CHAIN BIOBANK GOVERNANCE, INTERNAL REGULATIONS AND POLICIES 2023-2024

Prepared by: Executive Commission

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INDEX

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1. Mission

The Comprehensive Health Biobank (CHAIN Biobank) is a collaborative initiative led by the Comprehensive Health Research Centre (CHRC) and the NOVA Medical School|Faculdade de Ciências Médicas of Universidade Nova de Lisboa (NMS|FCM). Its main mission is to be a supporting tool for biomedical and clinical research, as a bank of human biological samples and a database of scientific data information. This project aims to contribute to the development and enhancement of novel research in health and promote collaboration between several clinical and/or research centers.

Principal aims:

- Support researchers in the development of SOPs, experimental design, sample processing, and analysis.
- Sample storage, maintaining an optimized Quality Management System (QMS) to ensure the highest quality control (QC) and quality assurance (QA) of samples and treatment processes.
- Guarantee the confidentiality and protection of donor data and samples.
- Conduct activities in accordance with national and international legal and ethical guidelines.
- Build human biological samples collections with high value for the scientific and medical community and provide national and international collaborations.

2. Concepts and general procedures

A human sample is any sample of biological material that contains nucleic acids, where the characteristics of the individual are present. The sample has a dual nature, on one hand it is a biological sample, as it is part of the individual's body, on the other, it is a source of information since data will be extracted from its analysis.

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There are several definitions of biobank, all of which assume that it is a collection of biological samples and/or human tissues and related information, stored long-term identified by a code.

According to Portuguese legislation (article 19 of Law no. 12/2005, of January 26) a "bank of biological products" means any repository of biological samples or their derivatives, with or without a limited storage time, whether using prospective collection or previously collected material, whether obtained as part of routine health care provision, or in screening programs, or for research and which includes samples that are identified, identifiable, anonymized or anonymous."

The collection of biological samples from a donor requires that the donor is previously informed about the implications of the decision and expresses free and informed consent freely or disinterestedly on this issue, signing the informed consent.

Prior to collecting personal data and biological samples, the donor must be informed about some fundamental elements for the decision, namely:

- the existence of a database containing clinical information and who will have access to the information, as well as the measures taken to guarantee its confidentiality.
- the mandatory or optional nature of answering the questions that will be asked.
- the implications of accepting or refusing data collection.
- the possibility and consequences of refusing consent or, in the case of collection, revoking it.
- the purpose of collecting the samples and the type of research to be carried out, as well as potential risks/benefits for the donor.

In the case of collecting samples from donors who have some degree of disability, or are minors, informed consent will be the responsibility of their legal representatives. Even after accepting the conditions present in the document and collecting the sample, the right to biological material remains

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the property of the donor, article 3rd of Law 12/2005, of January 26, and the right to revoke consent is safeguarded, as described in Article 18 of the same Law. However, according to the National Ethics Council for Life Sciences, and considering that article 20 establishes that the human genome is a Common Heritage of Mankind, the samples collected for the CHAIN Biobank must also be considered the responsibility of the entity that collects them after signing the informed consent by the donor. Therefore, signing informed consent is mandatory for obtaining and using biological material, following the regulations described in the Law.

The biological material must be collected according to the procedures described in the collection protocols and the sample must be collected and processed appropriately for its intended purpose.

When the sample enters the CHAIN Biobank, registration must be completed, and a code assigned to the sample. At the same time, a restricted access database will be created with the decoding of the sample designation and data relating to the donor, in accordance with the regulations of the National Commission for Data Protection and General Data Protection Regulation (EU GDPR).

The samples will be stored with the aim of preserving their integrity and allowing future uses for the most varied purposes. Data anonymity is guaranteed at all stages of the process. This procedure will be described in greater detail later.

