**Joint Research Management Office**

**Protocol for Research Tissue Banks and Research Databases**

*This template is suitable only for RESEARCH TISSUE BANKS (RTB) and/or RESEARCH DATABASES (RD); for full definitions see Glossary and Definitions section.*

*This template should NOT be used for:*

*- clinical trials or medical device studies regulated by the Medicines and Healthcare products Regulatory Agency (MHRA);*

*- interventional studies that change patient’s standard clinical care or treatment;*

*- specific research studies (including observational studies).*

*Furthermore, it is not appropriate to complete this Protocol template if proposing to conduct an audit or service evaluation.*

***How to use this document:***

***The text in green italics is guidance text only intended for the investigator to read and interpret in the context of their own protocol. On reading, replace (and delete) the guidance text with black text completing full details relating to specific RTB/RD. Text in black standard Arial font 11 is mandatory text that should not be deleted.***

**Full Title** *<full title>*

**Short Title** *<short title>*

**Sponsor** *<delete as applicable>*

* Barts Health NHS Trust (Barts Health)

*OR*

* Queen Mary University of London (Queen Mary)

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**IRAS Number** *<IRAS number>*

***(*Integrated Research Application System)**

**Sponsor (EDGE) Number** *<Sponsor’s EDGE number>*

**REC Reference** *<REC Reference number>*

***(*Research Ethics Committee)**

**Chief Investigator (CI)** *<CI title and name>*

*<CI job title>*

*<CI postal address>*

*<CI telephone number>*

*<CI email address>*

**Operations Manager** *<title and name>*

*<job title>*

*<postal address>*

*<telephone number>*

*<email address>*

**List of Tissue/Data Collection Centres (TCC/DCC)**

*<name of TCC/DCC>*

*<Principal Investigator (PI) name>*

*<postal address>*

*<telephone number>*

*<email address of main contact>*

*<REPEAT FOR EACH TCC/DCC>*

**List of laboratories, including central facilities**

*<name of laboratory/central facility>*

*<name of head of laboratory/central facility>*

*<postal address of laboratory/central facility>*

*<telephone number of laboratory/central facility>*

*<email address of main contact at laboratory/central facility>*

*<REPEAT FOR EACH LABORATORY/ CENTRAL FACILITY>*

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# Amendment history

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol Version No.PM-V001** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
| 1 | V002 |  |  |  |

# Glossary and Definitions

***Research tissue banks (biobank)***

*“A research tissue bank or biobank is a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific study with ethical approval or for which ethical approval is pending” (Source: Health Research Authority (HRA)).*

***Research database***

*“A research database is a structured collection of individual-level personal information, which is stored for potential research purposes beyond the life of a specific research study with defined endpoints. Research purposes in this context refers to analysis of data to answer research questions in multiple studies” (Source: HRA).*

***Research***

*“The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.” (Source: HRA).*

***Audit***

*A study designed to assess a clinical service against a standard. It may aim to answer the question ‘does this service reach a predetermined standard?’ Does not involve randomisation or allocation to an intervention.*

***Service Evaluation***

*Evaluates a clinical service but is not generalisable to other services and does not compare to a standard. May aim to answer the question ‘what standard does a service achieve?’ Does not involve randomisation or allocation to an intervention.*

# Abbreviations

APR Annual Progress Report

Barts Health Barts Health NHS Trust

CI Chief Investigator

DCC Data Collection Centres

DI Designated Individual

GCP Good Clinical Practice

GDPR General Data Protection Regulation

HRA Health Research Authority

HTA Human Tissue Authority

IRAS Integrated Research Applications Systems

JRMO Joint Research Management Office

MHRA Medicines and Healthcare Products Regulatory Agency

PI Principal Investigator

PPI Patient and Public Involvement

Queen Mary Queen Mary University of London

RD Research Database

REC Research Ethics Committee

RTB Research Tissue Bank

TCC Tissue Collection Centres

*Please insert any additional abbreviations and key terms.*

# Signature page

**CI Agreement**

The *<Research Tissue Bank / Research Database>*, as detailed within this Protocol, will be conducted in accordance with the principles of Good Clinical Practice (GCP), the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki, Human Tissue Act (HTA) (RTBs only), GAMP 5 (RDB only) and any other applicable regulations. I agree to take responsibility for the oversight of this *<Research Tissue Bank / Research Database>*

