Access Requirements to the QUOD biobank

The application for access to the QUOD biobank is a two-stage process.

> **Part A:** Preliminary application to determine if the biobank has the required samples/data for the requestor. If the sample types required by the requestor are available a full application is invited. Further information regarding the sampling time points and sample handling is available from the QUOD website (ww.quod.org.uk).
>
> **Part B:** Full application submission is reviewed by the Steering Committee. Applications may be externally reviewed by scientific experts in the field and may be sent for technical review. Further information is available in the access policy

Please see the notes below for help in completing the preliminary (Part A) and full (Part B) application forms.

1) Part A:

PRINCIPAL INVESTIGATOR: This is the primary responsible investigator for the proposed study. The Principal Investigator holds overall responsibility for the academic coordination of the project.

RESEARCH QUESTION: Please outline in 2–3 sentences what the research question is that you will be addressing. The QUOD NMT will be aware if other projects are being conducted in a similar area and may highlight to you opportunities to collaborate.

SAMPLE TYPES REQUIRED: Please indicate the types of samples required. Please read the information below regarding sample types available and sample handling to ensure that the samples are appropriate for your research project. Please review the basic donor data set to see if there any donor characteristics for selection of samples. If there are any other characteristics for sample selection required please contact the National Data Manager on contact@quod.org.uk.

ETHICS: Please indicate if you have already received ethical approval for the use of samples for the research proposed. For researchers proposing projects concerning improving quality in organ donation, the QUOD biobank holds generic ethical approval for research projects in this area, subject to access being awarded by the Steering Committee. Please see the access policy for further information on ethical approval for projects.

2) Part B:

SECTION 1: INFORMATION ABOUT THE STUDY: This section provides detailed information about the project including the Principal Investigator and Collaborators, the research area and detailed information on the proposed methodology.

PRINCIPAL INVESTIGATOR: This is the primary responsible investigator for the proposed study. The Principal Investigator holds overall responsibility for the academic coordination of the project. Please indicate whether the PI is a QUOD Consortium member.

NAMES AND INSTITUTION OF COLLABORATORS: Please list all of the collaborators working on the project both from within the institution and outside. Note samples cannot be passed from one institution to another without the agreement of the Steering Committee as stipulated in the Material Transfer Agreement.

NOMINATED CONTACT (FOR ENQUIRIES): This is the nominated person responsible for handling the application. This may be a researcher, laboratory assistant or administrative assistant.

CONTACT FOR BIOSPECIMEN TRANSFER: Please provide the name and contact information for the person responsible for receipt of the bio-specimens.

STUDY START AND COMPLETION DATE: Please state the estimated start and completion date of the project. Regular reports are required following receipt of the samples until the end of the project. Please see the Access Policy for further information.

PROJECT SUMMARY: Please outline in less than 100 words in language suitable for a lay reader a summary of the proposed project. This summary may be published on the QUOD website. If you do not wish this to be published please indicate this on the application and your reason for this.

PROJECT OUTLINE: Please outline in less than 500 words the background, aims and objectives of the project, the main hypotheses and outcome measures and the proposed methods. Outlines longer than the specified word limit will be sent back to the requestor.

REFERENCES: Maximum 5 references

SECTION 2: FINANCIAL INFORMATION: This section concerns financial information relevant to receiving the samples and being able to conduct the study including the research funder. Prior to the release of samples proof of funding arrangements may be requested by the Steering Committee.

FINANCIAL COORDINATOR/CONTACT: Please provide the details of the department financial coordinator or contact

SECTION 3: SAMPLE REQUIREMENTS: Please list the number and types of samples you require. Review the types of samples available and the sample handling, further information is provided below and on the QUOD website (www.quod.org.uk). Please list any donor characteristics required for the samples.

DATA FIELDS REQUIRED: Please list the desired donor and recipient demographic, biological and outcome data required. The QUOD team work with NHSBT to provide this information for researchers. A few selected data types covering mainly donor biometrics is available at QUOD, and further data types can be requested by researchers directly from NHSBT by contacting Statistics and Clinical Audit group as described on this webpage:
https://www.odt.nhs.uk/statistics-and-reports/access-data

OTHER REQUIREMENTS: Please list any other requirements for either the samples or data. Please discuss any queries with the National Data Manager prior to submission (contact@quod.org.uk).

ETHICS: Please indicate if you have already received ethical approval for the use of samples for the research proposed. For researchers proposing projects concerning improving quality in organ donation, the QUOD biobank holds generic ethical approval for research projects in this area, subject to access being awarded by the Steering Committee. Please see the access policy for further information on ethical approval for projects.

3) Sample types available:

Samples collection and storage cost recovery is applied for samples provided to research projects (see section 4). The cost is defined per biobank items, the definition of which is explained below according to each sample type.

