UMC Utrecht

PROCEDURE FOR SUB-BIOBANK REVIEW BY THE MREC IN PARALLEL TO WMO REVIEW

Since the entry into force of the Biobank Regulations of UMC Utrecht in June 2013, sub-biobanks have been reviewed by the dedicated Biobank Research Ethics Committee (TCBio). To avoid investigators having to go through the process of a separate review by the TCBio for certain studies subject to the Dutch Medical Research Involving Human Subjects Act (WMO), the MREC takes care of that review based on the Biobank Regulations for that specific situation (see below) at the request of the TCBio.

FILE CATEGORIES:

1) **WMO file with sub-biobank**: WMO file where **(additional) human biological material** is obtained from the same subjects for future research (which has not yet been specifically defined at the time when the material is obtained). (This was previously also referred to as 'for similar research' or 'research within the same research field'.) This type of collection falls within the scope of the sub-biobank definition of UMC Utrecht's Biobank Regulations.

2) **WMO file with storage of residual material from a WMO study**: WMO study where **human biological material** which was specifically obtained for the research question of that study is **left over** and is **not destroyed** afterwards (see ABR F6). Note: Only the review via the TCBio will apply here (Article 10 of the Biobank Regulations).
   Note: Storage for future research of residual material from diagnostic procedures or treatment which the subjects have had in parallel to the WMO study as part of regular care: Article 10 of the Biobank Regulations applies to this as well (release review).

WHAT ARE THE REQUIREMENTS FOR THE FILE TO BE SUBMITTED TO THE MREC?

- **File of category 1 (WMO file with sub-biobank)**: Check whether (additional) material is also being obtained for research which has not yet been specifically defined. If so, describe the biobank component in the file.

  Biobank protocol: An investigator may choose to either describe the sub-biobank in a separate protocol or integrate the sub-biobank description in the WMO protocol. The basic principle is that the sub-biobank must be clearly recognisable and therefore reviewable in the documents in the file. If a separate biobank protocol is drawn up, the WMO protocol may be referred to for identical information (e.g. for the recruitment of donors, if applicable). The biobank protocol template can be found on the TCBio website. If the sub-biobank is integrated into the WMO protocol, all aspects of the biobank protocol template must appear in the WMO protocol and must be clearly recognisable as a description of a sub-biobank. See the annex for points for attention.

  Biobank information letter: You may choose to draw up a separate information letter for the sub-biobank. In principle, it is also possible to integrate the two letters. However, separating them will probably make for greater clarity. If the biobank component is integrated into the WMO information letter, the biobank must be described in a clearly recognisable manner in the information letter. A separate consent form for participation in the biobank is strongly preferred. See the annex for points for attention.

- **File of category 2 (WMO file with storage of residual material from a WMO study)**: If leftover human biological material is not destroyed (see ABR F6): text must be included in the WMO protocol and the WMO information letter about the review of other use by the TCBio. See the points highlighted in yellow in the annex with points for attention.

SUBMISSION TO AND REVIEW BY THE MREC:

The WMO file must be submitted to the MREC along with the biobank file.

Parallel review by the MREC: The MREC reviews the biobank component based on the list of points for attention (see annex).

CONCLUSION OF REVIEW:

- The MREC makes a decision on the WMO component based on the WMO.
- The MREC issues a positive recommendation on the biobank component (separate letter).

Annex:

- List of points for attention for incorporating sub-biobank into biobank protocol and information letter

Other documents:

- *Template for biobank protocol (see TCBio website)*
- *Templates for biobank information letter, consent form and withdrawal form (see TCBio website)*
- *Biobank Regulations of UMC Utrecht (see TCBio website)*

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Annex to *Procedure for sub-biobank review by MREC in parallel to WMO review*

POINTS FOR ATTENTION FOR INCORPORATING SUB-BIOBANK ESTABLISHMENT IN WMO PROTOCOL FOR REVIEW IN PARALLEL TO WMO REVIEW BY MREC

The points below must be incorporated into the WMO protocol and/or the WMO information letter, and must be clearly recognisable as a description of the sub-biobank.
In case of the storage of residual material from a WMO study (ABR F6), only the points highlighted in yellow apply.

Prior to submission: Has an agreement with the Central Biobank (CBB) been enclosed?

