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Central Biobank Erasmus MC Regulatory document

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1 Preamble

The CB Erasmus MC regulations:

- Describes the way Erasmus MC wants to execute the Biobanking policy.
 - Is meant as framework guideline for the collection, storage and transfer of Biomaterials and Accompanying Data by the Central Biobank Erasmus MC (CB).
 - Is a public document, primarily focused on those directly involved in the CB as well as those that have any interest in how Body Materials are processed within the CB and/or would like to know how the CB is organized.
 - Is applicable to collections of Biomaterials and Accompanying Data stored for medical scientific research in CB, CB Collection Points or Sub-biobanks.
 - Follows the Erasmus MC research codes on:
 - Scientific integrity
 - Intellectual property
 - Patient data and Biomaterial
- 1) Makes a distinction between “Medical Research” Biobanks, which are collecting Biomaterial and Accompanying Data primarily for medical scientific research and “Secondary Use” Biobanks, which collect samples primarily for diagnostic purposes where the leftover material and coded Accompanying Data is made available for medical scientific research through secondary use after approval of the qualified ethical committee.
 - 2) Follows the in force legislation, like the Dutch Law on medical scientific research with people (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)), the Dutch law on the medical treatment agreement (Wet op de geneeskundige behandelingsovereenkomst (Wgbo)), The General Data Protection Regulation (GDPR) combined with the Dutch applied General Regulation Data Protection (Uitvoeringswet Algemene Verordening Gegevensbescherming (UAVG)) and the Law on Corpse Delivery (Wet op Lijkbezorging). In addition this regulatory document follows the last version of the Human Tissue and Medical Research: Code of Conduct for responsible use, issued by the Federa. This code describes the regulation on the use of leftover and Body Materials for medical research are processed. As far as the code deviates from European or Dutch legislation in force, the European and Dutch legislation is followed.
 - 3) Is examined and approved by: the Board of Directors, Staff Convent, the Program Board, the Directors Consult Group, the Pillar of Research & Education , Biobank Advisory Committee and commented on by juridical affairs.

2 Definition of Terms

- a) Accompanying Data: clinical, epidemiological and/or research data coupled to the Body materials in the Biobank.
- b) Biobank Advisory Committee: Consists of representatives from all Erasmus MC themes, who directly or indirectly represent the Stakeholders like PI's and Sub-biobank managers within the Erasmus MC theme. This committee gives advice, upon request or unrequested, to the CB Board and/or the Dean.
- c) Body Material: All parts of the human body that were secreted obtained otherwise. This can be leftover material or material which was made available specifically for medical scientific.
- d) Biomaterial: Body Material and/or Images (adapted for the readability of this document).
- e) Centrale Cold Storage: Service Platform where long term storage at ultra-low temperature is organised in an optimal, efficient, standardized and secure way.
- f) CB Erasmus MC (CB): A centrally directed Erasmus MC wide Biobank harbouring differently structured collections of Biomaterials (including cell lines and xenografts), which are available for scientific research. In certain cases (when the Donor has given consent) the Biomaterial is coupled to accompanying clinical and/or epidemiological data. The CB includes Collection Points and Sub-biobanks:
 - 1. Collection Point: Location where a certain type of human Biomaterial is optimally collected, processed, stored and managed under responsibility of Erasmus MC. The amount of Collection Points is limited and selected by the CB Board. During selection, it is taken in to account that the Collection Point is: 1) coupled to the existing routine diagnostic pathways, 2) the accessibility for Donors, 3) the continuity and high quality of the collected and processed Biomaterials, 4) professional relation towards the Donors and 5) existing well equipped research centres.
 - 2. Sub-biobank: 1) An already existing biobank, which is incorporated in the CB at the moment the CB was founded. The collection of Biomaterials can continue, however the CB strives for all collections and storage to make use of the CB Collection Points and the Central Cold Storage facility. 2) A Sub-biobank can be started when certain research activities cannot be facilitated by the CB. 3) A Sub-biobank can be started when the CB cannot facilitate certain research activities efficiently enough to the judgement of the PI. A Sub-biobank keeps its own management.
- g) CB Board: Is composed of the managers of the CB and the CB Collection Points. The chairman of the CB Board is also the manager of the CB and will be appointed by the Board of Directors.
- h) Consent: Every free, specific informed and evident expression of one's will through which the Donor declares or evident active act to agree to the storage and use of his or hers Biomaterial and where applicable Accompanying Data for medical scientific research.
- i) Custodian: The person that on legal grounds can give Consent in name of the Donor for using Biomaterial and where applicable Accompanying Data.
- j) Donor: Person who has made his/hers Biomaterials with or without Accompanying Data available for scientific research.

