Data Sharing Policy

Version	Lead Author	Description of changes	Date
1.0	Mark Forrest	New document	28/04/2022
1.1	Mark Forrest	Clarification	01/08/2024

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1. Objective

1.1 **Purpose**

This document is the Centre for Healthcare Randomised Trials (CHaRT) policy for sharing data for purposes other than those they were collected for. All data exchanged must comply with Information Governance and Data Protection Policies of the University of Aberdeen. This policy will be used as the basis for any specific data sharing agreement.

1.2 **Scope**

This policy applies to all research data held on CHaRT servers and managed by the CHaRT programming team. It applies to all research data, including research datasets, shared outside of CHaRT, and research data shared within CHaRT with those not directly involved in the original research project.

This document does not apply to study teams and researchers accessing data from their own study for the purpose it was collected.

2. Introduction

CHaRT recognises the obligation to ensure that optimal use is made of the data that we collect for our research and the value of sharing individual level data. However, when sharing data, we have an obligation to ensure that the interests of research participants, researchers and other stakeholders are appropriately protected.

2.1 Planning

Planning for data sharing should be part of all new studies. The study specific Data Sharing Plan provides information on data sharing principles and methods. It may also include a description of data collection, management, and storage.

2.2 Data shared appropriately

This policy defines controlled access for data sharing. Controlled access means data are shared only with suitable persons and that the shared data protects participant privacy.

2.3 Legislation

The sharing of clinical research data is governed by legislation (2018 Data Protection Act) and in most cases, data sharing requests can, and therefore should, be satisfied using an anonymised dataset[1].

2.4 Who is affected by this policy and what are their responsibilities?

The senior IT development manager is responsible for ensuring staff have appropriate operating procedures and tools for adhering to this policy.

All Chief Investigators are directly responsible for implementing this policy within their trial teams.

2.5 Policy application

This policy applies to all datasets for which CHaRT is the data owner or data controller or has agreement from the data controller to share data.

2.6 Onward sharing

Onward sharing is not permitted without CHaRT consent. Recipients of the data do not have the right to pass on data shared by CHaRT to any other organisation, or partner organisation unless it has been agreed as part of the original Data Sharing Agreement.

[1] Anonymisation is where data that directly or indirectly, in combination with other data, allows a participant to be identified, is removed from the dataset.

Any requests to further share the data are likely to be the subject to a separate Data Sharing Agreement where necessary.

3. Data Sharing Standards

3.1 **The Data Sharing Plan**

The Data Sharing Plan provides information on the proposed management of research data for data sharing.

If a funding body requires a data sharing plan, the study protocol must state that data will be shared as outlined in both the data sharing plan and the Patient Information Leaflet. This policy should be referenced along with the funding bodies own data sharing policy, if provided.

The data sharing plan is normally expected to cover the following topics:

- A description of the datasets.
- Data security and information governance.
- Timescales for dataset release.

3.2 **Data pack**

The data pack would be expected to contain the dataset which is to be made available for sharing plus supporting documentation below:

- Dataset
- A data dictionary
- Additional metadata, such as annotated case report forms
- Reference to any data standards used
- Transformations applied to the data
- Relevant version(s) of the protocol

3.3 **Data security**

All use, storage and handling of the data must comply with the Data Protection Act 1998. It is the responsibility of the applicant to ensure adequate security levels are in place for data storage.

3.4 **Preparation and transfer**

Care must be taken in preparing or releasing identifiable or sensitive data on individuals. Identifiers should be removed prior to disclosure wherever possible e.g. no names or detailed geographical locations; using ages or years of birth instead of full date of birth. Consideration should be given to further anonymising the data by including new ID numbers and breaking the link to the original dataset.

The University File Transfer Service, Zendto, should be used to transfer all data which is

available at zendto.abdn.ac.uk/. If it is not possible or appropriate to use ZendTo, please use an appropriate alternative (OneDrive for Business SHARE).

4. Responsibilities and Roles

The processes of receiving and processing data sharing request documents (DSR), developing agreements, producing and transferring data, and responding to subsequent requests for clarification of data involves a number of different staff with specific roles across CHaRT and the UoA. These include:

Role	Responsibility
Applicant	DSR requester
CHaRT, CI, PI, Researcher	Recipient of request
Data Sharing committee (made up senior members of CHaRT), CI	Review of DSRs
Research & Innovation(R&I)	Work in conjunction with the DSR committee trial team to prepare and conclude a data disclosure and agreements, including any financial implications
Programming & Statistics Group as required	Data extraction, cleaning, and documentation of dataset.
Programming	Log all DSR requests Ensure secure transfer of data

4.1 **Data Sharing Committee**

The Data Sharing Committee (DSC will have at least four members drawn from different CHaRT teams including a senior member of the programming team, a senior statistician, senior member from the trial team and a senior member from the CHaRT management team.

5. Data Sharing Process

1. A contact email address (DataSharing@abdn.ac.uk), managed by the CHaRT programming team, is provided on the Unit website to enable all DSRs to be made. The programming team will endeavour to reply to an initial enquiry within one week.

2. All DSRs will be logged by the programming team. All applicants are required to complete a ‘Data Request Form’ to access the data.

3. Once a ‘Data Request Form’ has been received and forwarded to the members of the DSR committee, it will be reviewed by the DSR committee on a case by case basis. The DSR committee may ask for guidance or input from other groups as appropriate (e.g. Sponsor, Trial Steering Committee, Trial management Group). Any queries or issues relating to the DSR will be discussed with the applicant so the DSR can be revised if necessary.

4. The final decision to share and release the data is made by the CI of the trial or the DSR committee.

5. If a DSR has been approved, a member of the DSR committee will issue a data sharing agreement (DSA) to the applicants for signing. If the applicant raises any issues with the DSA then R&I will resolve any issues with applicant.

6. Research & Innovation will inform the DSR committee once the DSA is signed and finalised.

7. Thereafter the programming team will prepare the data pack for release.

8. The application process should be completed in a timely manner.

9. If the DSR committee rejects a DSR, they must notify the applicant in writing/email and provide them with an explanation for why their DSR was rejected.

10. The DSR committee must ensure that the applicant acknowledges receipt of the data and checks immediately to confirm the integrity and suitability of the data.

6. Further Considerations

6.1 **Costs**

Usually, no charge is made for providing data packs to external users. However, if a particular time-consuming request is received, for example, that required inputting and coding of significant amounts of data, then applicant may have to contribute to the cost.

7. Appendix

7.1 Appendix 1 –Data sharing Flow Chart