**CI Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Summary and synopsis

|  |  |
| --- | --- |
| **RTB/ RD Title** | *RTB/RD Title including any Short Title/ Acronym* |
| **Data/ tissue collection methods** | *briefly outline the data / tissue collection methods* |
| **Type of Data/Tissue** | *list the type of material/data to be collected* |
| **Aims** | *brief statement of key aims* |
| **Number of samples / data points** | *number of participants expected to be recruited in the whole RTB/RD* |
| **Inclusion and exclusion criteria** | *summarise inclusion and exclusion criteria* |
| **Planned approval duration** | *estimated duration for the RTB/RD* |

# Introduction

## Background & Rationale

*Give an outline of the background to the RTB or requirement for the research database, with references to literature and other relevant research. Include a thorough literature review of relevant studies and analysis. Outline the scientific justification and rationale for the RTB/RD. Describe the population/cohort from which samples/data will be collected. Include references as appropriate.*

## Risks & Benefits

*Provide a summary of any known or potential risks and benefits of any of the procedures by which the samples/data will be collected, handled, and stored. It is highly unlikely that the storage of data and tissue for use in future research studies, completely anonymous and with no intention to link back to participants, will have any discernible benefit to the cohort group. However, there may be the risk (albeit minimal) associated with venepuncture of taking blood, but illustrate proportionality needed if blood is being taken anyway and not for the purpose of the RTB. Possible risk in RD is the loss of data/ possible breach of confidentiality.*

# Aims

*State the key aims and expected outcomes of the RTB/RD.*

*IMPORTANT NOTE: if you have a specific research question and hypothesis then that is a specific research study (as opposed to an RTB/RD) and the Protocol template for Research Studies template should be completed instead (see Joint Research Management Office (JRMO) SOP 13a.)*

# Purpose / Description of the RTB/RD

1. ***What****? (What samples and data will be collected?)*
2. ***When****?*
3. ***Where****? (Where are the samples/data collected?)*
4. ***Storage*** *(Where are the samples stored, and how is this facility secured/monitored? Describe any preparation required to materials prior to storage).*
5. ***Downstream processing*** *(any downstream processing of samples that will be made available to researchers? E.g. DNA/RNA extraction, TMA creation?)*
6. ***Bioinformatics*** *(will there be any bioinformatics development/creation of databases? Who will oversee this?)*
7. ***Research & Development (R&D)*** *(will any R&D be performed for the Tissue Bank e.g. to explore optimal tissue preservation?)*
8. ***Follow-up and patient data collection****. (Who will do this? How and when? Mention regulations that will be followed. List clinical and demographic information to be collected (e.g. sample information, patient, pathology, treatment, outcome information) and the fields of information that will be collected for each of these).*

*Specifically for RTB:*

*Give an overall description of the participants and samples to be collected.*

*Describe the data to be collected and how this will be linked to the samples.*

*Describe in general terms what the tissue samples will be used for.*

*Specifically for RD:*

*Give a detailed description of the data to be collected including what personal identifiers are to be collected and stored. If applicable, include the name of any database that data is being extracted from; individuals/ roles that will have access; details of all data extractions; source data and verification; authorisations required for access; coding/encryption details; anonymisation procedures and any specific data removal procedures.* *Describe in general terms what the data will be used for.*

## Inclusion criteria

*The set of criteria which determines the participant is eligible. The following are examples:*