- k) Incidental and Accidental Findings: Unsolicited and unforeseen results from research (or diagnostic) findings that are not related to the underlying research protocol and which, in the case of residual material, were not seen during the original use.
- l) Leftover Material: Biomaterial obtained during the medical treatment of the patient which can be used for medical scientific research if the no objection was made by the patient.
- m) Manager: The person primarily responsible for the collection, preparation, storage and distribution of a collection of Body Materials and/or Images and Accompanying Data. The CB, the CB Collection Points and Sub-biobanks are each managed by a manager.
- n) Material Transfer Agreement (MTA): Contract that reflects the rights and duties of the requestor and distributor of Biomaterials on the moment of exchange.
- o) Medical Ethical Test Committee (METC): Is determined on grounds of the Dutch Law on medical scientific research with people (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)) and acknowledged as Medical Ethical Test Committee by the Dutch Central Committee of Human related Research (CCMO (Centrale Commissie Mensgebonden Onderzoek)).
- p) Medical Practitioner: The qualified medical doctor responsible for the medical treatment of the Donor/patient according to the Dutch law on the medical treatment agreement (Wgbo).
- q) 'Medical Research' Biobank: A collection of Biomaterial and Accompanying Data which is primarily collected for medical scientific research.
- r) None-WMO compliant research and Biobank test committee (NWBTC): Ethical testing committee for compliant research and Biobanks not subject to the Dutch Law on medical scientific research with people (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)). The NWBTC is part of the METC.
- s) Person in Power of Decision: Usually the Principal Investigator (PI) who has set up the collection and the Donor who has given consent which can be revoked at any time.
- t) Personal data: To the Body Material related data of Donors from which the person can be directly or indirectly identified.
- u) Power of Decision: Authority to collect, process, store, distribute and use for scientific research Biomaterials and Accompanying Data under the conditions of law and regulations.
- v) Principal Investigator (PI): An Erasmus MC employee primarily responsible for the execution of the medical scientific research using Biomaterials.
- w) Researcher: Person who is in part responsible for the setup and execution of a medical scientific research project using Biomaterials stored in the Biobank.
- x) 'Secondary Use' Biobank: A collection of Biomaterial and where applicable coded Accompanying Data which is primarily collected for usually diagnostics or follow-up, but which can be used for medical scientific research.
- y) Stakeholder: An Erasmus MC employee with a direct interest in the collection of Biomaterials to be evaluated.
- z) Scientific Review Committee (SRC): In Dutch: Wetenschappelijke Toetsingscommissie (WTC). Is composed by the PI or department head and has Power of Decision over the collection of

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Chapter Definition of Terms

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Biomaterials and where applicable Accompanying Data. The PI or department head is part of the committee.

3 Scope

This regulatory document applies to the collection, processing, storage, distribution and usage of Biomaterials and Accompanying Data for medical scientific research.

The Body Materials and data of the Parelsnoer Initiative (PSI) fall under the CB. PSI has a national regulatory document approved by the Board of Directors, which will be followed where researchers want to collect or use Body Materials, Images and/or Accompanying Data within this initiative. Where the National PSI regulatory document is not responsible for, this regulatory document applies.

