# Clinical Directorate Clinical Research Governance Team

# Standard Operating Procedure

# Sharing Data from University Sponsored Trials

# SOP033

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|---|---|
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# Contents

## 1. Introduction

The University of Liverpool, as a Sponsor organisation, strongly supports the sharing of data in the most appropriate way. We support open access to research data, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK.

Sharing of research data must protect the confidentiality and privacy of research participants, respect the terms of consent provided by research participants and be consistent with relevant legal, ethical and regulatory frameworks.

## 2. Scope of Procedure

This SOP details the process of sharing individual participant data from clinical trials[1] Sponsored by the University of Liverpool, after the trial has formally closed. This applies to data requests from both internal and external colleagues.

This SOP only applies to requests for data that has not been made available via a national data centre or subject specific repository[2]. Data requests for trials that are still open should be considered by the Trial Management Group (TMG).

Requests for data related to samples held within a Research Tissue Bank will be reviewed by the specific Research Tissue Bank (RTB) and if deemed appropriate this SOP will be followed.

This SOP does not detail processes for data management through the lifecycle of a research project. The University of Liverpool Research Data Management Service provides advice and signposting to experts on how to manage and prepare data for sharing from the initial stages of planning research.

## 3. Who

This SOP only applies to University of Liverpool Sponsored research.

This SOP will not apply where a trial, study or team have an established process for receiving and reviewing data sharing requests. It is noted that these processes need to involve a Sponsor representative.

## 4. When

This SOP will be applied once a request for data sharing has been received, the party/individual making the request will hereby be referred to as the "Requestor" throughout this SOP.

[1] Clinical Trials includes - Clinical trial of an investigational medicinal product; Clinical investigation or other study of a medical device; Combined trial of an investigational medicinal product and an investigational medical device; Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

[2] More details on storage of data can be found via the University Research Data Management team - https://www.liverpool.ac.uk/library/research-data-management/

## 5. Receipt of Requests

Requests for data sharing may be received via various routes (e.g. direct contact to Sponsor, via the Clinical Trials Unit (CTU) that managed the trial or via the Chief Investigator (CI)). Requests should be formalised using FORM022 Data Sharing Request Form which must be shared with the Senior Clinical Research Governance Manager once complete.

The scientific validity of the Requestor's new project should be reviewed by a peer reviewer with adequate level of expertise in the research area and the Requestor must provide a copy of their project's protocol or grant application, along with any ethical or regulatory approvals that have been received. The Participant Information sheet and Informed consent form from the original project will also be reviewed to ensure consent stipulations have been appropriately defined.

The Senior Clinical Research Governance Manager will review the information provided in FORM022, assess the request and discuss with University of Liverpool departments and any third parties as required. Applications will be noted at the next Clinical Research Regulatory Oversight Committee (CRROC) information. If an application requires more extensive review or input, it can be escalated to the CRROC at the discretion of the Senior Clinical Research Governance Manager and Chair of CRROC.

The Research Contracts Team and the Data Protection Officer will also be approached for review and input. If the request is approved the Senior Clinical Research Governance Manager will obtain approval from any third-party organisations before a decision is communicated.

The Senior Clinical Research Governance Manager will also ensure the decision is communicated in a transparent manner. The Senior Clinical Research Governance Manager will direct the Data Custodian to share the data, if the request is approved. The Senior Clinical Research Governance Manager must be informed when the sharing is complete.

## 6. Review of request

The review of the request to share data will consider;

**Current Data Custodian and type of dataset (anonymity)**

The current Data Custodian (e.g. person responsible for safe and confidential storage of the data) should be identified and informed of the request for data sharing. The Data Custodian should inform the Senior Clinical Research Governance Manager of the timeframe for the data being provided, and any cost implications of preparing the data.

Wherever possible, fully anonymised datasets should be shared. If an anonymised dataset is not available for sharing it should be established if one can be produced. It should be noted that fully anonymised data cannot be linked back to any participant or sample data.

**Restrictions and Risks of sharing data**

Are there any restrictions on sharing the data? For example, are there any restrictions within the original consent? If consent for sharing of data is optional has the data been removed for participants that did not consent? Have any participants withdrawn consent?

Are there any specifics with the way that data has been collected or coded that may impose restrictions on sharing?

Does the dataset include any data provided by a third-party provider (e.g. NHS England data, external laboratory data etc)? Are there any contractual restrictions to sharing this data?

