

University Medical Center Utrecht

Biobank Regulations

Version of 19 June 2013

Preamble

These Regulations describe the biobank policy adopted by the Executive Board of University Medical Center Utrecht (UMC Utrecht), in compliance with the applicable national and international laws and regulations.

On 27 November 2007, the Executive Board officially decided to set up a Central Biobank (CBB) at UMC Utrecht, to ensure the uniform and efficient storage and coordinated management of the various existing collections of human biological material ('sub-biobanks') and associated (personal) data. Before a sub-biobank covered by the scope of these Regulations can be set up, the UMC Utrecht Biobank Research Ethics Committee must issue a positive recommendation, and permission must be obtained from the Executive Board. All requests for the release of human biological material and associated data must be submitted to the Biobank Research Ethics Committee for approval. The Executive Board has authorized the Committee to grant such approval. The powers of the Committee are laid down in these Regulations, while the Committee's organization and working procedures are laid down in its Rules of Procedure.

Article 1 Definitions of terms used

- a) **Anonymous data:** Data that cannot reasonably be traced back to an identified or identifiable natural person.
- b) **Competent committee:** The competent committee as defined in the Rules of Procedure of the Biobank Research Ethics Committee.
- c) **Sub-biobank:** A collection of human biological material and associated data that is being compiled or has been compiled with a view to future medical research, the nature of which was not specifically defined when the samples were taken; or
A collection of human biological material and associated data that have been obtained in the context of diagnostic procedures and/or medical treatment and that are no longer required for the purpose of quality assurance and/or additional individual diagnostic procedures (also referred to as 'residual material'). This definition also covers residual material that can be amplified, for instance by growing stem cells or creating cell lines from residual material. The provisions of Article 10 of these Regulations apply to human biological material that was collected for the purpose of a specific study subject to the Medical Research Involving Human Subjects Act (WMO), and that was not used (in full) for the study concerned.

- d) **Biobank data:** Data relating to the nature, quality and quantity of human biological material stored in the Central Biobank.
- e) **Broad consent:** Broad (informed) consent given by the donor for the use of his/her biological material and (clinical) personal data for the purpose of future medical research, the nature of which has not yet been specifically defined, without being unrestricted.
- f) **UMC Utrecht Central Biobank (CBB):** A facility established at UMC Utrecht under Executive Board decision no. 07/11742 for the primary purpose of storing, managing in a coordinated manner and releasing all human biological material and associated data stored in all sub-biobanks established at or under the responsibility of UMC Utrecht. CBB also assesses the quality of the processing of human biological material. The CBB Head is responsible for running the CBB, and reports to the Head of the Laboratory & Pharmacy division.
- g) **Donor:** A patient or (healthy) volunteer who donates or has donated biological material and/or (clinical) data. Where appropriate, references to donors in these Regulations may also be interpreted as pertaining to the donor's legal representative as defined in item n) below.
- h) **Coded data:** Data that have been processed in such a manner as to exclude any data that may be used, either directly or indirectly, to establish the identity of the donor, and to which a code has been added that can only be traced back to an identified or identifiable donor by the intervention of one or more independent third parties using one or more encryption keys, in accordance with the provisions of the Personal Data Protection Act and the Code of Proper use of human tissue (2011) published by the Foundation Federation of Dutch Medical Scientific Societies (Federa).
- i) **Human biological material:** All tissues, cells or other organic material separated from the human body, with the exception of foetal tissues, embryos and reproductive cells.¹
- j) **Personal data:** Any information relating to an identified or identifiable natural person (refer to Section 1 of the Personal Data Protection Act).
- k) **Preferred partner:** A UMC Utrecht department or an external organization approved by CBB that processes human biological material on behalf of the sub-biobank coordinator.
- l) **Incidental findings:** Unforeseen research findings (or diagnostic results) not related to the underlying study protocol and not noticed upon initial use of the human biological material (in the case of residual material).

