

Material Deposit Agreement

Under the terms of the present human Material Deposit Agreement (MDA) ("Agreement"), the Principal Investigator/others ("Depositor") agrees to deposit human biological samples collection ("Collection") and associated data ("Data"), in CHAIN Biobank ("Biobank") of NOVA Medical School, NOVA University Lisbon (collectively referred to below as "Institution"). The Biobank, which is responsible for receiving, storing, and transference the samples, according to the specified Standard Operating Procedures (SOP), to potential users ("THIRD PARTIES"), under the following terms and conditions.

SECTION I – DEFINITIONS

- a. COLLECTION: CHAIN Biobank's Collection.
- b. DEPOSITOR: natural or legal person who deposits HUMAN BIOLOGICAL SAMPLES in the custody of the COLLECTION.
- c. MATERIAL: HUMAN BIOLOGICAL SAMPLES, PROGENY, a UNMODIFIED DERIVATIVES. The MATERIAL shall not include MODIFICATIONS.
- d. HUMAN BIOLOGICAL SAMPLES: that which was supplied to the COLLECTION by the DEPOSITOR. The HUMAN BIOLOGICAL SAMPLES is described on the DEPOSIT FORM.
- e. PROGENY: unmodified descendant from the HUMAN BIOLOGICAL SAMPLES, such as cell from cell, or organism from organism.
- f. UNMODIFIED DERIVATIVES: substances created by the RECIPIENT which constitute an unmodified subunit of the MATERIAL.
- g. MODIFICATIONS: substances created by the RECIPIENT using the MATERIAL, which are not HUMAN BIOLOGICAL SAMPLES, PROGENY or UNMODIFIED DERIVATIVES, and which have new properties.
- h. RECIPIENT: The person or institution who requests a sample of material provided by the COLLECTION. The recipient is submitted to the terms and conditions of the COLLECTION's Material Transfer Agreement defining the terms and conditions applicable to the use, handling, and

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transfer of the material.

i. DEPOSIT FORM: official form of the COLLECTION recording the minimum data set of administrative, technical, and scientific information enabling the unambiguous identification of the HUMAN BIOLOGICAL SAMPLES. The DEPOSIT FORM is an integral part of the MATERIAL DEPOSIT AGREEMENT.

SECTION II - COLLECTION DEPOSIT

To be fill by the Biobank

DEPOSIT FORM N°:	(Annex I)
Number of samples to deposit:	
Date of deposit*:	
Type of deposit: One time / _____ deposits during a period of time of _____months.	
Brief Description:	

**This could be the date the biological material was received, or a later date, depending on the Collection's procedures.*

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Documents providing evidence of legal access in the Country of Origin and providing terms for use of the MATERIAL

Is the original material or the source sample subject to an International Recognized Certificate of Compliance (IRCC, see definition under Part II below)?

- YES, the IRCC number: _____
- NO, but I am providing relevant information and/or copies of documents at my disposal, namely:
Prior Informed Consent (PIC) or other sampling authorization (e.g., permit):
 - YES (attach document)
 - NO, because _____
 - Not applicable, because _____

Reference, document identifier(s):

Competent authority, landowner (including i.a., nature management body) or other person who authorized sampling (e.g. PIC, or permit)

Name and address/website:

Mutually agreed terms (MAT) or material transfer agreements (MTA)

Copies of documents settling details of any agreed benefit sharing arrangements or other form of agreements between initial provider and recipient (you, or person or persons before you) will be needed.




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SECTION III - DEPOSIT TERMS AND ACCESS LEVELS

1. The DEPOSITOR is willing to permanently deposit the HUMAN BIOLOGICAL SAMPLE in the custody of BIOBANK. BIOBANK has the right to preserve, to study and to process the MATERIAL under the terms and conditions specified in this MDA, including storage, cultivation, amplification, replication, and/or transfer.
2. The DEPOSITOR confirms that he/she has acquired or obtained, lawfully the HUMAN BIOLOGICAL SAMPLE and that nothing has come to its attention that impairs its right to transfer the HUMAN BIOLOGICAL SAMPLE to BIOBANK. More specifically and if applicable the DEPOSITOR will observe the laws and regulations applicable in Portugal.
3. The DEPOSITOR accepts the terms and conditions of the MDA by effectively transferring the HUMAN BIOLOGICAL SAMPLE in the custody of BIOBANK and filling in the DEPOSIT FORM.
4. The Ethics Committee of the NMS will evaluate each request for deposit of a collection of human biological samples, unless previously obtained.
5. BIOBANK receives and is willing to keep the HUMAN BIOLOGICAL SAMPLE in custody. BIOBANK will assign a unique identifier to the MATERIAL and record it in catalogue. If previously agreed with the DEPOSITOR, BIOBANK will make data and information concerning the HUMAN BIOLOGICAL SAMPLE publicly accessible.
6. BIOBANK makes every effort to ensure optimal preservation of the MATERIAL. It is understood that biological material is subject to contingencies, therefore no express or implied warranties are given as to the preservation of the MATERIAL in time.
7. The storage of the deposited collection at the Biobank will be carried out during five (5) years from the date of this Agreement. After this period, the Biobank's Scientific Committee will discuss the relevance of

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maintaining this collection and the access levels will be reevaluated with the principal investigator. After the five (5) year period, if the principal investigator does not reply to the biobank contact after 6 months, the access level of the collection will be automatically transfer to the green level. If the relevance or quality of the deposited collection is compromised at any time.