BLOOD SAMPLES:

1 Biobank Item = 1x 0.5 ml aliquot

Available in 0.5 ml aliquots; typically 4–6 aliquots per time point (DB1/2/3/4) are available, depending on the success of collection and previous utilisation, with the DB4 time point available only for DBD donors. For each time point, separate samples are typically collected in the following formats: EDTA plasma, lithium heparin plasma and SST serum.

URINE SAMPLES:

1 Biobank Item = 1x 0.925 ml aliquot

Available in 0.925 ml aliquots; typically up to 4 aliquots per time point (DU2/3/4) are available, depending on the success of collection and previous utilisation, with the DU4 time point available only for DBD donors. Samples are collected in a single format, i.e. without variation in additives.

TISSUE SAMPLES:

Available for liver, kidney (left/right/both), ureter and spleen. Tissue samples are collected for a single time point at organ retrieval. Samples of liver, kidney and ureter are typically split into two parts, one preserved in RNAlater and another preserved in formalin and subsequently processed into FFPE blocks. Samples of spleen are preserved only in RNAlater.

An RNAlater sample can be requested in one of the following formats:

An entire RNAlater sample (up to approx. 3 mg of tissue)	3 Biobank Items
One section equal to one-third of a sample (approx. 1 mg of tissue)	1 Biobank Item
One section equal to two-thirds of a sample (approx. 2 mg of tissue)	2 Biobank Items
Two sections each equal to one-third of a sample (approx. 2 mg of tissue as two 1 mg fragments)	2 Biobank Items

A formalin sample can be requested in units of sections, in the following formats:

Single tissue section on a non-coated slide	1 Biobank Item
Single tissue section on a charged/coated slide	1 Biobank Item
Levels	1 Biobank Item per level
FFPE tissue scroll	2 Biobank Items
Multiple consecutive sections from same FFPE block	2 Sections = 2 Biobank Items 3 Sections = 2 Biobank Items 4 Sections = 3 Biobank Items 5 Sections = 3 Biobank Items 6 Sections = 4 Biobank Items 7 Sections = 4 Biobank Items 8 Sections = 5 Biobank Items 9 Sections = 5 Biobank Items 10 Sections = 6 Biobank Items

The exact availability of tissue sample types and amounts depends on the success of collection and previous utilisation of a sample. For more details please email contact@quod.org.uk.

4) Data Sharing:

The Data Release Agreement for usage of data provided by NHSBT and relayed by QUOD to the applicants is provided as an attachment to the MTA that requires to be signed before samples are allocated to research projects. This NHSBT document summarises rules that the users of data should follow. A modification to these rules is that the Steering Committee for QUOD approves applications, which updates points 7 and 9. Another difference is that published papers, abstracts, datasets, and other public outputs as a result of QUOD sample analysis should be reported to QUOD in response to periodic requests, updating point 6. Users of NHSBT data should follow all other rules when data was received from QUOD, as these rules cover third-party sharing and usage of this data. Since QUOD integrates clinical data with biological sample availability, it is advised to treat all data received from QUOD as falling under these rules.

5) Sample collection and storage recovery charges:

The QUOD Programme is required to recover some of the cost associated with the running of the biobank. A cost recovery target was set by our funder, NHSBT, and is part of the agreement for the allocation of the QUOD budget.

QUOD would like to ensure that material is provided to research projects without burdening researcher with high costs. Therefore, the calculation of the cost recovery charge per biobank

item is reviewed annually and takes into consideration the utilisation of the resource and the number of samples collected during the previous year.

Yearly cost recovery updates are discussed and approved by the QUOD Steering Committee in the Autumn Steering Committee meeting of each year and applied from the 1st of January of the following year.

In addition, it was agreed by the QUOD Steering Committee that access to biobank material would be provided to research projects in a "tier" approach:

The first tier includes application from researchers from non-profit institutions directly involved in the transplantation field. Calculation of cost recovery is done on a basis of 10% cost recovery.

The second includes applications from researchers from non-profit institutions in a field other than transplantation. Calculation of cost recovery is done on a basis of 25% cost recovery.

The third includes applications from researchers from businesses including pharmaceuticals companies. Calculation of cost recovery is done on a basis of 40% cost recovery.

Current charges applied for QUOD biobank access (01/01/2018 – 31/12/2018):

Category	**Cost recovery level**	**Cost per biobank item** (as defined in section 3)
1st tier	10%	£11.95
2nd tier	25%	£29.87
3rd tier	40%	£47.80

6) Additional costs:

The QUOD programme is being charged for invoice processing therefore, some of this cost is being applied as an admin fee on the following basis:

A 5% fee, will be applied for applications costing between £100, and £2000. Applications costing less than £100 will be charged a flat rate of £5 and those costing over £2000 will be charged a flat rate of £100.

The cost of transport from the biobank to the researcher is also added to the overall invoice; alternatively, transport can be arranged by the researcher.