University of Hertfordshire

DATA SHARING IN THE UNIVERSITY OF HERTFORDSHIRE SPONSORED AND CTSN ADOPTED CLINICAL STUDIES

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Data Sharing in University of Hertfordshire sponsored and CTSN adopted clinical studies

SOP Number : gSOP-27-01	**Effective Date:** 28th July 2022
Version Number: 1.0	**Review Date:** 2 – 3 years (or as required)

1.0 BACKGROUND

This standard operating procedure applies to all research data generated for University of Hertfordshire (UH) sponsored/CTSN adopted clinical studies held on UH servers. It applies to all research data generated for UH sponsored/CTSN adopted clinical studies shared outside of the University and also research data shared within the University with those not directly involved in the research. UH will facilitate appropriate research data sharing to maximize the value of research data.

The UK General Data Protection Regulation (UK GDPR) sets certain restrictions and conditions when UH shares personal data with third party organisations. This is to ensure that the personal data are protected adequately and handled properly by others. Restrictions only apply to sharing personal data, that is information about living identifiable individuals (and not, for example, truly anonymised data).

The lawful basis on which UH relies to process data is Article 6(1)(e) of the GDPR which describes processing of personal data that is “necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller”.

Therefore, any data shared will be required to fulfil this requirement and any other legislative requirement.

2.0 PURPOSE

This SOP will be used as the basis for any specific data sharing and data sharing agreements for research data.

Sharing personal data must comply with the data protection principles. The following must be ensured:

- there is a good reason for the sharing to take place (e.g., to meet a contractual obligation or pursue a research project),
- the individuals have been made aware their data is being shared,
- the minimum amount of personal data is shared,
- the sharing is for the minimum time and it is clear what then happens to the data,
- the sharing is done as securely as appropriate for the data involved,
- the sharing is documented.

Sharing may be with:

- a third party to be used for joint purposes,
- a third party for the third party to use for its own purposes,
- a data processor engaged to store or use data for UH.

Where the University shares personal data with a third party for joint purposes, the organisations are known as 'joint data controllers' (Article 26 of the UK GDPR).

In these circumstances, it is **mandatory** to:

- Have a documented arrangement setting out respective roles and responsibilities with regard to data protection matters, including who individuals can contact if they want to complain or exercise any of their rights under the UK GDPR.
- Be transparent, by making the essence of this arrangement available to the individuals whose data is shared, if not included in the privacy notice.

Where UH shares personal data it controls with a third party for it to carry out operations in relation to that data on behalf of UH, the third party is known as a 'data processor' (Article 28 of the UK GDPR). The sharing might be one-off or long-term or ongoing, and it applies primarily to situations where UH is outsourcing or offering a function involving personal data (whether storage or more active management) that it could have chosen to do for itself.

In these circumstances, it is **mandatory** to:

- Have a contract that commits the data processor to certain standards, including with regard to security, the engagement of further 'sub-processors', helping UH to meet its GDPR obligations with regard to individual rights and accountability requirements, and cooperating with UH audits and inspections.

3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH and/or adopted by the CTSN, including but not limited to: Chief Investigators (CI), Principal Investigators (PI), Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Co-ordinators/Managers, Clinical Studies Officers, Data Managers Research Assistants and Students.

This SOP applies to all research data held on University servers and managed by the Clinical Trial Support Network (CTSN).

4.0 RESPONSIBILITIES

The Clinical Trial Support Network Management Group (CTSNMG) will be responsible for the oversight of the sharing of research data generated from clinical research conducted by the CTSN.

The University Legal Team will be responsible for ensuring the relevant information regarding data protection to comply with UK GDPR is documented appropriately in the contract.

The CI is responsible for ensuring that personal data collected for the clinical study is shared in a fair and transparent manner and is consistent with the relevant agreements and contracts in place relating to the data being shared.

The Data Protection Officer (DPO) will be responsible for providing advice in relation to data sharing in compliance with the UK GDPR.