¹ Foetal tissues, embryos and reproductive cells fall under the scope of the Embryos Act.

- m) **Sub-biobank coordinator:** A head of a (medical) department or a person in an equivalent position at UMC Utrecht who bears responsibility for a sub-biobank.
- n) **Legal representative:** A person authorized by law to exercise control rights in addition to or on behalf of the donor.

Article 2 Scope

These Regulations apply to the Central Biobank (CBB) of UMC Utrecht and all sub-biobanks established under the responsibility of UMC Utrecht.

Article 3 Establishment of a sub-biobank

- a) A sub-biobank may only be established after permission to do so has been obtained from the Executive Board of UMC Utrecht.
- b) The Executive Board only grants permission to the sub-biobank coordinator to establish a sub-biobank if the following two conditions have been met:
 - i) A protocol for the sub-biobank has been drawn up in accordance with the requirements stated in these Biobank Regulations. The storage period of the human biological material must be specified in the protocol, and adequate quality assurances must be put in place right from the start, in accordance with Article 6 of these Biobank Regulations. The biobank protocol may not include any provisions that are not in keeping with the provisions of these Biobank Regulations.
 - ii) The competent committee at UMC Utrecht has issued a positive recommendation regarding the biobank protocol.

The competent committee at UMC Utrecht will only issue a positive recommendation if the following conditions have been met:

- (1) Any special or additional collection of human biological material must be carried out in such a way as to minimize the risks of collection, and the burden must be proportionate to the purpose of the study for which the specific tissue or blood samples are taken.
- (2) Burdensome procedures may only be considered if the relevant biomarkers cannot be obtained from other human biological material that can be collected using a less burdensome procedure.
- (3) The necessity of collecting the human biological material for the specified scientific purposes has been sufficiently substantiated.
- (4) The information provided to the donor and/or his/her legal representative about the release, storage, use and destruction of human biological material must be clear and easy to understand, in accordance with the provisions of Article 4 h) and Article 7 a).

- (5) Human biological material and the associated data must be stored and encoded in accordance with the provisions of the Personal Data Protection Act.

Article 4 Responsibilities of CBB Head

- a) The CBB Head is appointed by the Executive Board in consultation with and subject to the approval of the Laboratory & Pharmacy division. The CBB Head reports to the Laboratory & Pharmacy division, and is accountable to the management of this division for the operational management and financial performance of the CBB.
- b) The CBB Head is responsible for the healthy financial performance of the Central Biobank.
- c) The CBB Head is responsible for the storage, coordinated management and release of all human biological material included in the sub-biobanks, as well as the associated biobank data.
- d) The CBB Head is responsible for setting up a quality management system to govern the CBB's procedures for processing human biological material and the associated data.
- e) The CBB Head is responsible for preparing a list of preferred partners authorized to process human biological material, and monitors the performance of these preferred partners.
- f) The CBB Head must submit a six-monthly report to the competent committee and the Advisory Council on the inclusion of human biological material in the Central Biobank and the release of these materials for research purposes.
- g) The CBB Head is responsible for preparing a catalogue that describes which sub-biobanks and associated biobank data have been included in the Central Biobank.
- h) The CBB Head is responsible for ensuring the availability of generally accessible and clearly understandable written information for donors on the collection , storage, use and destruction of human biological material included in the CBB.

This information must cover at least the following topics:

- (1) Manner in which the donor's privacy is protected during the process of collecting, storing and releasing human biological material and the associated personal data
- (2) The possibility of incidental findings as a result of the use of the human biological material, and the manner in which the donor, his/her family (if applicable) and any third parties will be informed about these findings under the responsibility of the (family) physician in charge²
- (3) The manner in which the donor can exercise control over the storage, use and destruction of the biological material, including the exercise of control after death.

Article 5 Biobank Advisory Council

² If necessary, the physician in charge may be assisted in this matter by a properly trained, BROK-certified healthcare professional (e.g. a clinical geneticist in the case of individual findings in genome studies).