* + *Able and willing to give informed consent (additional measures have to be in place if children, vulnerable adults or adults unable to give consent are included)*
  + *Gender*
  + *Age range*
  + *Description of study population or cohort (including clinical diagnoses, if relevant)*
  + *Ethnicity*
  + *Socio economic grouping*

## Exclusion criteria

*The set of criteria which determines that the patient is ineligible to participate. The following are examples:*

* + *Unwilling or unable to give consent*
  + *Gender*
  + *Inability to understand written and/ or verbal English*
  + *Medical history*
  + *Participation in other studies*

# Screening and Recruitment

*Describe the screening and recruitment process (for RD, describe how databases will be screened for the appropriate records).*

## Data and/or Sample Collection

*Arrangements for data collection and consent from data subjects; policy on withdrawal of consent. Describe all procedures and assessments in detail as applicable. Add visit numbers if appropriate. Schedule of data/tissue collection (per participant, per visit): example table template below. Delete if not applicable.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Data point* |  |  |  |  |
| *Medical History* |  |  |  |  |
| *Questionnaire* |  |  |  |  |
| *Interview* |  |  |  |  |
|  |  |  |  |  |

*Add schedule of procedures as an appendix if appropriate. Describe the data associated with the samples to be collected. Include a list of all data points to be collected.*

## Management of RTB/RD

*Describe the overall policy of the RTB/RD for use of the samples or data, including release to other researchers or research organisations (including those inside and outside the UK, EU, EEA area and worldwide). If suitable, a separate document may be created outlining the RTB/RD release policy, management and oversight.*

*Describe the processes for effective de-identification of data extracts prior to release to external researchers. Explain the format in which data will be transferred and provided.*

*Describe the conditions of data sharing agreements with external researchers, in particular no attempt to re-identify data subjects through linkage with other databases and no onward disclosure to third parties.*

*Describe the scope of the RTB/RD including what analyses are, and those that are not, considered to fall under the RTB/RD’s REC approval (if applied for) rather than needing to seek a separate REC favourable opinion.*

*Read and refer to the applicable Barts Health and/or Queen Mary Information Security Policies, Data Protection Policy and relevant procedures.*

## Access to RTB/RD

*Use this section to describe in detail all arrangements regarding internal and external researcher access to the tissue stored in the RTB or data stored in the RD.*

*Eligibility criteria for individuals, organisations and studies that request samples / data*

*Outline the process for submitting a request for access.*

*The logistics of how the samples are transferred to and from the recipient and the standards they must meet when they are custodians of the tissue / data.*

*Any fees charged for providing the samples / data.*

*Any restrictions on what the recipient is allowed to do with the results of their analysis on the data or samples, for example, acknowledgements of the RTB/RD owner in any publications.*

# Sample Size & Analysis

## Number of samples/data points to be collected

*Insert details including rationale and justification. State approximate number of samples/data points expected to collect; either per annum or over a 5-year period. State maximum number of tissue samples that have capacity to be held in storage. Describe any statistical considerations.*

# Ethics

*This section should state whether Research Ethics Committee (REC) approval will be sought; and the details of. {If REC approval is not being sought, please justify and give further details.}*

*Where REC approval is being sought, and the ethical approval is likely to expire over the course of the RTB/RD, provide further information about maintaining and extending ethical approval for the duration.*

*Summarise the main ethical, legal, or management issues arising from the RTB/RD and say how you have addressed them. Possible areas for consideration include, but are not limited to:*

* *Informed consent*
* *Recruitment*
* *Inclusion/Exclusion criteria*
* *Data management*
* *Risks, burdens and benefits*
* *Confidentiality and data protection*
* *Conflicts of interest*

## Annual Progress Reporting

*The CI should send an Annual Progress Report (APR) to the REC and the sponsor using the HRA template on the anniversary of the REC favourable opinion letter.*

## Confidentiality Advisory Group (CAG) Approval

*A requirement if the study intends to access confidential patient information without consent in England and Wales.*