This regulatory document does not cover:

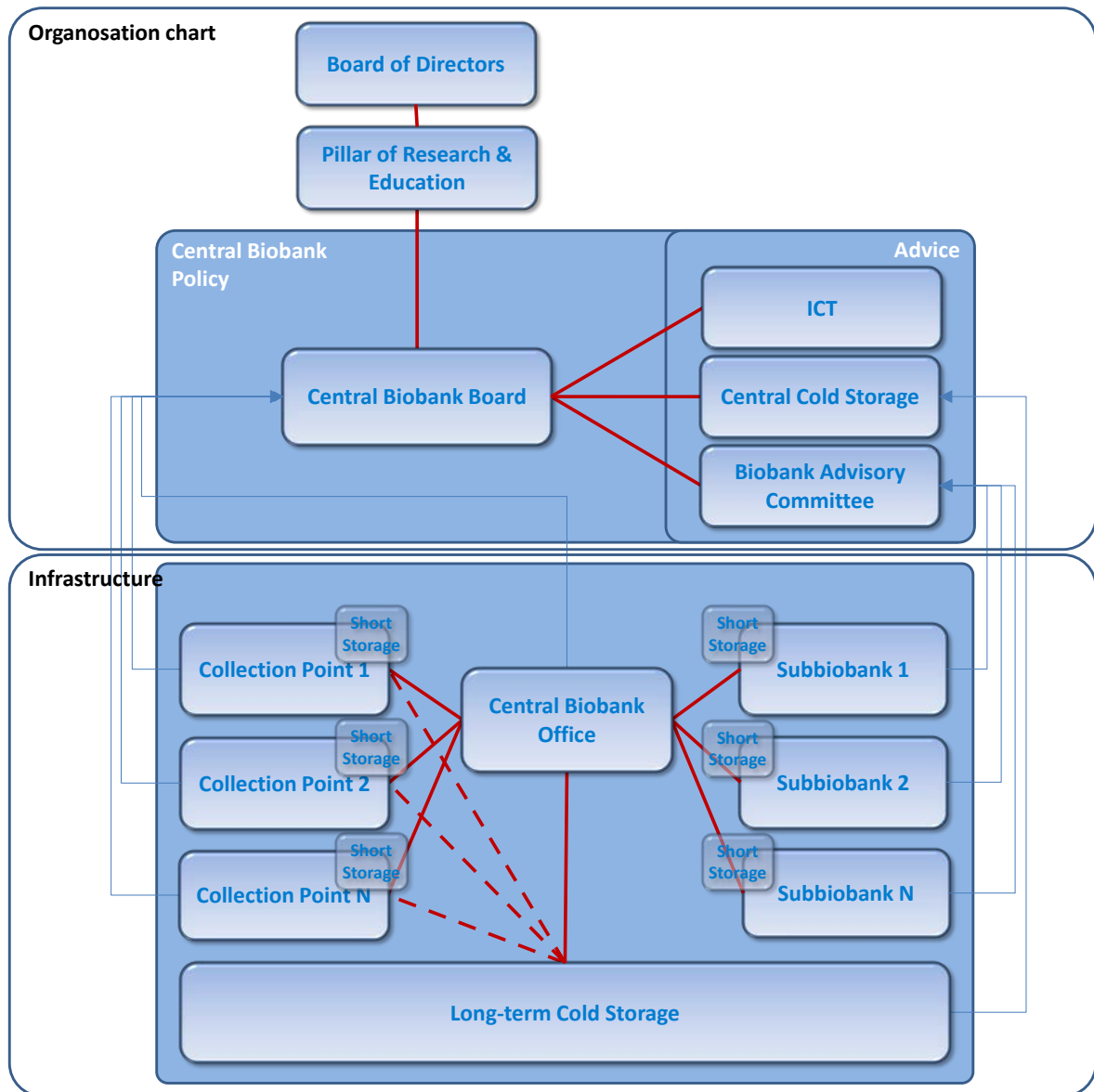
1. The use of human embryonal or fetal tissue for scientific research, regardless of the way this has been obtained. According to the Dutch law on embryos, requests are to be submitted to the Dutch Central Committee of Human related Research (CCMO).
2. Collections of Body Materials primarily meant for therapeutic purposes or any other form of reuse in or on the patient.
3. Storage of Body Material originating from a human body that has been donated to science.