- a) UMC Utrecht has established a Biobank Advisory Council.
 - (1) The Council consists of representatives of the so-called ‘focus areas’ of UMC Utrecht; the Council chair is appointed from their ranks.
 - (2) The Council offers solicited and unsolicited advice to the CBB Head.
 - (3) The Council reviews these Biobank Regulations annually or more frequently if necessary, and is authorized to submit proposals for amendment to the Executive Board.
 - (4) In consultation with the CBB Head, the Council develops strategic policy on the use of biobanks at UMC Utrecht, and monitors the implementation of this policy.
 - (5) The CBB Head attends the meetings of the Biobank Advisory Council.
- b) The Executive Board appoints the chair and the members of the Biobank Advisory Council for a term of three years, and takes care of secretarial duties.

Article 6 Responsibilities of the sub-biobank coordinator

- a) The sub-biobank coordinator ensures that the sub-biobank processes described in the biobank protocol are performed in accordance with the protocol.
- b) The sub-biobank coordinator ensures that all processing of human biological material as described in the biobank protocol is carried out only by preferred partners.
- c) The sub-biobank coordinator ensures that the human biological material is properly submitted for inclusion in the Central Biobank.
- d) The sub-biobank coordinator ensures that any incidental findings are reported to the competent committee, and ensures that the committee’s recommendations are complied with.
- e) The sub-biobank coordinator ensures that the written information referred to in Article 4 h) is made available to donors.
- f) The sub-biobank coordinator notifies the competent committee if he/she intends to make any changes that may affect the implementation of the biobank protocol or parts thereof.

Article 7 Collection, processing, retention, release and use of human biological material in accordance with ‘broad consent’ procedure

- a) Human biological material and the associated data may only be collected, processed, stored, released and used if so-called ‘broad consent’ has been given in writing.
 - (1) The sub-biobank coordinator must ensure that broad consent is requested and obtained. The person obtaining consent must make sure that the donor and/or his/her representative possesses the information referred to in Article 4 h), and has received specific verbal and written information on the release, storage, use and destruction of human biological material, including information on the burden and risks associated with the collection of human biological material.

- (2) By way of exception to Article 7 a) (1), human biological material may be collected in the context of providing emergency care, provided verbal consent has been obtained from the donor and/or his/her representative, and provided this does not result in increased risk. All the provisions of these Biobank Regulations once again enter into effect immediately after the emergency situation has ended. In that case, any remaining informed consent procedures must still be completed.
- b) The donor and/or his/her representative may revoke broad consent at any time after granting it. This revoking of consent only applies to future research involving the collected human biological material and the associated data.
 - c) If the donor and/or his/her representative grants broad consent, he/she is told that he/she will be informed of any incidental findings that may result from the actual use of the human biological material. If the donor and/or his/her representative does not wish to be informed, the human biological material cannot be included in the sub-biobank.
 - d) The sub-biobank coordinator ensures that a file is created for each donor, and that the consent statements referred to in section a) of this article and the revokal statement referred to in section b) are retained in this file.

Article 8 Processing, storing, release and use of human biological material in accordance with 'no objection' procedure

- a) By way of exception to the provisions of Article 7, human biological material and the associated data may be processed, stored, released and used without broad consent if the following conditions have been met:
 - (1) The relevant sub-biobank contains residual human biological material and associated data that have been obtained in the context of diagnostic procedures and/or medical treatment and that are no longer required for the purpose of quality assurance and/or additional individual diagnostic procedures (also referred to as 'residual material').
 - (2) It may be reasonably assumed that the donor and/or his/her representative have been able to take note of the information referred to in Article 4 h), and did not object to the processing, storing and use of the human biological material for the aforementioned purposes.
 - (3) The human biological material and the associated (clinical) personal data must be fully anonymized or encoded, and may not be used for commercial purposes.
 - (4) Human biological material may not be amplified to create immortal (stem) cells and cell lines.
- b) The donor and/or his/her representative may lodge an objection at any time after granting consent. Any objection only applies to future research involving the collected human biological material and the associated data.
- c) The donor and/or his/her representative will be informed of any incidental findings, unless he/she has objected to this. In that case, the biological material is not included in the sub-biobank.