# Public involvement

*Public involvement is fundamental to ensure high quality clinical research that brings real benefits for patients and participants. This section should describe the public involvement activities that have already taken place and how they have informed the development of the research study. This section should also describe plans for future public involvement activity which will take place during and after the research study. Examples include Patient and Participant Involvement (PPI) review of participant information sheets and consent forms, and the inclusion of lay persons on the Steering Group/ Committee responsible for release of data and tissue.*

*For information and guidance on how to involve patients and the public in your research, please contact the Research Engagement and Diffusion team via* [*Patientsinresearch.bartshealth@nhs.net*](mailto:Patientsinresearch.bartshealth@nhs.net) *or visit* [*www.jrmo.org.uk/performing-research/involving-patients-in-research/*](http://www.jrmo.org.uk/performing-research/involving-patients-in-research/)

# Data handling, storage and record keeping

## Data management

*Describe in detail:*

* *a description of the methods of data capture*
* *the method of data entry*
* *design of data capture forms*
* *transfer and storage of the data in a central study database*
* *security arrangements for the transfer and storage of data (see section 12.5 for further guidance on cyber security)*
* *Methods for maintaining data quality, such as completing quality checks on all received or transcribed data and maintaining an audit trail for all changes to the data (see section 15 for further guidance).*

## Data Sources

*Source data are the original data used in the RTB/RD. Some source data will be generated directly by the data collection (e.g. questionnaire responses) while others may need to be collected from other ‘source documents’ (e.g. a participant’s medical history in their case notes).*

*In this section:*

* *Define the source data and documents for the RTB/ RDB e.g. hospital health records, questionnaires, existing datasets.*
* *Define the responsibilities of contributing organisations for maintaining source documents.*
* *Describe any activities that the central RTB / RDB team will complete to confirm the integrity of source data.*

## Confidentiality

*Information related to participants should be kept confidential and managed in accordance with the Data Protection Act, the General Data Protection Regulation (GDPR), NHS Caldicott Principles, the UK Policy Framework for Health and Social Care Research and the conditions of Research Ethics Committee favourable opinion. This section should explain the arrangements to ensure the confidentiality of participants. Areas to consider include:*

* *The identification of potential participants (note: only members of the patient’s direct care team (defined as “healthcare professionals directly responsible for providing routine care and treatment to individual patient”), or others with permission by explicit consent, can access a patient’s medical records.)*
* *Describe in detail how the data will be anonymised, including methods to prevent unauthorised re-identification.*
* *Maintaining confidentiality when transferring samples / data within and outside of the organisation*
* *Describe where personal data will be stored, for what purpose, and who has authorised access*
* *Whether organisational Caldicott approval is required*
* *Access to participant healthcare records and source documents and by whom.*
* *The security requirements that external recipients of data and tissue must abide by*

## Record retention and archiving

*The Sponsor policy on document retention will be adhered to. All research documentation must be archived in accordance with JRMO SOP 20 Archiving. For studies involving Barts Health patients, undertaken by Barts Health staff, or sponsored by Barts Health or Queen Mary the approved repository for long-term storage of local records is the Trust Corporate Records Centre. This section should explain the arrangements for archiving study documentation (including electronic databases) after the study has ended, and the final destruction of the records.*

## Computer Systems

*Refer to JRMO SOP 38c Research data management systems for non-regulated research when writing this section.*

*It is acceptable to provide a high-level summary with reference to standalone database documents. Describe:*