4 Principles

- 1) The CB is responsible for the management of Body Materials and/or Images
- 2) The CB is a cross-departmental Service Platform that was set up to facilitate and unburden researchers in conducting medical scientific research with biomaterial and associated data.
- 3) The CB guarantees that the laws and regulations concerning biomaterials are complied with and that the Biomaterial with Associated Data is stored with a consistent high quality.
- 4) The CB wants all necessary documentation to run as quickly and efficiently as possible and will strive to automate and digitize as much as possible.
- 5) The CB gives access to the Biomaterials in a fast and efficient way, as soon as it has been established that distribution is permitted.
- 6) The activities of the CB focus on offering basic services that (almost) all departments will use, at the best possible price.
- 7) Founding a CB Collection Point or Sub-biobank and can only take place if the CB board has given Consent for this.
- 8) The CB supports the PI in obtaining high-quality Biomaterial collected in a standardized way by stimulating cooperation with organizational units that are already optimally equipped for this. These can include for example Clinical Chemistry, Pathology, Virology, Hematology, ERGO and Generation R.
- 9) The collection, storage and publication of Body Materials and/or Images and Associated Data can only take place if the qualified ethics committee (METC or NWBTC) has given approval.
- 10) Scientific integrity is promoted through the documentation of the collection and issue process. This documentation can be used to demonstrate that the Investigator had the correct approvals at the right time and carried out the intended research.
- 11) The collections present in the CB will be made available to researchers from inside and outside Erasmus MC through an online catalogue, to stimulate collaboration. The PI determines which information about the collection is provided.

5 Responsibilities

The organization chart of governance, policy and infrastructure of the CB is shown below:



The CB Board is responsible for the coordination and collaboration between the various CB Collection Points and Sub-biobanks in the joint CB infrastructure. The Managers of the CB Collection Points and Sub-biobanks are primarily responsible for the design of the local infrastructure of the CB Collection Point for collecting, processing, storing and distributing certain types of Biomaterial. These CB Collection Points are located where there is optimal contact with the Donor, the collected Biomaterials can be processed if necessary and made available for research, whereby the quality of the routine diagnostic process must not be disturbed.

The chair of the CB is primarily responsible together with the CB Board for:

1. The storage, integral management and distribution of Biomaterial and Associated Data that are stored in the CB in accordance with applicable laws and regulations.
2. The financial management and operations of the CB.
3. Annual reporting of CB activities including selected Key Performance Indicators such as amount of material stored and number of material distributions.
4. Feasible agreements between the CB collection points, the Sub-biobanks, and the Central Cold Storage Manager.
5. Creating and maintaining the catalogue which makes the collection in the CB accessible to Researchers from inside and outside Erasmus MC.
6. Consultation of the SRC where necessary whereby the composition of the SRC is activated per application from the persons or delegates nominated by the PI and registered by the CB Board.
7. Ensuring the presence of a decision-making PI / Principal Investigator or Department Head as well as an SRC for each collection in the CB.

The Manager of a CB Collection Point is responsible for:

1. The storage, integral management and distribution of the Biomaterials and Associated Data which they manage in accordance with applicable laws and regulations.
2. The report to the CB Board in every first month of the year on what has been collected for medical scientific research and has been issued or distributed.
3. Performing the biobank processes as described in their quality system.
4. Participate as a board member on the CB board.
5. The financial management of the CB Collection Point, for which planning and expenditure overviews must be submitted to the CB Board.
6. Ensuring that the CB's scientific activities do not disrupt the quality of the routine diagnostic process.
7. Reporting changes to the CB Board if he/she intends to make changes that may have consequences for the implementation of (parts of) the Biobank protocol, so that the CB Board can take note and agree or give advice to the CB Collection Point about the proposed change.