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3. Governance Structure

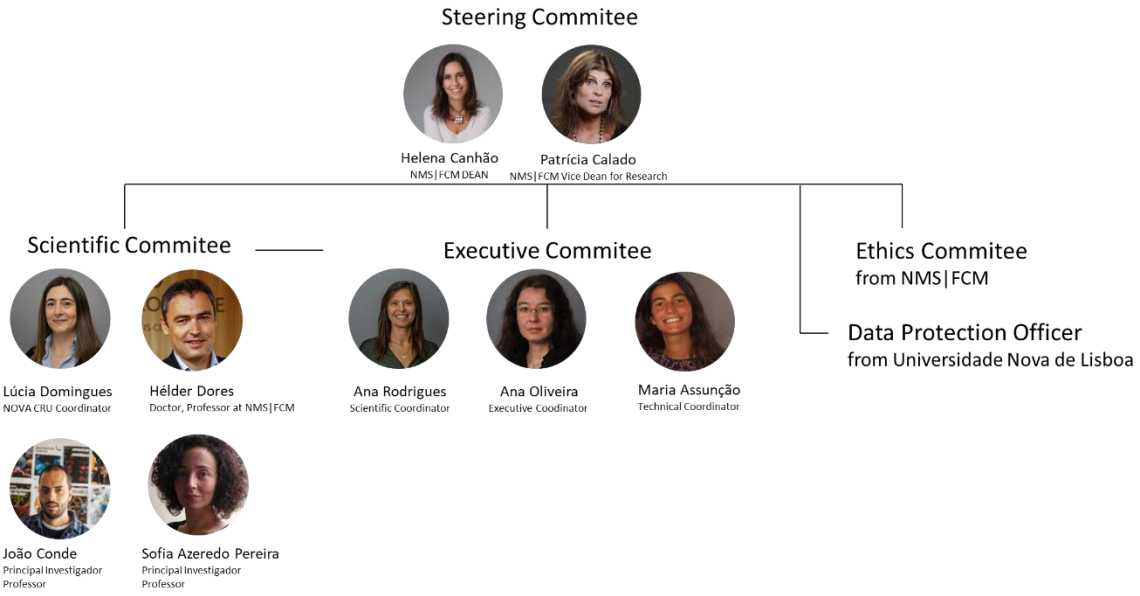

Figure 1. CHAIN Organizational chart.

The **Steering Committee** is composed by:

- Helena Canhão, NMS|FCM Dean
- Patrícia Calado, NMS|FCM Vice Dean for Research

The **Steering Committee** is responsible for:

1. Establish sustainability and growth strategies for CHAIN Biobank in partnership with the executive committee.
2. Develop and validate the structure and management of the CHAIN Biobank.
3. Ensure compliance with current legislation.
4. Approve the annual activity plan and report.
5. Promote CHAIN Biobank to external organizations and the internal community.
6. Approve the annual financial report
7. Approve the annual communications report.

The **Executive Committee** is composed by:
- Ana Oliveira, Executive Coordinator/ Coordinator of Research Infrastructures Operations NMS Research
- Ana Rodrigues, Scientific Coordinator
- Maria Assunção Technical Coordinator

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The **Executive Coordinator** is responsible for:

1. Ensure the sustainability of CHAIN Biobank.
2. Develop, in partnership with the scientific and technical coordinator, the CHAIN Biobank activity plan.
3. Ensure that the use of the samples has scientific relevance and is in accordance with the purpose for which informed consent was obtained and has been approved by the Scientific Committee.
4. Represent CHAIN Biobank in all processes and interactions with public or private entities, including other national and international Biobanks.
5. Coordinate the functional integration of the different areas of CHAIN Biobank.
6. Supervise infrastructure maintenance and ensure proper operation.
7. Supervise communication with the Financial, Legal, and Communication department of Nova Medical School.
8. Ensure compliance with safety regulations.
9. Monitor execution and financial viability.
10. Contribute to the decisions on CHAIN Biobank growth strategies.
11. Provide guidance in determining current pricing in collaboration with the Financial Service of NMS|FCM.
12. Supervise internal and external communication about CHAIN Biobank activities.
13. Prepare an annual activity report, together with the scientific coordinator and technical coordinator.
14. Give a comment the annual financial report.

The **Scientific Coordinator** is responsible for:

1. Ensure the sustainability of CHAIN Biobank.
2. Develop, in partnership with the executive director and technical coordinator, the CHAIN Biobank activity plan.
3. Ensure that the use of samples has scientific relevance and is in accordance with the purpose for which informed consent was obtained and has been approved by the Scientific Committee.
4. Represent CHAIN Biobank in all processes and interactions with public or private entities, including other national and international Biobanks.
5. Analyse researchers' requirements and requests together with the technical coordinator.
6. Decide, together with the Technical Coordinator, which collections will be part of the CHAIN Biobank.
7. Supervise the quality, safety, and traceability of data and samples.

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1169-056 Lisboa · Portugal

8. Supervise clinical and phlebotomy teams in collecting samples.
9. Identify problems related to data collection.
10. Ensure compliance with ethical regulations.
11. Supervise the organization and filing of clinical information in the database.
12. Prepare an annual activity report, together with the scientific coordinator and technical coordinator.
13. Give a comment on the annual financial report.

The **Technical Coordinator** is responsible for:

1. Ensure the sustainability of CHAIN Biobank.
2. Develop, in partnership with the executive director and scientific coordinator, the CHAIN Biobank activity plan.
3. Ensure that the use of samples has scientific relevance and is in accordance with the purpose for which informed consent was obtained and has been approved by the Scientific and Ethics Committee.
4. Represent CHAIN Biobank in all processes and interactions with public or private entities, including other national and international Biobanks.
5. Analyse researchers' requirements and requests together with the scientific coordinator.
6. Decide, together with the scientific Coordinator, which collections will be part of the CHAINBiobank.
7. Provide information about the CHAIN Biobank.
8. Ensure the quality, safety, and traceability of data and samples.
9. Ensure the correct entry and management of data in the LIMS database.
10. Ensure compliance with current legislation.
11. Ensure compliance with ethical regulations.
12. Develop and keep SOPs updated in accordance with the respective ISO standards *(International Organization Standardization*).
13. Supervise laboratory teams and the quality control procedures.
14. Identify problems related to sample processing and storage.
15. Ensure compliance with sample safety and storage regulations.
16. Provide consultancy services to researchers in the preparation of Research projects.
17. Develop and send the material transfer agreements for sample transfer to the Vice-Dean for Research for approval (in accordance with the "*Despacho de Competências*").
18. Maintain a record of CHAIN Biobank activities.
19. Manage queries and complains.

