ] On the premises:[ ] Magnetic card key[ ] Traditional key[ ] At the workstation:[ ] Password protected[ ] Other, specify: [ ] On-site security officer[ ] Other, specify:* Describe method for storing the Data for the duration of its use:

[ ] Server (network)[ ] Stand-alone laptop computer[ ] Stand-alone desktop computer[ ] Removable medium, e.g. USB key, external disk, etc.[ ] Other, specify:* Describe the main workstation:

[ ] Desktop computer[ ] Laptop computerSpecify if the computer used is equipped with protective equipment, e.g. Firewalls, antivirus software, etc.): |
| **6.3 List of all individuals who will have access to the Data**

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| **Name** | **Reason for access** |
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| **6.4 Retention and Destruction of Samples and/or Data**Describe the procedure for retention and destruction |

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| **APPENDIX 7 External Researcher’s Subcontractor Agreement** |
| *Each subcontractor shall sign this form.*As a subcontractor working with *name of researcher,* I agree to the following:* Respect to the confidentiality of the Data
* To adhere to the Biobank’s Management Framework
* To use the Samples and/or Data in a manner consistent with the XYZ Biobank’s *(fill in name)* objectives:
	+ To build a cohort of frequent donors (*modify if limited to plasma donors*) who consent to their blood samples being used in research studies.
	+ To systematically collect and store these samples in the Biobank repository.
	+ To develop and maintain a secure database that will contain certain information pertaining to the Biobank donors.
	+ To allow internal and external researchers to have access to the Biobank’s samples and data for conducting scientific studies as approved by the Biobank’s Steering Committee.
	+ To ensure diligent management of the Biobank, comply with all local, state/regional (modify as applicable) and national regulatory requirements, including confidentiality rules, and to ensure the robustness of the process for assessing the scientific quality of proposed studies/projects.

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| **Name of subcontractor** | **Signature**  | **Date** |
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