- d) The CBB must ensure that any objections are kept on file.

Article 9 Destruction of human biological material

Human biological material is destroyed in the following cases:

- a) If the donor and/or his/her representative has revoked consent for any use of the biological material, or has given consent which is null and void under the law, or has lodged an objection against any form of use referred to in Article 8.
- b) If a sub-biobank coordinator has stated that he/she wishes to discontinue the sub-biobank, or if the CBB considers the continued storage of the biological material to be inadvisable for quality reasons. In both cases, advice will be obtained from the Advisory Council as referred to in Article 5. In its decision, the Advisory Council will specify whether responsibility for the sub-biobank will be transferred to another sub-biobank coordinator, or whether the sub-biobank and the biological material contained therein is to be destroyed.

Article 10 Release of human biological material for research purposes

- a) All actual research involving human biological material and associated (clinical) data stored in a sub-biobank must be performed in accordance with a release protocol drawn up for this purpose and approved by the competent committee at UMC Utrecht.

The competent committee at UMC Utrecht will only approve a release protocol if the following conditions have been met:

- (1) The request for release has been submitted by an employee of UMC Utrecht, who is also responsible for the use of the released human biological material.
 - (2) The responsible sub-biobank coordinator has approved the request for release.
 - (3) It is reasonably likely that the research will produce new scientific insights.
 - (4) The use of human biological material and the described level of traceability to personal data are necessary for the performance of the research.
 - (5) The anticipated use of the human biological material is proportionate to the importance of the research.
 - (6) The release and use of human biological material is in keeping with the donor's control rights and is covered by the scope of the broad consent given, or the donor has not objected to such release and use.
- b) By way of exception to Article 10 a), release of human biological material may have been approved by a sub-biobank specific review committee. The working procedures and composition of this committee must be described in the biobank protocol in accordance with Article 3. The composition of the committee must meet the requirements laid down in the Rules of Procedure of the Biobank Research Ethics Committee. This means that the committee's members must include at least a physician, a methodologist, an ethicist, a

lawyer, and a person representing the interests of the donors. The approval criteria stated in Article 10 a) continue to apply in full to the Sub-Biobank Research Ethics Committee.

- c) Research involving human biological material that has been collected for the purpose of a specific study subject to the Medical Research Involving Human Subjects Act (WMO) and that has not been used in full for the study concerned must be performed in accordance with a release protocol drawn up for this purpose and approved by the competent committee at UMC Utrecht in accordance with Article 10 a). If the planned research falls outside the scope of the previously obtained informed consent, the committee may approve a request for re-use of human biological material, provided reasonable efforts have been made to obtain the donor's consent.
- d) The CBB will only make human biological material and/or associated biobank data available to parties other than UMC Utrecht employees in accordance with the UMC Utrecht Material Transfer Agreement. This agreement contains provisions stipulating that any transfer of material involves only the transfer of a right of use, and not ownership of the material. UMC Utrecht is and remains the owner of the biological material, except if it concerns the release of human biological material that has been collected under the responsibility of one or more parties other than UMC Utrecht.
- e) If the relevant sub-biobank coordinator does not approve an applicant's request for release of biological material, the applicant may lodge an objection with the Executive Board of UMC Utrecht.

Article 11 Transitional arrangements

These Biobank Regulations apply to sub-biobanks established after these Regulations enter into effect. Existing sub-biobanks must submit their biobank protocols to the competent committee within one year after these Biobank Regulations enter into effect. In addition, the relevant sub-biobank must be included in the Central Biobank catalogue within one year after these Biobank Regulations enter into effect. All human biological material must be submitted for inclusion in the Central Biobank within three years after these Biobank Regulations enter into effect.