BIOBANK PROTOCOL

Part of template document		**Comment**
Signature page	Has a (medical) head of department signed the protocol as the coordinator with final responsibility for the sub-biobank?	Use form B2 for this.
	Has the Research Manager or possibly their deputy signed the document on behalf of Division Management?	
Section 1	Has the **necessity** of obtaining the human biological material for the scientific purposes specified been sufficiently substantiated? Necessity of starting a new biobank? What is the connection with UMC Utrecht's focal points?	
	Has the increased burden (if applicable) been substantiated? Is it not possible to obtain the material via a less burdensome procedure?	
Section 2	**General objective**: e.g. establishing a collection of xx material from xxx patients, etc.	
Section 3	General description of the **biobank's donor population**, estimated number of people whose material is to be stored, with a rationale for the quantity; any connections with other biobanks or studies.	The protocol template is not yet suitable for biobanks with material obtained from children.
Section 4	The origin of the material: description of all **collection procedures** (special or additional) for the **human biological material**. Are the burden and the risks minimal? Are they proportional to the purpose of the **biobank**? Or does it concern a sub-biobank containing residual human biological material and associated data left over after being obtained in the context of diagnostic procedures and/or treatment which are no longer required for the purpose of quality assurance and/or additional individual diagnostic procedures (also referred to as **residual material**)?	
	Description of procedures for **processing of the human biological material** from collection to storage in the CBB. In connection with the quality of the material: will any **preferred partners** be used for processing of the material if they are not being processed by the CBB? ➢ If it concerns a biobank based on a 'no objection'	If in exceptional cases the storage of human biological material will occur externally instead of at UMC Utrecht's CBB, clearly explain the reasons for this external storage, and state the

	arrangement, human biological material cannot be amplified to immortal (stem) cells and cell lines.	location. The MREC must review the deviation from the standard storage location. Note: In case of external storage, the responsible sub-biobank coordinator will still be responsible for ensuring proper use of the biobank material in accordance with UMC Utrecht's Biobank Regulations. Also answer the questions of Section 4.3 of the biobank protocol template.
	Has the applicable **privacy legislation** (GDPR) been adhered to when storing and encoding human biological material and associated data? ➢ In case of a biobank based on a 'no objection' arrangement: the human biological material and the associated (clinical) personal data must be fully anonymized or encoded, and may not be used for commercial purposes.	Make sure all aspects of Section 4.3.2 A + B of the biobank protocol template have been addressed in accordance with the policy of UMC Utrecht. See the UMC Utrecht intranet Connect and the pages below. GDPR FAQ: UMC Utrecht intranet Connect Information on data management policy: UMC Utrecht intranet Connect
	Has the **storage period** of the material to be stored been laid down? Definite or indefinite term?	
Section 5	Reports of privacy incidents recorded? (standard section in protocol template)	
Section 6	**Release procedure via TCBio?** (standard section in protocol template). In case of TCBio: submit the study to the TCBio instead of to the MREC.	In exceptional cases of future release via different committee than the TCBio: include a description of the committee's composition and approach in the protocol (see Article 10b of UMC Utrecht's Biobank Regulations).
Section 7	Will the biobank be managed in accordance with the Biobank Regulations of UMC Utrecht? (standard section in protocol template).	Do not mention the WMO or the Declaration of Helsinki version 2013 here.
	Recruitment and selection: Distinguish between a biobank based on broad consent and a biobank based on a 'no objection' arrangement here: ➢ **Biobank based on broad consent**: standard section in the protocol template and specific questions. Description of the broad consent procedure and creation of a file per donor for recording broad consent statements and withdrawal of broad consent. ➢ **Biobank based on 'no objection' arrangement (residual material from diagnostic procedures /**	

	treatment): It must be demonstrated that the donor and/or their representative have been able to take note of the information referred to in Article 4, under h, of the Biobank Regulations (general biobank information and/or leaflet on use of human biological material) and have not objected to the processing, storage and use of the human biological material for the purposes listed; description of how donors who object will be dealt with.	
	Findings on serious conditions which are clinically relevant for the donor and/or relatives: reporting procedure via the TCBio. (standard section in protocol template)	
Section 8	Amendments. (standard section in protocol template)	
Section 9	Publication of results of research with biobank material. (standard section in protocol template)	

INFORMATION LETTER, CONSENT FORM AND WITHDRAWAL FORM

Specific, comprehensible verbal and written information for the donor and/or his/her representative on the following points:

	Comment
Purpose and background of the biobank	
Formulation of broad consent with a view to future research = purpose for which the material is being stored. Here a description must also be included of the sub-area of medicine for which the material can be used in the future, e.g. cardiovascular disease, cancer, degenerative muscle disease. Broad general consent cannot be unlimited (e.g. medical scientific research).	
Description of release, storage, use and destruction of human biological material; descriptions of types and quantities of material obtained.	
Information on the burden and risks associated with the collection of human biological material.	
Section on approval from the TCBio (MREC) and the Executive Board.	
Section that describes that specific research will be performed by, or under responsibility of, UMC Utrecht investigators, and how this will be reviewed (in principle by the TCBio).	
In principle no feedback on results of research with biobank material.	
Information on relevant findings will be provided. 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.	
Ownership: no rights of ownership of results.	
Voluntary nature.	
Duration of participation and retention period (in principle indefinitely).	
Procedure for withdrawal of broad consent. This revoking of consent only applies to future research involving the collected human biological material and the associated data.	
In case of inclusion of minors: section on what will be done when a participant turns 16.	See the biobank information letter template, Duration of participation.

Safeguards (privacy) must be sufficiently assured.	See also the biobank protocol, Section 4.