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1169-056 Lisboa · Portugal

20. Acquire equipment and materials necessary for the operation of CHAIN Biobank.
21. Ensure billing for services.
22. Prepare an annual activity report, together with the scientific coordinator and executive coordinator.
23. Prepare an annual financial report.
24. Prepare an annual list with collection specifications.

Scientific Committee, will be made up of the scientific coordinator and 4 other members nominated by the Steering Committee for a period of 4 years. Nominated members:
- Hélder Dores, doctor, and NMS|FCM professor
- João Conde, principal investigator, and professor at NMS|FCM
- Lúcia Domingues, NOVA Clinical Research Unit Coordinator
- Sofia Azeredo Pereira, principal investigator,and professor at NMS|FCM

The scientific committee is responsible for:
1. Scientifically evaluate the samples requests.
3. Provides scientific guidance to CHAIN Biobank to ensure the highest quality of service, resources, and infrastructure.

Nova Medical School Ethics Committee (EC), is responsible for monitoring, with impartiality and independence, compliance with CHAIN Biobank's legal and ethical guidelines.

Data Protection Officer (DPO) of Universidade Nova de Lisboa (UNL), will be responsible for ensuring the implementation of the data protection strategy in accordance with Law nº 58/2019, of 8 August, which transposes Regulation (EU) nº 679 /2016, of April 27th, relating to the General Data Protection Regulation (GDPR).

4. Deposit Policy

The deposit of samples in CHAIN Biobank and respective clinical information may arise from projects that have already been completed, with samples already collected, or from new projects with samples yet to be collected. In addition to these projects, whose collection responsibility lies with the Principal Investigator (PI) or depositor, there is also the possibility of donations

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where the responsibility for these samples is or becomes the responsibility of CHAIN Biobank, as described in section 4.3 of this document.

Nevertheless, in any case, all publications made based on samples provided by CHAIN Biobank must make explicit reference to the fact. CHAIN Biobank must be informed of publications that resulted from the use of the CHAIN Biobank human biological samples.

The deposit of these collections in CHAIN Biobank generally follows the process outlined in Figure 2.

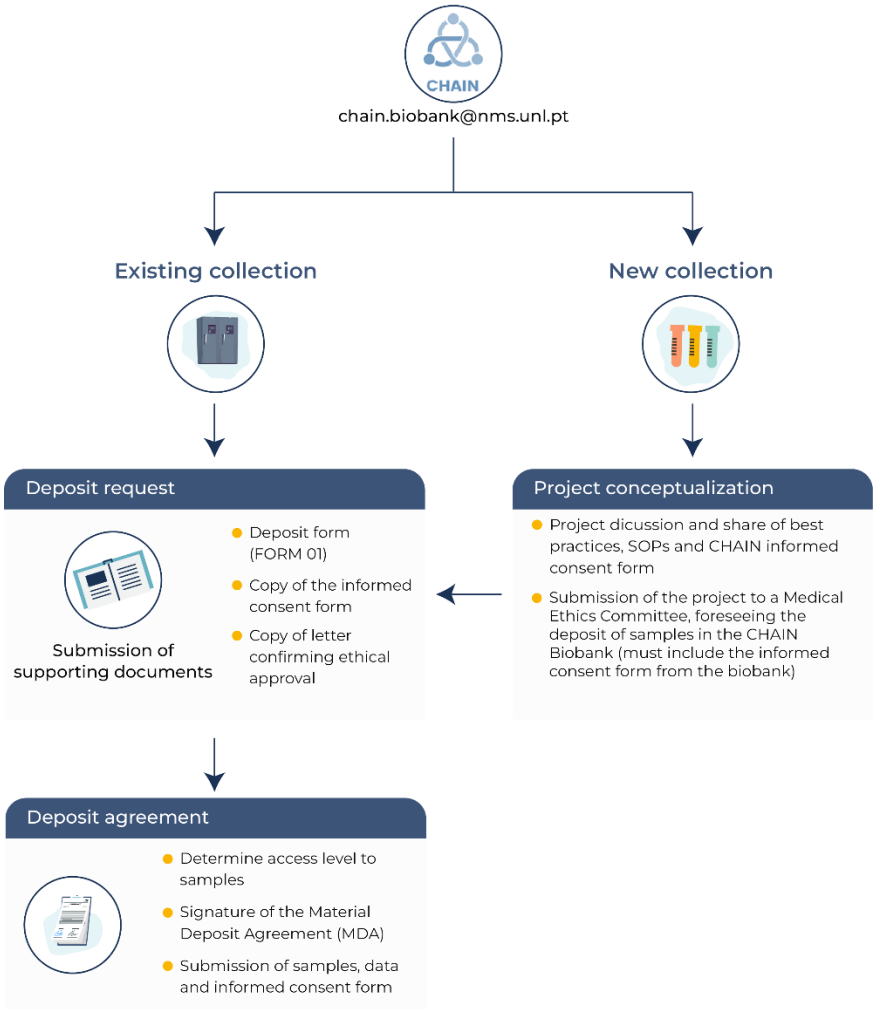

Figure 2. Sample deposit procedure.

