

Data Sharing Policy

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Author:	Arouna Woukeu
Reviewed by:	Mike Waring, Anita Patel, Sally Kerry

Authorisation:	
Name / Position	Professor Sandra Eldridge, Director of the PCTU
Signature	
Date	

Purpose and Objective:
This document is the Pragmatic Clinical Trials Unit (PCTU) policy for sharing study data as per Good Clinical Practice Guidelines and the Data Protection Act 1998 [1]. The policy will be used as the basis for any specific data sharing agreement.

Scope

The policy applies to all clinical research data held on PCTU servers and managed by the PCTU Information Technology (IT) & Data Management team. It applies to all research data shared outside of the PCTU and also research data shared with those not directly involved in the research, whether or not the data remain wholly within the defined secure area, and control, of the PCTU.

Facilitating data sharing

The PCTU will facilitate appropriate data sharing to maximize the value of research data, including for patient and public benefit.

The PCTU will share data in a timely and responsible manner, recognising that original study investigators should have a period of exclusivity before key trial data are made available to other researchers. Researchers wishing to access data are encouraged to approach the study investigators prior to approaching the Data Sharing Committee. Where study investigators are no longer in post, the Data Sharing Committee will appoint a member of PCTU staff to facilitate access to relevant documentation.

Anonymised individual patient data can be shared without specific consent, as anonymised data are not covered by the Data Protection Act 1998. To facilitate data sharing, we recommend that the following statement (recommended by the Health Research Authority [2]) is included in the consent form and the patient information leaflet for research studies, if appropriate.

“I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.”

Data may be shared either by transferring the data out of the PCTU secure servers or by granting the recipient researcher access to the data while it remains on the PCTU secure servers. A 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 of the data.

Anonymisation of data

Anonymising data is a process that balances producing safe data with reduced utility of the data [3]. Fully anonymising the data such that the risk of disclosing information referring to individuals is negligible, is required in order for the data to be exempt from the Data Protection Act. For the purposes of this policy anonymous data will refer to data which fulfils these criteria. (reference PCTU_GUI_IG_05)

In other situations some anonymization work may still be carried out to reduce unnecessary risk but the data cannot be considered to be outside the Data Protection Act [4]. Such data may still be shared subject to appropriate safe guards as laid out in this policy.

Resource implications

Preparation of the data for sharing may require significant PCTU resources in order to appropriately anonymise the data and prepare the data for sharing, including providing appropriate documentation. The burden is likely to be higher for archived studies or where there are no PCTU staff currently assigned to the study and where full anonymization is required.

The PCTU will assess resource implications and may charge data requestors for services if necessary. The senior statistician and Head of Information Services and Data Management will ensure sufficient resources are available to undertake work required, prior to signing the Data Sharing Agreement or Data Access Request Form. Where data is accessed on the PCTU Safe Haven requestors will be required to undergo Information Governance training in line with PCTU policies and the a charge may be levied for access accounts.

Where funders are willing to support data sharing activity, the PCTU recommends Chief Investigators include the statistician and data management time for preparing anonymised data in the funding application.

PCTU Data Sharing Committee

The PCTU has a Data Sharing Committee, comprising the following PCTU staff; Head of Information Services and Data Management, a senior statistician, Quality Assurance Manager and Head of Operations or Senior Trial manager

The Data Sharing Committee will review the application to ensure that

1. a valid reason has been provided to access the data and that the data requested is relevant and necessary to fulfil the stated purpose
2. 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,
3. Where data's to be removed from PCTU Safe Haven, 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 Chief Investigator may be invited to attend the meeting or send a representative. The committee will recommend a decision to approve or not the data sharing request.

Transfers of data outside the EU

The PCTU will act in accordance with the Data Protection Act 1998 which states “Personal data shall not be transferred to a country or territory outside the EEA unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.”

Wherever possible the PCTU will fully anonymise any data to be shared outside the EEA. If full anonymization is not possible, while maintaining the utility of the data, the Data Sharing Committee will assess and document the steps taken to ensure there is an adequate level of protection [5,6]. In addition to the member states, the European Commission has assessed a number of countries as having an adequate level of protection [7].

Agreement to data sharing

The data custodian(s) (usually the trial Chief Investigator(s)) or the lead recipient researcher will be responsible for justifying the purpose of sharing a particular dataset(s) and the data custodian will delegate responsibility to the PCTU IT & Data Management Team for implementing the sharing.

Data will only be shared with organisations that have adequate data security policy and procedures in place. These will be clarified in the specific Data Sharing Agreement.

Recipients of the data do not have the right to pass on data shared by the PCTU to any other organisation or partner organisation unless that has been agreed as part of the original Data Sharing Agreement. Recipients must agree not to link the anonymised

data provided with any other data set without the permission of the Data Sharing Committee. Recipients must not attempt to identify any individual from the data provided.