* *The location of the server on which the research database and any other computer systems are hosted.*
* *The software or programming language that has been used to build the database (e.g. REDCAP version x) and any other computer systems such as data capture tools or analysis software.*
* *The methods of validating the database and any other computer systems including any necessary security arrangements e.g. relating to servers.*
* *The security arrangements for the database software. The database should be stored on a location where only those who need to access it can do so. Access to the database should be password protected, ideally with individual user accounts, and the data should be encrypted at rest.*
* *The physical and virtual security arrangements for the servers (see SOP 38 for guidance). It is recommended that the database is hosted on a Barts Health server or within the Queen Mary safe haven. If you do so, you can state that the organisational security procedures will be followed. If your database will be hosted with a third party or on a standalone hard drive (not recommended) then describe your arrangements for keeping the database secure. Consider:*
  + *Protection from environmental damage e.g. fire, flooding and vermin*
  + *Preventing unauthorised individuals from accessing the server room*
  + *Firewalls and antivirus software*
  + *Penetration testing*
* *The arrangements for backing up the stored data and the location of the data backups. Databases hosted on Barts Health servers or the Queen Mary safe haven will be backed-up by the IT department. If you will host your database on an external server or on a standalone hard drive (not recommended) then describe how the data will be routinely and accurately backed up and where the backups will be stored.*
* *Procedures for updating the database software and hardware.*

# Laboratories *<delete this section if not applicable>*

*For the sub-headings below, it is acceptable to provide a high level summary in this section if a separate laboratory manual will be submitted with the protocol.*

## Sample preparation and collection

*This section should describe the requirements for collecting, labelling and pseudo-anonymising samples, documenting sample receipt and the storage conditions of samples. Reference relevant material and the Human Tissue Act 2004.*

## Laboratory procedures

*This section should detail each type of laboratory procedure that will take place during the study and the time points when they will take place. Option to attach Standard Operating Procedures as Appendices.*

## Sample access, storage and transfer

*This section should describe the arrangements for transferring processed samples between labs, and the arrangements for storing samples. RTBs storing relevant material ordinarily require a storage licence from the HTA. Those storing other material (e.g. serum, DNA, cell lines) do not. As the Human Tissue Act, and the remit of the HTA, applies only to England, Wales and Northern Ireland, RTBs based in Scotland do not need a HTA licence. If the RTB will be storing relevant material then the details of the Designated Individual (DI) are required.*

*It is best practice to use an electronic sample tracking system such as ‘Item tracker’ or ‘Tissue Auditor’ to track samples. A detailed description of the system used should be included here.*

*Give details on the arrangements and requirements on external researchers applying for access to data/tissue held within the RTB/RD. Further details about what Committee will be set up to facilitate the access to and transfer of tissue/data should be given in Section 15.*

*Provide details regarding length of retention of samples.*

## Incidental Findings

*This section should discuss the RTB/RDs policy towards incidental findings such as discovery of previously unknown diseases or disorders (this policy may be a separate document to this protocol). Provide information regarding how researchers will report incidental findings to the RTB/RD and/or participants. If researchers are required to comply with a separate policy, it is sufficient to provide only high-level information.*

## Sample Security and Integrity

*Describe the methods for ensuring the continued security and integrity of any stored samples. This may include, for example, routine temperature monitoring, automatic temperature excursion notification, environmental controls and physical security arrangements.*

*Details of evidence for sample stability and integrity should be included here; include references where possible to justify sample retention plan and medium.*

# Governance and Quality Management

*<Mandatory text (not to be deleted):>*

The Sponsor or delegate retains the right to audit any and all parts of an RTB/RD. In addition, any part of the RTB/RD may be audited by the funders where applicable.

*Describe the methods of governance and quality management that will be implemented to maintain oversight of the RTB / RD. The aim of this section is to ensure participant safety and data integrity as well as compliance to the protocol and GCP. Process to achieve this can include:*

* *Establishing a quality management system and a quality assurance manager.*
* *Establishing internal quality control procedures.*
* *Establishing a RTB/RD governance committee.*
* *Establishing training programmes for RTB/RD staff and recruiting site staff.*
* *Planning monitoring visits of the RTB/RD to confirm that:*
  + *All required documentation is in place.*
  + *Sample storage conditions are adequate.*
  + *Server location and security is adequate.*
* *Planning monitoring visits to identified recruiting sites to confirm that:*
  + *Donors meet eligibility criteria.*
  + *Donors have given informed consent for the storage of their samples and data.*
  + *Recorded data are accurate.*
  + *Meeting the HTA standards (where required)*