4.1 Existing collections

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This is the case where the collection already exists and comes from a research project completed or ongoing.

To deposit the PI/depositor must establish a first contact with CHAIN Biobank. CHAIN Biobank will send the deposit rules described in the Material Deposit Agreement (MDA), and the deposit form (FORM 01) so all necessary documentation is sent to the collection depository.

These samples, collected within completed/ongoing projects can be integrated into the CHAIN Biobank if the research project has been previously approved by an EC for Health and the participants have signed an informed consent to collect the biological sample. The deposit form (FORM 01) requests a summary of the project, a copy of the approval of a Health ethics committee, copy of the informed consent, and some information about the material to be deposited, namely whether the samples are accompanied by a detailed record of clinical data, sample type, and number, number of participants, collection procedure, storage conditions, history of freezing cycles and the available clinical data. The project will be evaluated whether the informed consent (IC) allows secondary studies or whether the samples can only be used for the project for which they were collected and then destroyed. If the Informed Consent does not allow the use of samples in other projects, the possibility of the responsible doctor asking the donors to sign the CHAIN Biobank informed consent will be discussed.

After a positive evaluation for the deposit, CHAIN Biobank will contact the PI to sign the Material Deposit Agreement (MDA) and discuss the access restriction policy (table 1) and if there is a need for additional services such as transportation and/or processing.

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1169-056 Lisboa · Portugal

4.2 New Collections

New collections are samples collected in the aim of new projects.
In this case, after a first contact, CHAIN Biobank, should ensure that samples will be collected following Good Clinical Practice (GCP) and that the CHAIN Biobank IC is signed by the donor, as it is already suitable and approved by the ECs for the future use of the deposited samples. Therefore, CHAIN Biobank must send the MDA, the SOPs, and the biobank informed consent.
In these projects, for submission to an ethics committee, it must be described in the project that the samples will be collected in accordance with Good Clinical Practices and deposited in the CHAIN Biobank and the informed consent of the CHAIN Biobank attached. All these procedures are the responsibility of the PI/depositor.

At this point the access level of the samples will be discussed and the need or not of other services beyond storage, like transportation and/or processing services. Another crucial aspect for consideration involves the valorisation of the research project's results. If the generated results are anticipated to be instrumental in the creation of a new tool or technology that can significantly contribute to the advancement of medical and scientific knowledge or benefit healthcare, health and/or wealth of the population or a specific group of individuals, this possibility should be explicitly stated in the informed consent document. The informed consent containing this information will be subject to approval by the Ethics Committee. Simultaneously, the Principal Investigator (PI) or depositor stands to benefit from the technical support provided by the Innovation and Value Creation Office of the NOVA Medical School.

After approval by an Ethics committee, the PI/depositor must send the deposit form (FORM 01) to CHAIN Biobank for formal approval and send a quotation. Finally, the MDA must be signed, and the samples and clinical

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1169-056 Lisboa · Portugal

data transferred.

4.3 Donations

CHAIN Biobank can establish protocols with Hospitals for sample collection. According to this protocol, part of the samples collected can be donated to CHAIN Biobank. In this case, there must always be a prior approval by the Biobank Scientific Committee and the NMS|FCM Ethics Committee. Furthermore, samples must be accompanied by the CHAIN Biobank informed consent and respective clinical data. In this case, the appropriate SOPs are guaranteed by CHAIN Biobank, and the collections responsibility is attributed to the Biobank in the person of the Scientific Coordinator.

4.4 Sample access levels

When depositing samples, the PI/depositor can choose between three levels of restriction for their sample access;

- Green (free access); enables the unrestricted access to the samples;
- Yellow (restricted access); in which the PI is available to consider sharing samples upon a demonstration of interest.
- Red (total restriction); samples are totally restricted to others for during the project development, for a maximum period of 5 years. A more detailed description of these access levels and their characteristics is described in table 1.

Tabel 1. Access levels

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Access levels	Characteristics of the access restriction
Green	The PI/depositor of the collection offers free access, without restrictions to their collection. The Depositor will always be notified in advance about the interest and intention on the collection utilization. Information about the samples will be made publicly available and can be advertised. No deposit-associated fees.
Yellow	The PI/depositor restricts access to their collection during the duration of the project or up to 5-years from the start of the project. At the end of this period, the access restriction is re-evaluated by both the BIOBANK and the PI responsible for the collection. The BIOBANK has the right to advertise this collection. The DEPOSITOR is available to reconsider sharing the collection with other PI. The BIOBANK will notify the DEPOSITOR in case of interest by other PIs. No deposit associated fees.
Red	The PI/depositor restricts access to their collection during the duration of the project or up to 5-years from the start of the project. At the end of this period, the access restriction is re-evaluated by both the BIOBANK and the PI responsible for the collection. The BIOBANK has no right to advertise this collection. The PI/depositor must pay a deposit fee. 50% of the fee should be paid in moment of deposit and the other 50% in the moment of requisition of samples. NMS and CHRC researchers are free of fees until the end of 2024.