5.0 PROCEDURES

5.1 <u>On funding approval</u>

For all projects which involve the collaboration of institutions and parties external to UH, data sharing and data protection should be considered. At the start of a project the University's legal team should be contacted to discuss the relevant contract/agreement required. At the same time the University's DPO should be contacted and a Data Protection Impact Assessment (DPIA) should be completed (UPR IM08 Appendix 1) with input from all stakeholders. The DPIA will inform the necessary information to include in the contract with respect to data protection.

The template data sharing agreement (UPR IM08 Appendix IV) should be used when UH is the Controller in relation to personal data and is contracting with another party as a result of which the other party will process personal data as a Processor on behalf of UH as Controller. Please note that this Agreement does not contain terms allowing transfer outside the European Economic Area (EEA), which must be added where such transfer of personal data is envisaged.

5.2. Transparency

The sharing of personal data must be reasonable and proportionate. The individuals must know what is happening to their data and must be informed what will be done with their personal data prior to sharing. Ethical factors must be considered when deciding whether to share personal data. Information on data sharing should be included in the Patient Informed Consent and/or Privacy Notice (CTSN TP-07 Patient Information Sheet Template).

5.3. During the project

The DPIA is a living document and should be reviewed regularly and whenever an amendment is made to ensure that any changes to data protection and data processing are addressed.

5.4. Data sharing requests

Requests for data (either anonymised or pseudonymised data) during the study, from a party that is not a collaborator on the project, will be considered by the CI and research team. A Research data sharing request form will be sent to the requestor and processed according to procedures below.

The Research data sharing request form will record as appropriate:

1. Specific data requirements.
2. Proposed research to be undertaken using the data.
3. Publication plan for the proposed research.
4. Justification of the data access request.
5. Summary description of data requested.
6. All data custodian(s): usually the chief investigator(s) of study(ies) involved in the agreement.
7. Data owner(s): i.e. study sponsor for the University of Hertfordshire.
8. Data recipient: this will be (a) named individual(s)/organisation(s) who will have access to the data.
9. Details about the controlled access approach for sharing anonymised/ pseudonymised individual patient data/study data aiming to protect patients' privacy and confidentiality.
10. Details on data destruction or data archiving by the recipient.
11. Secure data transfer method.
12. Time period for which the approval has been granted.
13. Where relevant, obligation on data recipients to commit to and apply security and confidentiality measures to the shared data.
14. Any constraints/requirements specified by data custodian/data controller.

5.5. Decision making process

The completed Research data sharing request form will be reviewed by the CI, a member of the CTSN and the DPO. Approval will be given by the Trial Management Group.

A valid reason must be provided to access the data and that the data requested is relevant and necessary to fulfil the stated purpose.

Requestors are expected to use the research data to generate new knowledge and understanding with the intention to publish research findings for wider scientific community and eventual public benefit, and to demonstrate this in their application to access the data. In any publications, the requestor should acknowledge the contribution of the original study team in accordance with academic standards.

Once the Research data sharing request has been agreed a data access and sharing agreement (UPR IM08 Appendix IV) should be prepared for use where UH is the controller and the other party is the processor.

5.6 Preparation of Data Pack

If the decision is made to share the data a Data Pack will be prepared. The following will be addressed:

1. appropriate steps have been taken to minimise risk of identifying participants, taking into account whether consent for data sharing was sought from the research participants (the reviewers should consider both the data and the environment together when assessing the risk of re-identification, recognising that manipulating the data may adversely affect the utility of the data);
2. where data are to be removed from UH secure servers, data security policies and procedures of the recipient organisation, including country of data recipient (if sharing abroad), and any other applicable regulatory requirements are adequate.

The study statistician and data manager will prepare the Data Pack.

When preparing the Data Pack the following will be ensured:

- Only the data necessary to respond to the request is included.
- The corresponding data dictionary that identifies the data, provides definitions of the data type and coding such that the data can be appropriately used for the intended purpose, is included.
- The format the data will be provided in is agreed with the requestor.
- For identifiable or pseudonymised data the data will be appropriately secured by encryption or password protection.