<p>Green</p> 	<p>The PI/depositor of the collection offers free access, without restrictions to their collection.</p> <p>The Depositor will always be notified in advance about the interest and intention on the collection utilization.</p> <p>Information about the samples will be made publicly available and can be advertise.</p> <p>No deposit associated fees.</p>
<p>Yellow</p> 	<p>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.</p> <p>The BIOBANK has the right to advertise this collection.</p> <p>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.</p> <p>No deposit associated fees.</p>
<p>Red</p> 	<p>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.</p> <p>The BIOBANK has no right to advertise this collection.</p> <p>The PI/depositor must pay a deposit fee. 50% of the fee should be</p>

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	paid in moment of deposit and the other 50% in the moment of requisition of samples.
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The maximum time expected to store the sample is twenty (25) years.

Table 1 - Access level description

8. The DEPOSITOR has the right to impose restrictions on access to their collection deposited in the biobank, in accordance with the following access levels:

9. The DEPOSITOR may alternatively specify the access restrictions that they consider appropriate to their deposited collection.

Please specify:	
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10. The DEPOSITOR shall pay the fees related to the access level chosen and the services required, if applicable, as agreed in the quote herewith in **annex II**.

SECTION IV - SAMPLES TRANSFER

11. BIOBANK is allowed to use, handling, and transfer the MATERIAL to third party and/or use them for its own purpose, in accordance with the access restrictions outlined in this Agreement and under the terms and conditions specified in BIOBANK's Material Transfer Agreement (MTA) published on the Biobank website.

12. The MATERIAL will be transferred under the responsibility of BIOBANK in compliance with all applicable laws and regulations. The DEPOSITOR recognizes that BIOBANK may charge THIRD PARTIES a fee, corresponding to the processing and storage costs associated with the transfer of human biological samples deposited in the biobank, and that BIOBANK shall not charge an additional fee for the Original Material

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itself.

13. Transfer of samples must meet the following conditions:
 - (a) Each request for transfer of samples from a deposited collection will be evaluated by the scientific committee of BIOBANK. The DEPOSITOR will be accordingly notified.
 - (b) In the case that the collection is deposited with a YELLOW or RED access level (see section III, point 1), or other subjectively defined restrictions (see section III, point 2), the DEPOSITOR will be notified by the biobank to provide written authorization to transfer the samples of the deposited collection for the REQUESTER. The depositor must communicate the decision in writing to the biobank within fifteen [15] working days from the date of the request. The DEPOSITOR has the right to accept or deny a request made by THIRD PARTIES, provided that their decision is duly justified.
14. The DEPOSITOR makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose.

SECTION V - ASSOCIATED DATA

15. The DEPOSITOR acknowledges that BIOBANK may need to transfer the information or copied documentation to THIRD PARTIES, if required by law or by the Access and Benefit Sharing (ABS) best practice and as far as it is not confidential. Except for data provided by the DEPOSITOR that are confidential, DEPOSITOR authorizes BIOBANK to include all data and documentation in the COLLECTION's databases and strain catalogue, if applicable, and DEPOSITOR also authorizes the release of the MATERIAL for transfer and associated data for public viewing.

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16. The DEPOSITOR will provide the Associated Data to BIOBANK in paper or digital format.

17. BIOBANK is committed to using the Associated Data in accordance with Article 89 of the General Regulation of Data Protection (RGDP) [Regulation (EU) 2016/679 of the European Parliament and of the European Commission, of April 27, 2016] using pseudo-anonymization (coded data) and according to the principle of data minimization (provide as little data as possible).

18. If applicable, the Data (and deposited samples collection) may have to be accompanied by a copy of the relevant Informed Consent.

19. In what concerns Intellectual Property Rights and Industrial Rights (IPR) (except for moral rights) CHAIN Biobank shall be considered the owner of the MATERIAL. Therefore, CHAIN Biobank grants to the DEPOSITOR and the RECIPIENT (if applicable) a revocable, worldwide, royalty-free, non-exclusive, non-transferable license (but not any ownership rights) to use the MATERIAL for the Permitted Purpose, subject to the terms and conditions of the MTA. Nevertheless, The DEPOSITOR shall own the IPRs in their Findings, the Results Data and the Other Data. The DEPOSITOR hereby grants a perpetual, irrevocable, worldwide, fully paid up, royalty free, fully sub-licensable non-exclusive license to CHAIN Biobank to use, handling, transfer, publish, store and otherwise disseminate the Findings, the Results Data and the Other Data..