5. Request Policy

When interest arises in using CHAIN Biobank samples, the researcher must contact CHAIN Biobank via email (chain.biobank@nms.unl.pt) or telephone (+351) 214956435 ext.27025. The request follows the steps outlined in figure 3.

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1169-056 Lisboa · Portugal

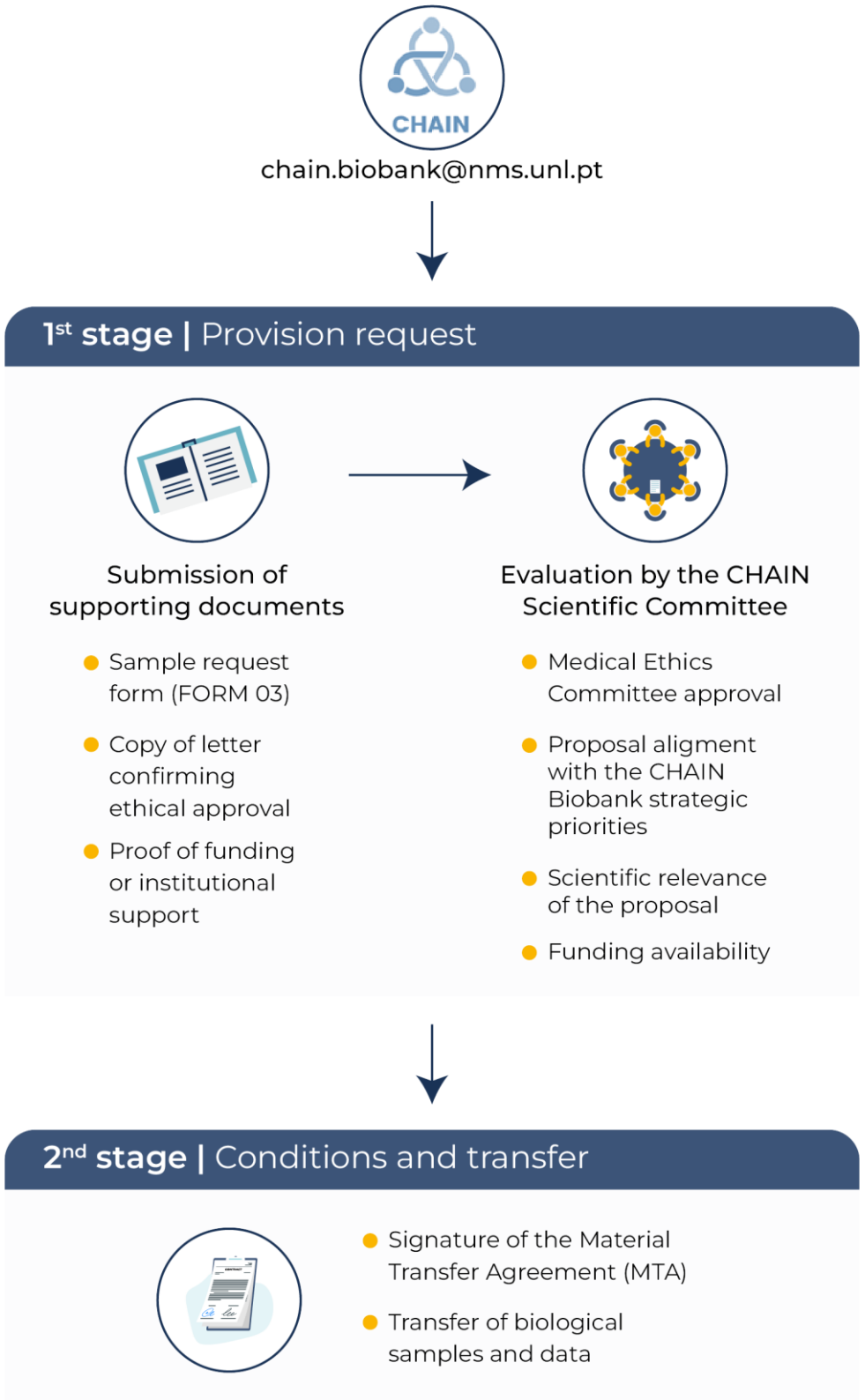

Figure 3. Sample request procedure.

