Biobank Research Ethics Committee (TCBio) of UMC Utrecht

Standard Operating Procedure 04

Title: **Review - Reporting of findings**

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1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the procedure for dealing with a report on a finding observed during medical scientific research for which the TCBio has approved the release of human biological material and/or clinical data.

2. DEFINITIONS

Advice: Advice concerning the desirability of providing information to the patient/donor about the finding and the way in which this information will be provided.
Adviser: An expert issuing advice to the Committee on a request, an amendment or a finding, after signing a confidentiality agreement.
Applicant: The party submitting a review request.
Chair: Chairperson of the TCBio as appointed by the Executive Board.
Committee: The Biobank Research Ethics Committee (TCBio).
Finding: A chance and unforeseen research finding (or diagnostic result) not related to the underlying study protocol and not noticed upon initial use of the human biological material (in the case of residual material).
Member/members: One or more members of the TCBio, as well as their possible deputies.
Release protocol: The standard application form for 'Release of human biological material and/or clinical data'.
Reporting party/parties: The party or parties reporting the finding to the TCBio.
Request: The request to the TCBio for a review of the collection of human biological material and clinical data, or the use thereof, for medical scientific research.
Research file: The set of documents which the TCBio is to review in order to form an opinion, including all annexes and associated correspondence.
Secretary: The secretary of the TCBio.
SOP: Standard Operating Procedure.
TCBio meeting: Regular meeting of the TCBio which takes place once every month.
TCBio number: The number assigned to a request by the secretariat.
TCBio: The Biobank Research Ethics Committee (TCBio). The Committee which as per its Rules of Procedure is composed of representatives of a variety of disciplines and which in accordance with UMC Utrecht's Biobank Regulations reviews requests for the use of human biological material and/or of clinical data collected for medical scientific research and subsequently issues an opinion in this regard.
Useful: This is a general term which refers to the relevance of the finding for which not only the medical and therapeutic relevance is taken into account but also all possible consequences of the finding for the patient/donor and/or relatives or surviving relatives (if applicable).

3. BACKGROUND

On 25 June 2013 the TCBio of UMC Utrecht was established by the Executive Board of UMC Utrecht, and on that same date the Biobank Regulations of UMC Utrecht became effective.

- The TCBio conducts professional, independent and efficient reviews of requests for medical scientific research with human biological material and associated (clinical) donor data that is subject to UMC Utrecht's Biobank Regulations and for which the TCBio is authorised to give its approval on behalf of the Executive Board;
- The TCBio conducts professional, independent and efficient reviews of requests for medical scientific research with clinical and other personal data obtained from the hospital information system and/or patient-focused database systems which exist at UMC Utrecht and at third parties;
- The TCBio acts as a central point of contact for the reporting of findings of medical scientific research for which it has approved the release of human biological material and/or clinical data, assesses the (clinical) relevance of each finding, and draws up advice on how the finding should be handled (administratively and otherwise).

4. RESPONSIBLE PERSONS

4.1. Adviser
4.2. Member
4.3. Secretary
4.4. Secretarial assistant of the TCBio
4.5. Chair

5. DESCRIPTION OF THE PROCEDURE

The procedure for handling the report on a finding is represented graphically in the overview at the end of this SOP. If it is necessary to act quickly, the reporting party may deal with the finding themselves, by way of derogation from this SOP. In that case the reporting party will report the finding to the Committee as soon as possible afterwards, providing a substantiation of why it was necessary to deviate from the existing procedure as well as a report on the procedure followed when informing the patient. The Committee will then decide whether they approve of the procedure followed.

5.1 Reporting of findings

A reporting party must report the finding via e-mail (TCBio@umcutrecht.nl) to the secretary of the TCBio. If the finding gives rise to this, the party reporting it may deal with it directly themselves. In that case the finding will be reported to the TCBio as soon as possible afterwards. The secretarial assistant will check whether the report on the finding includes the TCBio number of the associated request. If the TCBio number is missing, the requesting party will be asked to provide it. The information received will always be forwarded directly to the secretary. This report will be assigned the TCBio number of the previous request, supplemented with a T and a number, as is laid down in SOP 01, Registration of documents. This TCBio number will be stated on all correspondence and documents following on from this report. The reporting party will receive written confirmation of receipt of the report. This confirmation will state that the finding is being processed, that the TCBio will review its clinical relevance, and that the TCBio will draw up advice on how the finding should be dealt with (administratively and otherwise).

5.2 Agenda setting

Reports can concern new findings or, in case of an urgent matter, findings already dealt with, as described in Section 5.1 above. The secretary will assess whether the report is sufficiently complete for it to be discussed by the Committee. If necessary, additional substantive information will be requested in consultation with the Chair of the TCBio. The report will in all cases be put on the agenda for discussion during the next meeting.
If it is already known that there is, or has been, a treatment contract, the treating physician and/or the medical head of the department concerned will in any case be consulted as experts and involved in the decision-making process. For more details on further processing, please refer to Section 5.3 below.

5.3 Review

The TCBio will assess whether the finding is relevant for the patient/donor and/or any surviving relatives at the time of the review (*'hoc tempore'*). If the reporting party has already informed the patient/donor about the finding, the TCBio will assess whether it agrees with the procedure followed.
The TCBio will weigh up all relevant interests and on that basis decide, where necessary in consultation with experts, whether the finding will or will not need to be reported. Obviously, the clinical relevance as well as the consequences for the patient/donor and/or any surviving relatives are essential matters here. In addition, the Committee will draw up advice on how the finding should be dealt with (administratively and otherwise).

The discussion of the substance and the decision-making process will be recorded in the minutes, and various recommendations may be formulated depending on the outcome. The various options are explained below:

a. If the conclusion is that the finding does not have any clinical relevance for the patient/donor and/or any surviving relatives, and/or if it is not considered useful to inform them, the TCBio will advise the reporting party to not initiate any follow-up actions.

b. If the conclusion is that the finding is clinically relevant, and/or that it is useful to inform the patient/donor and/or any surviving relatives, the TCBio will advise the reporting party to take the necessary follow-up actions. In this advice they must also indicate what route should be followed here and which persons should ideally be involved.

c. If the finding has already been communicated to the patient/donor, the TCBio will indicate to the reporting party whether they agree with the steps taken, and will provide further advice where necessary.

The reporting party will receive all advice drawn up by the TCBio secretary in writing. After receiving the advice, the reporting party will be responsible for the execution of the necessary follow-up actions.

5.4 Secretary's duties

The secretary will take care of the correspondence with the reporting party in connection with the TCBio's decision-making process.

5.5 Registration

The report on a finding, as well as any advice from the members and any experts and advisers consulted, the relevant sections of the meeting minutes and/or e-mail deliberations and all correspondence relating to the report will be dealt with and filed in accordance with SOP 01 on the registration of documents.

6. REFERENCES

SOP 01 Registration and filing of documents
Biobank Regulations of UMC Utrecht

7. LITERATURE

Biobank Regulations of UMC Utrecht