The responsibilities of a Manager of a Sub-biobank are in principle the same as those of a CB Collection Point, except points 5-7.

6 Quality and Technical Standards

1. Every collection of Body Materials within the Erasmus MC follows international guidelines and best practices in the field of Biobanks wherever possible and all actions for collecting, storing, managing and distribution the Body Materials and Associated Data must be described in Standard Operating Procedures (SOPs).
2. The CB intends to obtain ISO 9001 certification, with possible extension to the yet to be published ISO Biobanking standard in which the CB Collection Points and Sub-biobanks can fall as suppliers under ISO accreditation 15189 of a department and can be regarded as a certified or accredited supplier. The CB ensures that the collection is structured according to SOPs and clear work instructions where efforts are made for quality improvement.
3. The CB processes quality as a subject in the annual report.
4. The application and issue process is described in a protocol that complies with local regulations.
5. The quality of healthcare and related diagnostics for the patient should not be reduced by the activities aimed at collecting Biomaterials with Associated Data for scientific purposes.
6. The Biobank data processing must be recorded in the Erasmus MC processing register in accordance with (privacy) legislation and regulations and must be FAIR (Findable, Accessible, Interoperable, and Reusable) so that they can be shared in partnerships.
7. The criteria that determine which Biomaterials can be considered for storage in the CB and the Central Cold Storage are set out in Appendix A.

7 Storage duration

1. In the event that a prospective collection for the purpose of a study is started, researchers must indicate a motivated maximum storage period (in years) for the Biomaterial and Associated Data.
2. If this time has elapsed, taking into account the 15-year retention period after the last publication based on the collection in question, the CB Board will evaluate the usability of the collection for the future in consultation with the PI. If no use is expected in the long term, the material will be destroyed.
3. When the PI is no longer working at Erasmus MC, or renounces the Decision-making authority over the collection, the department head will be approached. If no person in charge of the collection can be designated, the decision-making authority will be placed with the chairman of the CB board.
4. For "Secondary Use" biobanks, storage duration periods are determined by the professional groups. Once this period has expired, one can consider storage for medical scientific research or to destroy the materials.
5. The choice between short-term storage or long-term storage in the Central Cold Storage is determined by the expectation whether the Body Materials will be needed for scientific research within 3 months or not.

8 Review and Distribution

8.1 Review before collecting

1. The METC reviews research subject to the Dutch Law on medical scientific research with people (Wet medisch-wetenschappelijk onderzoek met mensen (WMO)) with Biomaterial and Associated Data.
2. The NWBTC reviews research not subject to the WMO, such as prospective studies without a defined research question and research using secondary use of leftover material.
3. The NWBTC reviews research with the reuse of Biomaterial and Associated Data that has been collected in the context of research that is subject to the WMO and that remains after implementation of this research that is subject to the WMO. In addition, the NWBTC assesses, among other things, on the basis of the used Patient Information Form (PIF) whether the intended reuse of the Biomaterial and the Associated Data fits within the Consent originally granted by the Donor in the context of the WMO study.