Campo Mártires da Pátria, 130
1169-056 Lisboa · Portugal

The researcher interested in the samples must send the sample request form (FORM 03) with the project description. It requests information on the responsible PI, proof of funding, institutional support, and a brief description of the project. This document will subsequently be sent to the Scientific Committee for evaluation, which will provide a response within a maximum period of four (4) weeks after the date of submission of the request. CHAIN Biobank will contact the PI/depositor responsible for the samples, even in the case of a green deposit, so that the PI responsible for the sample is aware and can express interest in collaboration, or if the sample access level is yellow or red, to authorize or not the sharing samples or clinical data.

Rules for evaluation by the Scientific Committee

The Scientific Committee will evaluate the requests based on the following criteria:

- Must be approved by the Ethics Committee for Health
- Scientific relevance
- Relevance to CHAIN Biobank priorities/strategy
- Financial support

It is CHAIN Biobank's responsibility to notify the Investigator/requestor about the decision of the scientific committee and inform about the rules for access to the collection, and rules for the transfer, use, and destruction of samples at the end of the project. All this information is described in the Material Transfer Agreement (MTA) that will be signed before the transfer.

6. Data Protection Policy and Security Conditions

The personal data protection at CHAIN Biobank follows the General Data Protection Regulation (GDPR), Law No. 58/2019, of august 8, which transposes Regulation (EU) No. 679/2016, of april 27. This regulation aims to increase the protection of European citizens' personal data, as well as transparency and accountability in its use.

Campo Mártires da Pátria, 130
1169-056 Lisboa · Portugal

Thus, and in accordance with the GDPR, informed consent, which must be signed by the donor must guarantee that:

- The donation is free, and consent is not provided as a precondition for a service or benefit.
- The consent is presented separately from other information given to the patient, such as clinical or other.
- Consent is comprehensive and informative: all donors must receive information about how CHAIN Biobank will use their material to support health research that goes in line with the public interest.
- The donor has the right to ask CHAIN Biobank any questions and withdraw informed consent at any time, for any reason. CHAIN Biobank must, in these cases, delete the data and samples from that donor.
- Consent must be clear, mentioning the specific purposes for which it is intended as the type and nature of the research in which the participants had to agree to before signing the form.
- CHAIN Biobank does not, in any circumstance provide personal data to Researchers that could be used to identify donors.

The informed consent used by CHAIN Biobank guarantees these principles and has been previously approved by the legal department and the DPO.
When samples and donor information enter the CHAIN Biobank, the technician enters the data into the LIMS platform and the computer system assigns a code to the donor and a code to the samples. The information that allows sample traceability must be stored in a different location than clinical data and access will be restricted to members of the Executive Committee. Clinical data cannot, under any circumstances, contain names, initials, dates of birth, or any term that identifies the donor. If donor identification is necessary, only the Technical, Clinical, and/or Executive Coordinators of CHAIN Biobank will have access to do so. This reversal of anonymization will be carried out in very specific cases, i.e., if it is found that a certain result can

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1169-056 Lisboa · Portugal

benefit the donor's health or after the donor requests the deletion of the samples.

CHAIN Biobank does not transmit results directly to the donor but works with the responsible doctor who transmits the test results to the donor.

Therefore, CHAIN Biobank guarantees compliance with the GDPR, namely article 89, and uses pseudo-anonymization by assigning a code to the samples and that the personal identifiers are removed from the data provided to Researchers. Additionally, the material transfer agreement (MTA) requires that the use of materials transferred to Investigators must be for research purposes only and applied to the approved project.

6.1 Safety Conditions

The CHAIN Biobank facilities are in the yellow building of the NMS|FCM Research Center located at Rua do Instituto Bacteriológico nº 5 in Lisbon, with access control to the building and surveillance present on site. The laboratories and sample storage cabinets have restricted access. Only the CHAIN Biobank and surveillance team have access to these spaces. The cold equipment has remote temperature monitoring probes and there is a back-up freezer where the deposited samples can be moved in case of failure. Samples stored at room temperature will be kept in safety cabinets with control access.

The data will be saved using LIMS software, LabCollector, ensuring compliance with applicable standards, namely ISO 20387:2018, GDPR, and good practices described by ISBER.

This software allows to manage samples from delivery to departure, as well as store all the information associated with each sample. It provides a flexible model for configuring and automating information and allows different users to have different levels of access to the database (for example, can view data but not modify, can view and modify data, can view code, etc..).

6.2 Storage Period

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1169-056 Lisboa · Portugal

The biological material is stored for a period of 25 years, and the quality of the collections is assessed by sampling every 2 years. In this way, only collections and/or samples that meet the required quality levels will be maintained. If a sample is deleted, this information must be registered on the LIMS Platform and clinical and personal data will be deleted. Collections with yellow or red access levels are evaluated after 5 years and their access level is reviewed.

7. Quality Control Policy

Biobanks require security and trust and, to achieve this, they must follow the highest quality standards.

Compliance with the requirements and procedures, processes, and specifications presented in the standards ISO (International Organization Standardization) allows SOPs procedures to be developed and tasks to be performed in a consistent and reproducible manner.

For the success of CHAIN Biobank, it is essential to follow the defined SOPs, maintaining the quality of storage facilities, pre-analytical processing tools, staff training and good governance and management policy.