5.7. Providing access / transferring data

Data may be shared either by transferring the data out of the UH's secure servers or by granting the recipient researcher access to the data while it remains on the UH's secure servers. A Research Data Sharing Agreement is required for the former, and a Data Access Request for the latter. The Data Access Request is a simplified form of the Data Sharing Agreement, which removes the need for institutional sign off, and descriptions relevant to transfer and storage of the data. The information asset owner (usually the trial Chief Investigator) or the lead recipient researcher will be responsible for justifying the purpose of sharing a particular dataset(s). The responsibility for implementing the research data sharing procedure will be a member of the study team who has been nominated with this responsibility. Data will only be shared with organisations that have adequate data security policies and procedures in place.

5.8 Data Sharing at end of trial

At the end of a trial a fully anonymised dataset may be made available to researchers. The publication of the final results will be made available on the University of Hertfordshire Research Archive. Once the data has been made available it should be linked to the publication including a data access statement. The data access statement details how and where the data can be accessed and should include a web link/DOI or departmental email address, and the conditions of use the data is subject to.

Making the data openly available does not necessarily mean making *all* of the data *completely* open; the aim is to be as open as possible but as closed as necessary. Data that concerns human participants can only be made available exactly as specified and agreed to by participants in consent forms.
If the data is sensitive then it may be made available on request, with users having to sign a data sharing agreement that determines their reusage.

Most funding bodies expect this as a condition of the grant. As well as linking the publication to the dataset(s), where possible, the data should be linked to the publication. In the metadata record for the dataset in the repository or other storage location, a statement should be added listing the publication(s) that the data has contributed to.
"This dataset supported the following publication(s): [insert citations including DOI or equivalent here]."

6.0 RELATED DOCUMENTS

- UPR IM08 Appendix IV: Template Data sharing agreement
- UPR IM08 Appendix 1: Template Data protection impact assessment
- Research Data Sharing Request Form
- Data Access Request Form

7.0 APPENDICES

- **Appendix 1 – Definitions**
- **Appendix 2 – Process flow chart**

8.0 VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature  **Date 16 June 2022**

Pro-Vice Chancellor (Research and Enterprise) Approval

Signature **Date 16 June 2022**
Professor J M Senior

10. AGREEMENT (MOVE ON TO A SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-027-01) and accept to follow University of Hertfordshire policies implementing it.

Recipient
Signature: ……Date: ……..
Name & Position: ……

Appendix 1- Definitions

Data Controller:
The data controller will be the organisation responsible for the management and oversight of the data. The data controller determines the purposes for which and the manner in which any personal data is, or are to be processed. The data controller is responsible for the lawfulness, fairness and transparency, data minimization, accuracy, storage limitation and integrity, and confidentiality of personal data.

Data Processor:
In relation to personal data, means any person (other than an employee of the data controller) who processes the data on behalf of the data controller. “Processing”, in relation to information or data means, obtaining, recording or holding the information or data or carrying out any operation or set of operations on the information or data, including
a) organisation, adaptation or alteration of the information or data,
b) retrieval, consultation or use of the information or data,
c) disclosure of the information or data by transmission, dissemination or otherwise making available, or
d) alignment, combination, blocking, erasure or destruction of the information or data
(For research this maybe the research team and when contracted to do

Personal data:
Personal data is any information that may lead to the identification of a living person.

Special category data
Special category data is personal data that needs more protection because it is sensitive. In order to lawfully process special category data, you must identify both a lawful basis under Article 6 of the GDPR and a separate condition for processing under Article 9.
Special category data includes the following information:
1. Race and ethnic origin.
2. Religious or philosophical beliefs.
3. Political opinions.
4. Trade union memberships.
5. Biometric data used to identify an individual.
6. Genetic data.
7. Health data.
8. Data related to sexual preferences, sex life, and/or sexual orientation

Anonymised data
Anonymised data is where all personal data including patient or participant identifiers (which can include name or initials, address, date of birth, hospital or NHS number) have been permanently removed. Anonymised data is not covered by the Data Protection Act (DPA 2018).

Pseudonymised data
Pseudonymised data is where all personal identifiers (which can include name or initials, address, date of birth, hospital or NHS number) are replaced with a unique identifier (e.g., patient study number). The key should be held separately from patient identifiers and allow for study un-blinding if required by the protocol.

Appendix 2 – Process Flow Chart