
Withdrawal from the Biobank Policy

1. Context

Taking part in a biobank is voluntary. Biobank custodians have an obligation to respect an individual's expressed preferences.

Biobank personnel, when consenting individuals, need to be clear about the withdrawal process so that they can explain it effectively to the individual in advance of consent. This ensures that they are informed, and their consent is freely given.

2. Purpose

The purpose of this policy is to provide specific information and guidance to biobank personnel and to research participants consenting to take part in a biobank on the withdrawal process. This should ensure a consistent approach when dealing with such requests.

If a patient provides consent to a biobank and passes away some time after, the family may request the withdrawal or otherwise of the patient's biological material and/or data. In this case, the wishes of the deceased are to be respected. However, a DPO or legal professional should be consulted before any decision or further discussion with the family.

3. Benefits

The benefits of having a withdrawal from the biobank policy in place, are numerous. It ensures that the biobank has clear, transparent and easily accessible guidelines in place which outline the process of withdrawal.

The policy ensures that individuals are appropriately informed at the time of consent, that they have the right to withdraw any biological specimens and/or data from the biobank at any time and that their decision will not have any negative repercussions on their current or future treatment or care pathway.

4. Scope

The scope of this withdrawal from the biobank policy is specific to the gastrointestinal (GI) biobanks in the Department of Surgery (including the Upper GI, Lower GI, Barrett's Oesophagus, Inflammatory Bowel Disease and Pancreatic Biobanks) under the Trinity St James's Biobank Network (TSBN). The TSBN is a working group of representatives from biobanks in Trinity College Dublin and its associated hospitals, namely, St James's Hospital, The Coombe Hospital, Tallaght University Hospital, Children's Health Ireland at Crumlin and one collaborating hospital, Beaumont Hospital.

5. Principles

During consenting of prospective individuals, it should be made clear of any practical limitations, circumstances or time points that would prevent the withdrawal of biological material and/or data from use. The following points are provided as guidance as to the possible limitations on withdrawal from a biobank:

It may not be possible to withdraw from a biobank/research study when:

- The samples and/or data have already been shared with a collaborator and cannot be retrieved as this would impact the research results.
- The results from a research study have already been published.
- Research results have already been disseminated in other ways, such as being deposited in a publicly accessible database in an anonymized format, so that there is no link available to remove these.
- Analysis has been conducted and withdrawal may impact the statistical validity of the results or follow-up data (secondary analysis).
- Data have to be retained for safety and regulatory purposes.
- Personal data and results have been irrevocably anonymized, preventing them from being identified for removal.

An individual cannot be limited as to how they can withdraw their consent. This can be in person, by phone, verbally or in writing. The individuals will have the contact information of the relevant biobank personnel (found on the participant information leaflet). Personnel need to be made aware of this, in addition to data protection implications to withdrawal, if the individual wishes to erase their data.

Every effort should be made to respect the wishes of the individual to withdraw from any further processing of their biological material or data.

All requests for withdrawal should be recorded where possible by biobank personnel using the appropriate Patient Withdrawal Form and making sure that everything is documented in the biobank database.

6. Definitions (optional)

Biobank: A centralised archive of human biological material and/or health-related data which are made available for research purposes.

Personal data: Any information relating to an identified or identifiable person (data subject). An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier.

Consent: Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research. Consent involves a process of communication about the proposed participation in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed participation in advance of giving their freely given consent.

Anonymized data: Data collected without identifiers such as name, address or date of birth that can never be linked to an individual.

7. Policy (mandatory)

This policy provides details as to what withdrawal is and what processes are in place should an individual decide to have his/her biological material and/or data removed from a biobank. It is intended to be clear, transparent and with no requirement for the individual to provide a reason for doing so.

8. Responsibility

It is the responsibility of the Biobank Manager to report and document any request for withdrawal of biological samples and/or data by an individual. Withdrawal requests may be made verbally, in writing or by phone to the Principal Investigator without the need to provide a reason for this. In doing so, the Data Protection Officer will also be informed.

Principal Investigator:

Professor Jacintha O'Sullivan

Tel No: +353 1 8962149

Email: osullij4@tcd.ie

For queries specific to pancreatic biobank, please contact Professor Stephen Maher on +353 1 896 2104 or by email: maherst@tcd.ie.

9. Related Documents

Patient Information Leaflet

Consent Form

Gastrointestinal Biobank Privacy Notice

TCD/SJH Data Protection Policy

10. Document/version control

This document (version 1.0) was drafted by members of the Trinity St James's Biobank

working group as a template for individual biobanks and last reviewed by the TCD Data Protection Office on 16. 01. 24 and the SJH Data Protection Office on 29.02.24

Approved by: Sharon O'Toole

Date policy approved: 5/4/24

Date of next review: 5/4/26