The Quality Management System (QMS) is guaranteed through compliance with ISO 20387:2018 standards for Biobanks and ISO 9001:2015 for Quality Management System. Biobanks must always be able to demonstrate that they follow the best practices in both data and sample management and their handling and storage, so CHAIN Biobank has Registration Control, Quality Control, and Quality Assurance procedures as can be seen in the following sections.

7.1 Record

There will be an internal record of all procedures performed, with the date, name of the technician, and any changes to the SOP with due justification.

The information must be registered in the NMS|FCM Cloud and there must be a copy on the NMS|FCM server that will be updated monthly. This information includes documentation related to sample collection, sample

Campo Mártires da Pátria, 130
1169-056 Lisboa · Portugal

processing, deposit or transfer of samples (MDA and MTA), and proof of shipping.

List of documentation that must be kept in duplicate and in a secure space:

- SOPs.
- Quality certificates.
- Instrument calibration record.
- Maintenance and repair records.
- Documentation of external and internal audits and evaluations.
- Registration of training for technical staff.
- Form and spreadsheet templates.
- Signed informed consent.
- Signed collaboration agreements, MDA and MTA.

Annually, the risks and opportunities and ways to improve the services provided by CHAIN Biobank must be included in the activity report.

The executive committee must meet annually with the NMS|FCM Board (Steering Committee) to discuss the report and propose concrete action plans for the continuous improvement of the CHAIN Biobank.

Procedures must be reviewed every 2 years to ensure and improve CHAIN Biobank practices.

Internal audits will also be carried out every six months with a blind test of 20 samples to assess their quality and periodic external audits. The international biobank organization, International Society for Biological and Environmental Repositories (ISBER) has launched a biobank proficiency testing program for external assessments that can be used by CHAIN Biobank.

7.2 Quality Control

To guarantee the quality of the samples, there are minimum information requirements that are described in the Deposit Policy, namely, detailed record of clinical data, collection procedure, storage conditions, history of freezing cycles, and other information considered relevant by the PI.

Campo Mártires da Pátria, 130
1169-056 Lisboa · Portugal

Furthermore, the technical parameters for evaluating the Quality of the samples are described in Table 3 and will be used for both deposit and collection, when requested.

Table 3. Samples criteria for quality control.

Samples	Quality parameter
Blood	• Processing time up to 4 hours. • Absence of coagulation
Serum/Plasma	• Processing time up to 4 hours, • Absence of erythrocytes
Other Biological Fluids	• Processing time up to 4 hours • No colour change
DNA	• Contamination: A260/A280 >1,8 e <2 and A260/230 >1.7 • Integrity: PCR
RNA	• Contamination A260/A280 >1,8 e <2 and A260/230 >1.7 • Integrity: RIN or agarose gel and or RT-PCR of reference genes

All equipment must be periodically maintained/calibrated according to manufacturers' requirements. All interventions carried out must be recorded on a specific form.

7.3 Quality Assurance

Quality is guaranteed by the standardization of the methods through Standard Operating Procedures outlined following the best international practices and the current national and international legislation. The SOPs, forms, and legal documents used by CHAIN biobank are attached to the document and listed in Table 4.

The training of Laboratory Technicians and compliance with the SOPs is guaranteed by the Technical Coordinator.

Table 4 – Standard Operating Procedures (SOPs) and International Organization for Standardization (ISO) for technical procedures.

Campo Mártires da Pátria, 130
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#	Title	Description	Version
STANDARD OPERATION PROCEDURE			
SOP 00	TEMPLATE	SOP template.	PT/EN
SOP 01	SAMPLE RECEPTION	This SOP defines the protocol for receiving and recording the entry of samples for processing and/or storage in the Biobank.	PT/EN
SOP 02	DOCUMENT MANAGEMENT	This SOP defines the general principles to be used by Biobank to ensure that records and documents are managed with standardized procedures in a clear, accurate and secure manner.	PT/EN
SOP 03	SAMPLE SHIPPING	This SOP defines the protocol for sending and recording the output of samples for processing and/or to customers.	PT/EN
SOP 04	BLOOD COLLECTION AND TRANSPORT	This SOP defines the protocol for collecting and transporting blood to the Biobank.	EN
SOP 05	BLOOD PROCESSING AND STORAGE	This SOP describes how blood and blood products should be processed, recorded, and stored.	EN
SOP 06	DNA EXTRACTION FROM BLOOD AND DERIVATIVES	This SOP describes how to extract DNA from blood samples using a kit with columns.	EN
FORMs			
FORM 01	SAMPLE DEPOSIT	This form must be used by the Investigator to request sample/data deposit.	PT/EN
FORM 02	SAMPLE RECEPTION	This form is used by CHAIN to record sample entries and unique code assignments.	PT/EN
FORM 03	SAMPLE REQUEST	This form must be used by the Investigator to make the deposit request.	PT/EN
FORM 04	SAMPLE SHIPPING	This form is used by CHAIN to record the localization and volume of samples to be shipped.	PT/EN
LEGAL DOCUMENTS			
IC	INFORMED CONSENT	The CHAIN Biobank Informed Consent must be signed by donors in projects that intend to store the collected samples or part of them in the Biobank. This document describes the legal and ethical conditions for sample collection, storage, and use.	PT/EN
MDA	MATERIAL DEPOSIT AGREEMENT	The MDA is the legal agreement made between the Investigator and the Biobank for the deposit of material in the Biobank. This document contains all information about the material to be deposited and the deposit conditions.	EN
MTA	MATERIAL TRANSFER AGREEMENT	The MTA is the legal agreement made between the Investigator and the Biobank for the transfer of material from the Biobank to the Investigator. This document contains all information about the transferred material and the transfer conditions.	EN
ISO STANDARDS			