8.2 Review before distribution

1. The SRC only reviews if: 1) the applicant is not the PI responsible for collection, or 2) the application has not yet been assessed elsewhere by a qualified ethics committee (such as METC or NWBTC), or 3) the application does not fall under the original purpose of creating the collection. The SRC tests 1) the scientific content 2) whether the application fits within the vision for which the collection has been prepared and 3) whether the application fits within the current and planned distributions. A positive decision for distribution can only be taken by consensus, unless the PI determines otherwise. The PI can decide to let other PIs with a direct interest in the to be assessed collection to co-decide or to delegate the SRC activity to, for example, Sub-biobanks or partnerships in consortia where an SRC is active. The composition of the SRC depends on the requested Biomaterials and can therefore differ per application. Even if no review by an SRC is required, the CB will ask for an approval from the PI for distribution.
2. Before the distribution of Biomaterials and Associated Data (Medical Research Biobank) or Body Materials and appropriate Associated Encoded Data (Secondary Use of Biobank) can take place, a member of the CB board or a delegated employee of the CB checks the following points:
 - a. SRC approval of the research protocol.
 - b. Ethical review approval of the research protocol by a recognized qualified committee (METC or NWBTC)
 - c. If Donors have objected.

Distribution can only start when the (electronically) signed application form shows that all mandatory review processes have been performed. The CB Collection Points and Sub-biobanks need to share correct (see 7.3.6) documentation of their distributions with the CB Board

8.3 Distribution

1. The Biomaterials and Associated Data made available by the CB for medical scientific research may

only be used for the research described in the application and under those conditions as indicated in the MTA.

2. The CB can only provide an MTA if the transfer of biomaterials takes place for research without commercial parties. This must be signed by both parties if the transfer is to external non-commercial parties, but only has to be provided for internal transfers.
3. If commercial parties are involved in the application, the PI will first submit a suitable MTA, based on the CB MTA, for signature by both parties to TTO for approval. This expires if there is such an agreement for the exchange of Biomaterials and data that is already included in a project agreement between institutes, such as, Consortium Agreements for European projects or the PSI framework regulations.
4. No reimbursement is requested by the provider for Biomaterial and Associated Data. A reimbursement may be requested for the costs incurred for processing, storing and documenting the Biomaterials and the Related Data. Agreements regarding a possible reimbursement must be recorded in the MTA. Under no circumstances profit can be made on the provision of the Biomaterials.
5. A copy of the MTA as well as the distribution request form (including research protocol) will be kept as documentation by the CB.
6. The PI is primarily responsible for (within the framework of the Consent obtained) conducting the research as described in the submitted research protocol on the application
7. The MTA can also provide long-term access to the collection if necessary and agreed. This may, for example, be the case with a prospective study or trial where material is used immediately or quickly after it has been taken.
8. For distribution to parties outside Erasmus MC, it must be guaranteed that this is clearly stated in the applicable patient information Form (PIF).
9. All MTAs are kept for documentation together with the application by the CB for a period of 15 years after finishing (refund or destruction of sample) of the latest issue.
10. Once the requested examination has been performed, the remaining Body Materials will be returned to the CB. This also includes derivatives isolated for the research. In the event that the Biomaterials or the isolated derivatives are no longer usable, it may be agreed with the person in charge to destroy the remnants. For storing the derivatives (such as: DNA, RNA and / or proteins), the then applicable fee (see Chapter 11 Charging costs / Pricing) for storage is requested.

9 Control, Consent, Power on Decision, and objection

9.1 Medical Research Biobanks

1. Through informed Consent, the Donor gives permission for the use of biomaterials and associated data for the scientific purposes described in the patient information. With the signature of the patient, the board of directors formally obtains Power on Decision what can be done with the Biomaterials and Associated Data. As a rule, the Board of Directors delegates this Power on Decision to the chain of management, including department heads, Biobank Managers, (Core) Facility managers and PIs. When a delegate leaves the company, this means that the obtained Power on Decision falls back to the next higher hierarchical manager. After the vacant position has been filled in again with an employee of the Erasmus MC, the decision-making authority can be delegated back by the hierarchical manager. In case there is nobody who can, may or wants to bear the responsibility for a collection, the Power on Decision is delegated to the CB.
2. The Consent given by the Donor for the use of the Biomaterials and Associated Data for scientific research can be withdrawn without reason by the Donor in part or as a whole free of charge.
 - a. How to do this is described in the patient information (pif), which was given to the patient when signing the Informed Consent. After revoking the Consent, no new Body Material will be taken from the Donor and the Body Material that has already been collected will in principle be destroyed.
 - b. Withdrawal of Consent does not lead to the destruction of findings already made.
 - c. Biomaterials and Associated Data that were issued prior to the withdrawal of the Consent will remain available for the purposes of that study. The written information on the basis of which the Donor has granted his previous Consent must, however, state that upon withdrawal of the Permission the Biomaterial that is already under investigation cannot be destroyed. Biomaterials and Associated Data are destroyed after a possible return.
 - d. The Consent obtained from a Donor alive and not withdrawn by him in the meantime remains in full force after his death.
 - e. The Donor is informed about the possibility and consequences of withdrawing his Consent, before signing the Informed Consent.
 - f. The PI is the Administrator of the Informed Consent statements and is responsible for complying with the destruction of Biomaterial and Associated Data upon withdrawal of Consent.