Are there any risks involved in sharing the data such as risks of participant identification or risks to the integrity of the trial? What methods have or will be employed to mitigate risks?

**Ethical Requirements & Scientific Validity**

Data being shared will usually be NHS data. Use of NHS data usually requires ethical approval. Therefore, it should be established if the Requestor's new project requires ethical approval and if it does, evidence of approval should be obtained (either at the time of request, or at a subsequent date but prior to sharing of data). (Do I need NHS Ethics approval?)

The suitability (competence/qualification/supervision/support) of the person requesting the data will also be assessed.

**Contractual Requirements**

Trials are subject to various contracts, including main funding agreements. A Review of all applicable contracts for the original trial must be undertaken to establish what (if any) restrictions / obligations are in place for the trial data. These should be reviewed against the Requestor's new project to ensure data sharing does not result in a breach of contract.

There may be restrictions on sharing data as well as requirements to obtain agreement from various organisations prior to sharing.

In addition to reviewing existing contractual documentation, additional contracts may be required prior to sharing any data once it has been approved by the CRROC. The drafting of such agreements will be managed by the Research Contracts Team. Such requests will be led by the CI or an appropriate member of the study team.

## 7. Legal Considerations - Common Law Duty of Confidentiality

The Common Law Duty of Confidentiality applies to information about an identifiable individual who is alive or deceased, which is not in the public domain, which has a degree of sensitivity and was given the expectation it will be kept confidential. This includes medical and healthcare information.

This requirement does not apply to anonymised datasets.

To lawfully access confidential personally identifiable information such as that contained in health records for research activities, the access must be in line with the reasonable expectations of the individual about whom the information relates.

For clinical trials and associated research projects, the default access route is reasonable expectations that is typically evidenced by written consent. The ethically approved Participant Information Sheet and Consent Form (PISC) must be reviewed to establish if a consent statement covers consent for "future research". If multiple versions exist each version should be reviewed.

If "future research" consent was sought on the original PISC, data may only be shared by those participants who have explicitly provided their consent.

Consideration should be given to whether this consent statement was optional (some participants may not have given consent), and also to withdrawals of consent. Information on which participants have consented may be obtained from the original Trial Statistician.

Where it is not practical to obtain consent to access data held under a duty of confidentiality, there is an alternative route under the lawful provisions of the NHS Act 2006 Section 251. This enables the Duty of Confidentiality to be set aside under limited and controlled circumstances. Such authorisation can only be provided by the Health Research Authority Confidentiality Advisory Committee (CAG), and evidence of this approval must be provided prior to data sharing.

## 8. Legal Considerations - 2018 Data Protection Act and UK General Data Protection Regulation (UK GDPR)

The 2018 Data Protection Act (DPA) applies to the processing of personal data, including special categories of personal data about people who are alive. Legal obligations cease once a participant is deceased.

This does not apply to anonymised datasets.

For other datasets, the following must be confirmed to allow sharing:

Legal Basis

The original trial should have the specific GDPR Legal Basis documented – usually this is Public Interest (GDPR Article 6.1.e) and Archiving for Research/Statistical Purposes (GDPR Article 9.2.j). This is usually documented within the original trial PISC.

The Requestor's project should be assessed against the original GDPR Legal Bases to ensure they are not incompatible.

GDPR "technical & organisational measures":

Reassurance should be obtained that the data will be handled safely and confidentially by the Requestor. This may be by establishing that the Requestor organisation has appropriate "technical & organisational measures" in place (e.g. current NHS Data Security and Protection Toolkit (DSPT) Registration). This may also be included as a condition of the sharing in the contract.

Location of Requestor – data flows out of UK

GDPR and DPA require that if data is to leave the UK, the participants are informed. Additional measures such as risk assessments and additional contractual provisions may need to be put in place to allow the physical transfer out of the UK. Where it is intended to share personally identifiable data outside the UK the University Data Protection Officer should be consulted.

Establish where the Requestor is located and whether the act of sharing data with them will involve transfer of data out of the UK (if so, establish to which country).

Where this is the case, prior to transfer, this information may need to be disseminated to participants and a contract may be required.

## 9. Third-party agreement (e.g. co-Sponsors, joint Data Controllers, etc.)

Once all the above assessments have been made, if the UoL is happy to share, agreement should be sought from other relevant organisations.