*When deciding on what should be in place, consideration should be given to how the CI can be assured:*

* *All participants are treated as per protocol and are safe*
* *That the data collected is accurate, of good quality and would stand up to robust scrutiny.*

*Resource should not be the determining factor in the level of governance oversight in place. It is acceptable to provide a high-level summary in the protocol with reference to more specialised documents e.g. monitoring plan, quality manual, and governance committee charter.*

*The JRMO is not able to offer monitoring or review monitoring reports but is happy to discuss the needed for monitoring and the type of monitoring relevant to the study.*

# Management Committees

*This section should outline how the CI will ensure appropriate oversight of the RTB/RD, data, samples and participant safety**and to outline any committees or groups involved in coordination and conduct.*

*Outline if there will be any data monitoring/steering/safety committees set up for this RTB/RD and explain their role. Describe the extent of the role of this committee and their involvement within the study. Refer to JRMO SOP 47 for guidance on the types of committees possible and when they are needed.*

*As a minimum, all RTB/RDs should convene a management group consisting of the CI, Principal Investigators (PI), collaborators, grant holders, statisticians and study coordination team that has oversight of the RTB/RD and makes decisions on the release of data and samples to external parties.*

*Include details where relevant of:*

*Policy/Management of Tissue Bank*

*The Centres*

*Proposed Operational/Governance Structure*

*Tissue Access Committee*

*Data Access Committee*

*Conflicts of Interest*

*Authorship Policies*

*Legal/Intellectual Property (IP) Issues*

*Resource utilisation*

# Finance and funding

*This section is important for transparency. Provide the names and contact details of ALL organisations providing funding and / or ‘support in kind’ for this study (including internal funding and donations) and free equipment.*

# Insurance and indemnity

*Delete only one of the statements in black below as appropriate, depending on sponsor institution.*

*Queen Mary sponsored*

The insurance that Queen Mary has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm.

*OR*

*Barts Health sponsored*

NHS indemnity scheme will apply. It provides cover for the design, management, and conduct of the study.

*The following areas should be addressed:*

* *What arrangements will be made for insurance and / or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?*
* *What arrangements will be made for insurance and / or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?*
* *What arrangements will be made for insurance and / or indemnity to meet the potential legal liability of investigators / collaborators arising from harm to participants in the conduct of the research? Note that if the study involves sites that are not covered by the NHS indemnity scheme (e.g. GP surgeries in primary care) these investigators / collaborators will need to ensure that their activity on the study is covered under their own professional indemnity.*
* *Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?*
* *If equipment is to be provided to site(s) for the purposes of the study, the protocol should describe what arrangements will be made for insurance and / or indemnity to meet the potential legal liability arising in relation to the equipment (e.g. loss, damage, maintenance responsibilities for the equipment itself, harm to participants or site staff arising from the use of the equipment).*

*Usually the responsibility for the first and second points lie with the sponsor, responsibility for the third point lies with the participating site, and the fourth point with the sponsor. The fourth point is not mandatory and should be assessed in relation to the inherent risks of the study; however, it may be a condition of REC favourable opinion to have these arrangements in place.*

*If additional insurance or indemnity has been obtained to cover the study, then this should also be stated here. This applies specifically to Queen Mary sponsored studies with international or non-NHS sites. Please seek advice from the JRMO in these cases.*

# References

*Please use a recognised referencing system. List the literature and data that are relevant to the RTB/RD and that provide background. Please ensure the text contains appropriate cross references to this list.*

*Before finalising the protocol, please update the table of contents (right-click any heading and select “Update field”, then change to the option of “Update entire table”).*

**This protocol is based on JRMO Protocol template for Research Tissue Banks and/or Research Databases:**

**V1.0 01.03.2021**