9.2 Secondary Use Biobanks

In the case of Secondary Use of Residual Material, the Board of Directors is authorized to decide what may be done with the Left-over Material and Accompanying Data, unless the Donor has objected. This decision-making authority is delegated in the same way as under 9.1.1

- a. A patient can at any time object to the Secondary Use of his Left-over Material that has been obtained as part of the medical treatment. How to do this is described in the brochure "Residual tissue / Residual material for medical scientific research. The remaining material that is primarily collected for diagnostics is marked in such a way that it is no longer issued for scientific research, but remains available for diagnostics.
- b. Withdrawal of permission does not lead to the destruction of findings already made.
- c. Left-over material and Accompanying Data that were distributed prior to submitting an objection will remain available for the purposes of that investigation.
- d. The CB Manager manages the objections. This digital list with objected Patient ID (PID)

numbers is compared at least once every 3 months with the Patient ID numbers present in the total collection of residual materials. By agreement, the Left-over Material belonging to a PID number with objection will be destroyed, unless the Left-over Material has already been issued or can still have a diagnostic function. If the Left-over Materials can still have a diagnostic function, they must be marked in the database or in storage so that the Left-over Material can no longer be issued for scientific research.

- e. In principle Secondary Use Left-over Material may only be used if it is processed anonymously, Permission must be requested for data use. However, there are exceptional grounds for conducting scientific research with the Secondary Use of Residual Material with Associated Data. The METC or NWBTC tests whether a research protocol falls within these exceptional grounds and whether the research can therefore be conducted under the objection regulation.

9.3 All collections

1. Power on Decision on the requested Biomaterials and Associated Data can be transferred via an MTA to a colleague Researcher, for the duration of the requested study.
2. For body materials that will be used for cell lines, xenografts and organoids, signed informed Consent is advised to the PI, as long as this is not described in the applicable legislation or regulations.

10 Distribution Priority and Protection

10.1 Distribution Priority

1. If several applications are pending for the same Biomaterial, Leftover Material and possibly Associated (coded) Data, priority will be arranged as follows:
 - a. For a "Medical Research" Biobank, the SRC determines the priority of distributing Biomaterials.
2. In the case of a "Further Use" biobank, the SRC determines the priority of issues.
3. In the case of a "Further Use" biobank, the following priority applies:
 - a. Diagnostics (Including immediate availability on request diagnostician)
 - b. WMO / Trial-related
 - c. Not subject to the WMO / Project-related
 - d. Prospective
 - e. Ad hoc application / retrospective
4. For external applications, the SRC must respond within a maximum of two months.
5. For external applications, the SRC must respond within a maximum of two months.

10.2 Data protection and traceability

Biomaterials and Associated Data will be stored and processed in accordance with (privacy) legislation and regulations, in which the conditions for scientific research will be followed. The person responsible for data is the Board of Directors as the client.