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ISO 20387	Biotechnology — Biobanking — General requirements for biobanking	This document specifies the general requirements for the competence, impartiality, and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality. In the case of CHAIN Biobank, it is applicable to biobanking of human biological material for biomedical research and development purposes.	EN
ISO 20186-1	Molecular in vitro diagnostic examinations. Specifications for pre-examination processes for venous whole blood Part 1: Isolated cellular RNA	This document gives guidelines on the handling, storage, processing, and documentation of venous whole blood specimens intended for cellular RNA examination during the pre-examination phase before a molecular examination is performed. This document covers specimens collected in venous whole-blood collection tubes.	EN
20186-2	Molecular in vitro diagnostic examinations. Specifications for pre-examination processes for venous whole blood Part 2:Isolated genomic DNA	This document gives guidelines on the handling, storage, processing, and documentation of venous whole blood specimens intended for genomic DNA examination during the pre-examination phase before a molecular examination is performed. This document covers specimens collected in venous whole-blood collection tubes.	EN
20186-3	Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell-free DNA from plasma	This document provides recommendations and requirements on the handling, storage, processing, and documentation of venous whole blood specimens intended for circulating cell-free DNA (ccfDNA) examination.	EN
23118	Molecular in vitro diagnostic examinations - Specifications for pre-examination process in metabolomics in urine, venous blood serum and plasma.	This document provides recommendations and requirements on the handling, storage, processing, and documentation for metabolimcs analysis in urine, venous blood, serum and plasma.	EN

8. Pricing and Services Policy

There are no anticipated costs related to equipment maintenance or fees related to the professionals involved. However, to ensure the Biobank's sustainability, there is a storage cost paid upon deposit or requisition.

NMS and CHRC researchers are free of charge during the two implementation years (2023 and 2024). These agreements will be reviewed individually after this period.

8.1 Deposit

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The PI responsible for the collection should establish access restrictions at the time of deposition. The green and yellow level of restriction is free of charge.

The PI who wants to deposit samples at the red access level will have to pay 50% of the total budgeted amount. This amount can be paid in full, at the beginning of the project, or annually during the agreed project years (3 to 5 years). The remaining 50% must be paid at the time of collecting the samples.

Table 5. Deposit Fees.

Storage	**(€/aliquot/month)** *
Storage at -80 °C	0,30
Storage at room temperature	0,10

* NMS and CHRC researchers are free of charge during the implementation years (2023-2024).

8.2 Requests

If the PI has not paid to deposit samples, the request for samples has a fee of 1 (one) euro per aliquot requested.

8.3 Other Services

The biobank also offers sample processing services.

Tabel 6 – Service Fees.

Services	**(Unit)**
Blood processing	1,0
Urine and Faeces processing	1,0
Serum and Plasma separation	1,0
DNA and RNA extraction	7,5
PCR and qPCR analysis	7,5
Other services upon request	
Ex: PBMCs isolation	upon request
Ex: Tissue processing for storage	upon request (Histology facility)

Besides these services, the CHAIN users can request any other services available in the NMS Research Infrastructures (https://www.nms.unl.pt/pt-pt/investigacao/servicos-e-infraestruturas). Also, we can provide sample

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collection and sample transport upon request.

The CHAIN Biobank has the right to change the fees presented here at any time.

9. Equipment and documents

- Freezer - 80°C
- Freezer -20
- Room temperature cabinet
- Rapid freezing unit (recipient for liquid nitrogen transport)
- Flow chamber
- Centrifuge
- Thermocycler for PCR/ RT-PCR
- Labels printer
- 2D barcode reader
- LIMS Software - LabCollector

Documents supporting the elaboration of this document

- ISO - 20387, International Standard - Biotechnology — Biobanking, General requirements for biobanking, 2018
- OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009.
- ISBER, Best Practices for Repositories Collection, Storage, Retrieval, and Distribution of Biological Materials for Research, 2012.
- IARC, Common Minimum Technical Standards and Protocols for Biobanks dedicated To Cancer Research recommendations guidelines for Biobanks, 2017
- Law n.º 58/2019, of 08th of August - Personal Data Protection Law
- EU General Data Protection Regulation (GDPR) n.º 2016/679, 27th of April
- Law nº 12/2005, Personal genetic information and health information

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