20. The RECIPIENT retains ownership of:

(a) MODIFICATIONS

(b) Findings and research data, both generated by RECIPIENT by the use of the MATERIAL or MODIFICATIONS

If either 2 (a) or 2 (b) results from the collaborative efforts of the DEPOSITOR and the RECIPIENT, joint ownership may be negotiated.

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Overall, the DEPOSITOR and the RECIPIENT (if applicable) agree that all publications made based on samples provided by CHAIN Biobank must make explicit reference to the fact. CHAIN Biobank must be informed after delivery of the samples, of the publications that resulted from their use (directly or from the MODIFICATIONS)

SECTION VI - RESPONSIBILITY

21. BIOBANK is responsible for disclosing, through its Annual Report, the information on the deposited collections, the DEPOSITORS and, in case of transfer, the respective THIRD PARTIES.

22. BIOBANK shall not be liable for any act or omission hereunder, including without limitation in connection with any alteration, damage or losses to any MATERIAL delivered to BIOBANK, even if BIOBANK is advised of the valuable nature of such MATERIAL.

23. BIOBANK shall only be responsible (as between the DEPOSITOR and BIOBANK only) for the direct and actual costs of any loss, damage, alteration, cost or expense arising from BIOBANK's receipt, storage, replication or transfer of the MATERIAL only to the extent, and in proportion, to the liability caused by the intentional misconduct or gross negligence of BIOBANK and for any third party claim of damage, injury, death or consequence related to the MATERIAL as a result of BIOBANK's gross negligence or intentional misconduct, after any such time as the gross negligence or intentional misconduct has been determined by a court of competent jurisdiction. In no event shall BIOBANK, its agents, and its successors, and their respective directors, officers, members, employees, and agents be liable for any indirect, special, punitive, or consequential damages arising from the use, alteration, or loss of the MATERIAL.

24. DEPOSITOR authorizes BIOBANK to assess the status of the samples for internal/external quality evaluation. Whenever the

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DEPOSITOR requests a sample, the sample shall be subject to the payment of a fee in the amount of the prices in force at the BIOBANK.

SECTION VII - TERMS AND CONDITIONS

25. Neither this Agreement nor any rights or obligations contained herein are assignable, whether by operation of law or otherwise, without the prior mutual consent of the DEPOSITOR and BIOBANK.

26. The DEPOSITOR shall be responsible for preparation and shipping costs related to the MATERIAL transfer.

27. This MDA constitutes the entire agreement between The DEPOSITOR and BIOBANK concerning the MATERIALS and supersedes any prior understanding or written or oral agreement.

28. This MDA is effective on the date of the latter of the two authorized signatures of parties.

29. This MDA shall be governed by the laws of Portugal and any conflict between the parties which is not settled amicably shall be exclusively submitted to the jurisdiction of the Judicial Courts of Lisboa.

30. Both parties have read and understood the terms outlined in this MDA and agree to abide by them regarding the deposit of the MATERIAL.

According to the terms and conditions established above, we agree to Sign this document in duplicate, and keep, respectively, a copy for the Depositor and another for the biobank.

Data and Samples will be transferred/integrated in the BIOBANK, after signing this document.

PI/Depositor of the collection

Biobank Representative

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Signature

Signature

Annex I (1/2)- Deposit form

Deposit Form N°:
Date of request:
(to be fill by CHAIN)

Principal Investigator Name:
Institution:
Contact:

Doctor Name:
Institution:
Contact:

Project Description:

1. DEPOSIT INFORMATION

Ethics Committee approval - send copy	Yes - No
Informed Consents sign by donors - send copy not signed	Yes - No
Clinical data	Yes - No
N° of participantes	
N° and type of samples Ex: Blood (12) feaces (10)	

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Collection data and storage methods - send document or fill this form accordingly	Yes - No
Storage history - N° freeze-thawing cycles (send document or fill this form accordingly)	Yes - No

Please check all the information available

Obs: In case of negative answers, please justify:

Annex I (2/3) – Deposit form

2. METHODS OF SAMPLING AND PROCESSING

3. TRANSPORT AND STORAGE CONDITIONS

4. DESCRIPTION OF THE CLINICAL DATA

Annex I (3/3) – Deposit Form

PATIENTS DATA					SAMPLES COLLECTION DATA					
PACIENT ID	BIRTHDATE	SEX	DIAGNOSIS	OTHER DISEASES	SAMPLE ID	DATE / HOUR	SAMPLE TYPE	COLLECTION TUBES ADDITIVES	N° ALIQUOTs	FASTING HOURS/ RELEVANT MEDICATION
									(volume)	

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Dear XXXX,

As requested, we send the quote for deposit in the CHAIN Biobank.

1. Deposit

Type of sample	N° of samples	Access Level	Price

The costs for the service(s) required are:

2. Service

Type of service	Price per unit	Units	Final Price
	Total		

CHAIN Biobank Collaborator

Date