10.3 Informing about research results, incidental and accidental findings

1. The policy on informing research results and random and incidental findings as described in the research protocol approved by the ethics committee will always be followed.
2. Where there is no specific policy on dealing with research results and random and incidental findings, the following applies:
 - a. The CB applies a cautious policy when it comes to informing patients/donors individually about research results. The reason is that medical scientific research on Biomaterials is usually carried out without validated methods in unaccredited routine laboratories, without sample swapping control and cross contamination. In addition, outcomes are often based on statistical analysis with large groups. For these reasons, the results cannot be reliably traced back to one specific Donor. Individual information can be provided where validated and routine observations have been made and where the above-described risks are minimized.
 - b. In the case of incidental and accidental findings, where the conditions determined in the "Human Tissue and Medical Research: Code of Conduct for responsible use" are met, attempts shall be made to provide individual information. In this case, the Investigator must report the finding to the CB or the Sub-biobank and codes or other digital protections can be broken at that time in order to be able to find out the identity of the Donor in order to inform the treating physician. The treating physician is responsible for verification of the results and whether or not to share the findings with the Donor.

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In general, the random and new findings, as well as the results found, can be published via the CB website and annual report.

11 Costs / pricing

1. The CB and the Sub-biobanks work on a non-profit basis and will under no circumstances make a profit on the collections. Costs may be charged for collecting, documenting, storing and publishing but not for the Body Materials and/or Images and Associated Data itself.
2. Sub-biobanks may determine the method of pricing themselves.
3. The CB will implement its costs in the following manner until 2023:
 - a. The costs will be charged to the PI or the department head who is responsible for the collection.
 - b. The costs are charged annually.
 - c. The user pays for the depreciation of the equipment depending on the usage. A price of € 0.02 per sample per year has been chosen (based on the use of an SBS rack with 96 positions).
 - d. To improve quality and efficiency, the Service Platforms staff will do the work related to storage, registration and collection of (the central) samples. For the processing and processing of samples at a collection point, the Researcher will pay a percentage of the costs. Starting with a 50% reimbursement.
 - e. In order to promote uniformity and ensure that material is future-proof, the Service Platforms use the SBS racks with 2D labeled tubes. Service Platforms reimburse 75% of the costs for these materials.
 - f. Other agreements apply to external academic and private users and the full costs for use are charged.
4. The CB is funded by the Integrated Construction and R&D Project to ensure that the Biobanks can be offered at the Erasmus MC at an easily accessible price.
 - a. The R&D waterfall overhead partly meets the high costs for personnel, IT costs and material costs.
 - b. Housing costs for the Central Cold Storage are covered by Project Integrated Construction.

12 Complaints

1. Complaints regarding the quality and delivery of Biomaterials and Associated Data with or without Images can be filed with all CB staff. The complaints are, if possible, resolved on the spot, reported to the CB Board and then discussed and recorded at the next CB working meeting. During this consultation, if necessary, a permanent solution is sought in accordance with the procedure described in the quality system, so that a recurrence of the reported incident is prevented in the future.
2. Complaints regarding the collection and storage of samples are registered in accordance with the quality system and the system for incident and/or calamity reporting applicable in the Erasmus MC. These complaints are discussed in the CB's working meeting, noted and considered whether these complaints can and should be prevented in the future. The reports are also discussed in the quality assurance team of the department concerned and if there are unexpected consequences for the Donor, analysed to arrive at a solution to prevent such an incident.
3. Donors with complaints about the state of affairs regarding the use of their Biomaterial with Associated Data can submit their complaint via the applicable Erasmus MC Patient Complaints Procedure.

Appendix A

Criteria for storage of Biomaterials

1. Biomaterials are only stored if there is sufficient data for medical scientific research with these Biomaterials, at least:
 - a. Sample name (Or code that can be traced back to the patient code)
 - b. Material type
 - c. Date of conservation (freezing)
 - d. Responsible, staff member / mandated / PI and / or operational analyst
2. Biomaterials must be fully digitally traceable and must be registered in the CB's Biobank Information Management System.