Trials may have multiple Sponsors and/or multiple Data Controllers. The appropriate contracts should be in place documenting these relationships and providing contact points (co-sponsorship agreement/joint Data Controller agreement). These must be reviewed to establish which organisations will be required to provide agreement for sharing of trial datasets.

There may be other third-parties from whom agreement is required prior to sharing – e.g. parties with Intellectual Property (IP) rights. The original trial contracts should be reviewed to ensure all applicable parties are consulted.

Where a third-party is required to agree prior to any data sharing, this must be obtained in writing and provided to the Senior Clinical Research Governance Manager. Where a request is not agreed, the third-party should be asked to provide their justification for feedback to the Requestor.

## 10. Decision & Transparency

Once all assessments have been made, and agreements (or refusal) from third-party organisation(s) obtained where applicable, the decision on whether to share or not must be communicated back to the Requestor. Any approval to share data must contain details of any costs and what they will cover.

It must be made clear that;

- The requestor is expected to cover any costs related to sharing the data
- The requestor must not share the data with any third party, and it is only for use within the explicit purposes included in the application.

Refusal to share data should be accompanied with rationale/justification.

## 11. Actioning the Data Sharing

Where a decision is made to share the data, this must be actioned as follows.

**Contractual arrangements**

The need for a Data Sharing Agreement (DSA) or other agreement must be assessed by the Research Contracts Team. Any required contracts will be drafted and negotiated by the Research Contracts Team. This may need a review by the University Data Protection Officer.

**Preparation to Share**

Data Sharing Pack

Data Sharing Packs may have already been prepared for the trial dataset – where this is not the case, the following should be compiled by an appropriate person. This will likely be the Statistics team involved in the trial:

- Relevant versions of the original trial protocol
- Blank Case Report Forms (if available and relevant to the data request)
- Relevant extracts of the original trial Statistical Analysis Plan
- Data Dictionary

Sharing complex datasets or those without adequate supporting information may require additional information to be provided to data recipients to minimise errors / misunderstandings.

Appropriate dataset

Only data required by the Requestor should be provided to ensure data minimisation. This may involve stripping out of data items form the original trial's main dataset. A process should be in place to document what has been removed from the original dataset. It is likely that any data to be removed will be identifiable. The data removal process should be discussed with the University Data Protection officer before data is removed.

Additionally, where Common Law consent is required for the sharing, data from participants who declined to provide this optional consent, or who provided it but subsequently withdrew consent, will also need to be stripped out prior to sharing.

Manipulation of datasets and stripping out of data must be performed by qualified individuals and subject to quality processes to ensure data is not corrupted and that only the agreed data is provided.

**Transfer to Requestor**

Once the above preparatory steps have been performed, the data sharing pack and dataset should be transferred to the Requestor.

Methods to transfer data from UoL to the Requestor must be encrypted and secure. Consideration should be given to use of Trusted Research Environments (TREs).

## 12. Roles and Responsibilities

**Chief Investigator**

Ensure data is appropriately managed throughout the research lifecycle with a view to sharing data

Provide any requests for data sharing to the Senior Clinical Research Governance Manager once received

Respond promptly to any requests for information or documentation to assist in the review of the request

**Senior Clinical Research Governance Manager**

Coordinate any requests for data sharing and communicate any outcomes with the applicant

## 13. Abbreviations

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| **CAG** | Confidentiality Advisory Group |
| **CI** | Chief Investigator |
| **CRROC** | Clinical Research Regulatory Oversight Committee |
| **CTU** | Clinical Trials Unit |
| **DPA** | Data Protection Act (2018) |
| **DSA** | Data Sharing Agreement |
| **DSPT** | NHS Data Security and Protection Toolkit |
| **PISC** | Participant Information Sheet and Consent Form |
| **RTB** | Research Tissue Bank |
| **TRE** | Trusted Research Environment |
| **TMG** | Trial Management Group |
| **UK GDPR** | UK General Data Protection Regulation |

## 14. Associated Documents and References

University of Liverpool Research Data Management Service

FORM022 Data Sharing Request Form

Do I need NHS Ethics approval?

The common law of confidentiality

Data Protection Act 2018

UK General Data Protection Regulation (UK GDPR)

## 15. Training and Resources

CIs, students, trial coordinators and other members of University Staff involved in sharing of research data should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

## 16. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.