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

Documentation

A written Data Sharing Agreement based on the PCTU Data Sharing Agreement template will detail:

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 (Joint Research Management Office (JMRO) for Queen Mary University of London (QMUL))
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 according to the Health & Social Care Information Centre Data Sharing Framework, which can be referred to for more guidance. [8]
14. Any constraints/requirements specified by data custodian/data controller

Where few data fields are to be shared these can be listed within the Data Sharing Agreement but in most cases a summary of the fields should be included in the Data Sharing Agreement with a full list of fields described in an accompanying technical document.

A written Data Access Request based on the PCTU Data Access Request template will detail items 1-6, 8,12-14 above.

Approval of agreement on behalf of the PCTU and individual researchers

The Data Sharing Agreement or Data Access Request will be reviewed and approved on behalf of the PCTU by the chair of the Data Sharing Committee, the senior

statistician, Head of Information Services and Data Management , the lead recipient researcher and the Chief Investigator (for ongoing or recently closed studies).

Review and Signing of agreement by legal entities (Data Sharing Agreement only)

The Data Sharing Agreement will be reviewed and signed by the Data Custodian, Data Owner, Data recipient. For studies that are not sponsored by JRMO, the JRMO will also approve the document. After sign off, data will be made available by the PCTU via a secure transfer method as agreed.

Data preparation

The PCTU will prepare the dataset(s), either anonymised or pseudonymised, prior to sharing, in line with the signed Data Sharing Agreement or Data Access Request and using recommendations to minimise the risk of patient re-identification. In order to do this, the PCTU will follow its own anonymisation and pseudonymisation procedures, which should be in line with guidelines on effective anonymisation of data [9].

Associated documents:
<p>PCTU_GUI_IG_04 Data Sharing Guidelines V 1.0 PCTU_TEM_IG_01 Data sharing template V2.0 PCTU_TEM_IG_02 Data Access Request template v 1.0 PCTU_Data sharing committee terms of reference v 1.0 PCTU_GUI_IG_05 Patient identifiable v Anonymised data v 2.0 PCTU_GUI_IG_06 PCTUs pseudonymisation and anonymisation Summary of procedures v3.0</p>
References:
<p>[1] GOV.UK – Crime, justice and the law – Your rights and the law – Data protection https://www.gov.uk/data-protection/the-data-protection-act [2] Health Research Authority – Content: Consent Form – General Content http://www.hra-decisiontools.org.uk/consent/content-form.html [3] UK anonymization network http://ukanon.net/ [4] Information Commissioner’s Office – Anonymisation: managing data protection risk code of practice https://ico.org.uk/media/1061/anonymisation-code.pdf [5] Information Commissioner’s Office –Sending personal data outside the European Economic Area (Principle 8) https://ico.org.uk/for-organisations/guide-to-data-protection/principle-8-international/ [6] Information Commissioner’s Office Model Contracts for the transfer of personal data to third countries http://ec.europa.eu/justice/data-protection/international-transfers/transfer/index_en.htm [7] EU Commission decisions on the adequacy of the protection of personal data in third countries http://ec.europa.eu/justice/data-protection/international-</p>

transfers/adequacy/index_en.htm

[8] Health & Social Care Information Centre – Data Sharing Framework Contract Guidance Version 1.0 [http://www.hscic.gov.uk/media/15731/Data-Sharing-Framework-Contract-Guidance/pdf/Data_Sharing_Framework_Contract_Guidance_v1 - FINAL.pdf](http://www.hscic.gov.uk/media/15731/Data-Sharing-Framework-Contract-Guidance/pdf/Data_Sharing_Framework_Contract_Guidance_v1_-_FINAL.pdf)

[9] Information Commissioner’s Office – For organisations: Guide to data protection – Data protection principles <https://ico.org.uk/for-organisations/guide-to-data-protection/data-protection-principles/>

[5]

Additional Note

None

Document Control

Version	Reason for Change	Author of change	Date
1.0	Not applicable	Anita Patel & Arouna Woukeu	13 Nov 2015
2.0	Changes to structure of document to align with other PCTU documents incl watermark logo; clarification of approval personnel; removal of abbreviation list Addition of the following sections 1. staff resources section 2. anonymization section 3. Data Sharing Committee 4. International Sharing 5. References on the above	Sally Kerry	21 st March 2016
2.1	Annual review. Data Sharing through Data Access Request	Sally Kerry	13 th March 2017
2.2	Changed wording of first para and minor edits in response to review by Julie Dodds, Anita Patel and Arouna Woukeu	Sally Kerry	15 th March 2017
2.3	Invitation of CI to committee. Response to Comments by Natasha Stevens and Domenico Giacco	Sally Kerry	22 nd March 2017
3.0	Reversion from 2.3	Sally Kerry	22 nd March 2017
3.1	Clarification over data security at recipient organisation is for data Sharing not Data Access. Addition of provision for exclusivity, requirement not to identify individuals	Sally Kerry	6 th February 2018

3.2	Change 'will invite CI' to 'may invite CI' under Data Sharing Committee and correct title for Head of IS and DM	Lisa Cammel following discussions with DSC	7 Feb 2018
3.3	Minor editing.	Sally Kerry	28 th Feb 2018
4.0	Reversion from 3.3	Sally Kerry	28 th Feb 2018

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