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 (www.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 quod-research@nds.ox.ac.uk.

ETHICS: Please indicate if you have already received ethical approval for the use of samples for the research proposed. For projects concerning improving quality in organ donation and transplantation, 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 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 visit the Research Variables page of the QUOD website https://quod.org.uk/research-variables/ to select the desired donor and recipient demographic, biological and outcome data required. This is an interactive list and your selection can be exported as a CSV file, which can then be attached to your Part B application. The QUOD team work with NHSBT to provide the requested data variables to researchers.

OTHER REQUIREMENTS: Please list any other requirements for either the samples or data. Please discuss any queries with the National Operational Coordinator or Data Manager prior to submission (quod-research@nds.ox.ac.uk).

ETHICS: Please indicate if you have already received ethical approval for the use of samples for the research proposed. For projects concerning improving quality in organ donation and transplantation, 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

Sample collection and storage cost recovery is applied for samples provided to research projects (see section 5). The cost is defined per biobank item, 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.

BAL SAMPLES:

1 Biobank Item = 1x 0.925 ml aliquot

Available in 0.925 ml aliquots; typically 4-6 aliquots are available, depending on the success of collection and previous utilisation. Samples are collected in a single format, i.e. without variation in additives.

TISSUE SAMPLES:

Available for liver, kidney (left and right), ureter, spleen and heart (left and right ventricle; hearts that have not been transplanted). Tissue samples are collected at a single time point at organ retrieval.

Samples of liver, kidney, ureter and heart are typically split into two parts: one preserved in RNAlater then snap frozen, the other 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, dependent on tissue type)	3 Biobank Items
One section equal to one-third of a sample	1 Biobank Item
One section equal to two-thirds of a sample	2 Biobank Items
Two sections each equal to one-third of a sample	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
FFPE tissue scroll	2 Biobank Items
Multiple consecutive sections on slides 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, including information on how biopsies are collected from each organ and approximate sizes of each sample please contact the National Operational Coordinator on quod-research@nds.ox.ac.uk.

WHOLE ORGAN BESPOKE SAMPLES

QUOD are currently able to offer bespoke sample collection through the Whole Organ research programme. Researchers are able to request samples tailored to their own requirements from heart, lung, kidney and pancreas. For more details please contact the National Operational Coordinator on quod-research@nds.ox.ac.uk.

DIGITISED SLIDE LIBRARY

For details of this new QUOD resource, offering digitised histology images linked to donor and recipient metadata, please visit quod.org.uk/digitised-slide-library/.

4) MTA and Data Sharing

Following approval of the research application by the QUOD Steering Committee, it is a requirement for an MTA to be signed, which contains conditions of access. A copy of the MTA can be supplied for review by the researchers' institution if needed prior to submission of the research application.

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 sign off 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 QUOD Steering Committee 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) Amendments

Data or samples supplied from the collection must only be used for the purposes proposed in the original research application and according to terms stipulated in the MTA. Secondary research questions are not permitted unless an amendment or new application has been submitted and approved. Amendment request forms are available via the National Operational Coordinator on quod-research@nds.ox.ac.uk.

6) Costs

6.1 Cost recovery model

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 aims to ensure that material is provided to research projects at the lowest possible cost to researchers. Therefore, the calculation of the cost recovery charge per biobank item is reviewed periodically and takes into consideration the utilisation of the resource and the number of samples collected during the previous year. Cost recovery updates are discussed and approved by the QUOD Steering Committee.

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:

- **Tier 1**: applications from researchers from **non-profit institutions**.
    - Set up research support by the QUOD team is provided, and application and amendment fees apply.
    - Calculation of cost recovery per biobank item (as defined in section 3) is done on a basis of 10% cost recovery.
- **Tier 2**: applications from researchers from **commercial organisations**, including pharmaceutical companies, in a **fully collaborative model**.
    - This collaboration model includes annual infrastructural support payments by the commercial organisation and full research support by the QUOD team.
    - Calculation of cost recovery per biobank item (as defined in section 3) is done on a basis of 25% cost recovery.
- **Tier 3**: applications from researchers from **commercial organisations**, including pharmaceutical companies, in a **partially collaborative model**.
    - This collaboration model includes an access fee per application and set up research support by the QUOD team.
    - Calculation of cost recovery per biobank item (as defined in section 3) is done on a basis of 50% cost recovery.

- **Tier 4**: applications from researchers from **commercial organisations**, including pharmaceutical companies, in a **sample access only model**.
    - This model includes an access fee per application and no research support by the QUOD team.
    - Calculation of cost recovery per biobank item (as defined in section 3) is done on a basis of 100% cost recovery.

6.2 Current charges applied (from 1/1/2025)

QUOD DONOR BIOBANK SAMPLES

Category	Cost recovery level	Cost per biobank item	Annual Infra-structure Support payment	Access fee	Application or amendment fee
Tier 1 **Non-profit**	10%	£15.30	-	-	£150
Tier 2 **Commercial - Fully collaborative**	25%	£38.25	Yes	-	-
Tier 3 **Commercial - Partially collaborative**	50%	£76.50	-	£7,500 per application	-
Tier 4 **Commercial - Sample access only**	100%	£153.00	-	£1,000 per application	-

Samples will be charged at the cost per biobank item for the year in which the research application was approved. This covers all samples originally requested in the Part B application form. Samples requested as an amendment at a later time point, which are in addition to the original request, will be charged at the cost per biobank item currently active at the time of amendment submission.

WHOLE ORGAN BESPOKE SAMPLES

Costings for researchers accessing bespoke samples through the Whole Organ research programme will be discussed and agreed between the QUOD team and the researcher following approval of the research application. Costs are dependent on the complexity of the request and will take into account the resources required and the organ transport costs.

6.3 Recharges for sample transport & admin fee

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

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

- Applications costing for biobank items less than £100 = flat rate charge of £5
- Applications costing for biobank items between £100 and £2000 = 5% fee
- Applications costing for biobank items over £2000 = flat rate charge of £100

6.4 Invoicing process

An invoice request form detailing biobank item and additional costs will be provided prior to shipment of samples. Samples will only be supplied once a PO has been received by QUOD.

7) Part C form

As stated in the MTA, researchers receiving QUOD samples are required to feedback to QUOD the outcomes of the research, including any presentations and publications resulting from the use of QUOD samples/data. A Part C form is used for this purpose and will be provided to the applicant shortly after samples are supplied.

Any publication or presentation using data or samples from QUOD should include an acknowledgement using the text below:
"This research has been conducted under the remit of the UK Quality in Organ Donation (QUOD) Consortium supported by NHS Blood and Transplant".

For presentations, the QUOD logo should be used. This is available from the QUOD website or by emailing quod-research@nds.ox.ac.uk.