Procedure for direct use of (fresh) residual material from routine care in a scientific study.

The UMC Utrecht biobank policy requires that a sub-biobank protocol is drawn up and reviewed by the Biobank Research Ethics Committee (in Dutch: TCBio) before collection of residual material from routine care. Before each use of the residual material from the residual material sub-biobank in a scientific study, review of a release protocol by the TCBio is required.

To use (fresh) residual material from routine care directly in a scientific study, a simplified review procedure applies when a defined set of criteria are met. This instruction outlines the criteria and the necessary steps.

Direct use of (fresh) residual human biological material from routine care in a scientific study.

Check if your study meets the following criteria:

1) It concerns human biological material (and associated data as applicable) 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) The residual material is collected and used **directly** (in other words: no material will be stored).
3) The residual material is collected and used for a **specific research study**.
4) All of the residual material is **completely used in the specific research study.**

➔ **YES,** the study meets all of the criteria. ***REQUIRED ACTION*:** Obtain an **approval** from the TCBio before use of the residual material (and associated data as applicable) by review of a **release protocol** (refer to: 'Use of human biological material' and TCBio website).

➔ **NO,** the research does not meet all of the criteria. ***REQUIRED ACTION***: Obtain **permission** from the Executive Board by TCBio review of a **sub-biobank protocol** before collection of the residual material (and associated data as applicable). Refer to: Collection of human biological material and TCBio website. Subsequently obtain an **approval** from the TCBio before use of the residual material (and associated data as applicable) from the residual material sub-biobank, by review of a **release protocol** (refer to: Use of human biological material and TCBio website).

Hints for the review procedure.

The review procedure will be most efficient if prior to submission careful consideration has been given to the grounds on which the residual material will be used: patient's consent or 'no objection' rule (refer to: Decision tree data processing (U)AVG/WGBO and the considerations below).

Consent: In principle, patient's consent can be obtained for use of (fresh) residual material that is collected during a planned procedure. For instance, consent can be asked at the pre-operative consult that always takes place before a planned operation.

ACTION: Add an information letter and consent form (download template here) for the specific research study to the initial TCBio submission of the release protocol.

No objection: Use of human material and associated data without explicit consent is only permitted when certain legal requirements are met (refer to: Decision tree data processing (U)AVG/WGBO). One of the requirements is that a substantiation can be given for why it is reasonably not possible to ask the patients consent or why asking the patient's consent involves a disproportionate effort. Because the residual material in this case will be used in research immediately after it becomes available from the patient, this requirement for use without consent can mostly likely not be met.

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