Data Sharing Policy

Policy Number	**PCTU_POL_IG_02**	Version	**5.0**
Publication Date:	**27th March 2019**	Review Date:	**27th March 2020**

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Authorisation:	
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Date	**26th March 2019**

Purpose and Objective:
This document is the Pragmatic Clinical Trials Unit (PCTU) policy for sharing study data in line with various pieces of legislation regarding how data is handled including the General Data Protection Regulation (2016)[1]; the Data Protection Act (2018) [2] and the related Data sharing code of practice [3] and the Good Clinical Practice Guidelines (2016) [4]. The policy will be used as the basis for any specific data sharing agreement.

1. 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 within the PCTU 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. This document does not apply to trial teams accessing the data while it remains in the PCTU Safe Haven

2. Facilitating data sharing

The PCTU will facilitate appropriate data sharing to maximize the value of research data. In common with other academic institutions, the lawful basis on which Queen Mary University of London relies to processes 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 fulfill this requirement. Requestors are expected to use the data to generate new knowledge and understanding with the intention to publish research findings for wider scientific community and eventual public benefit [5], and to demonstrate this in their application to access the data (section 7 and PCTU_SOP_IG_01). In any publications, the requestor should acknowledge the contribution of the original study team in accordance with academic standards.

Requesters should be employees of a recognised academic institution, health service organisation or commercial research organisation with experience in medical research; and should be able to demonstrate their ability to carry out the proposed study e.g. through their own, or supervisor's, peer review publications. Where the requestor is an employee of a commercial organisation the PCTU encourages the requestor to work in equitable partnership with academic researchers and conform to the same data sharing principles and practices as that required of the academic community [5].

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 for more information about the study, to ensure the data is appropriate for their purpose and avoid duplication of research effort. 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 about the data.

3. Mode of data sharing

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 and storage of the data.

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 policies and procedures in place. These will be clarified in the specific Data Sharing Agreement.

4. Information for Patients

Anonymised individual patient data can be shared without specific consent, as the Data Protection Act 2018 does not cover anonymised data. However, participants should be told if researchers intend to keep the data participants provide for use beyond a specific research study and if data may be shared anonymously with others in the future (see HPA for more information [6]). We recommend that the following statement 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."

5. Anonymisation of Data

Anonymising data is a process that balances producing safe data with reduced utility of the data, recognising that whether data are anonymised or not, is a function of both the data and the data environment. [7] 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 that fulfils these criteria [8]. In other situations, some anonymisation work may still be carried out to reduce unnecessary risk but the data cannot be considered to be outside the Data Protection Act [2]. Such data may still be shared subject to appropriate safe guards as laid out in this policy.

6. 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 no PCTU staff are currently assigned to the study, or where full anonymisation is required.

The PCTU will assess resource implications and may charge data requestors for services if necessary. Such charges will not be seeking to generate income, simply to recover costs. The senior statistician or statistics team lead and Head of Information Systems 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. When data are accessed on the PCTU Safe Haven requestors will be required to undergo appropriate training, which includes Information Governance training in line with PCTU policies, and a charge may be levied for access accounts.

Where funders are willing to support data sharing activity, the PCTU recommends Chief Investigators consider including the statistician and data management time for preparing a data sharing pack in the funding application. This will contain well structured data dictionaries, blank case report forms, and associated documentation. Documentation will highlight fields that are considered to pose a risk to identification and provide summary data for these fields. The data sharing pack can be made available, on request, to bona fide researchers through study website and/or PCTU website.

7. PCTU Data Sharing Committee

The PCTU has a Data Sharing Committee appointed by the PCTU Management Group. The committee will have at least four members drawn from different PCTU teams including a senior member of the data management team and a senior statistician, and a CI or representation from one of our affiliated units. It is expected that members will have undergone training or have experience in data sharing.

Members of the committee are encouraged to attend training events and national or international meetings on data sharing. The Chair should be experienced in data sharing issues. Membership of the committee will be reviewed annually and updated as required.

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 are 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 Data Sharing Committee will 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.

The Chief Investigator or a representative will be invited to attend the meeting of the Data Sharing Committee to provide input regarding requests relating to one of their studies. The committee will recommend a decision to approve or not the data sharing request and will communicate the decision with explanation to the requestor in a timely manner. Where the application has been rejected, the committee will describe what modifications are required to enable approval.

Details of the application process and response times and described in the PCTU Data Sharing SOP PCTU_SOP_IG_01.

8. Transfers of data outside the EU

The PCTU acts in accordance with the GDPR (2016) [1] which restricts transfers of personal data outside the EEA unless the rights of the individual are protected in another way. Wherever possible the PCTU will fully anonymise any data to be shared outside the EEA. If full anonymisation 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 [7,8]. In addition to the member states, the European Commission has assessed a number of countries as having an adequate level of protection [9]. For more information on international transfers, see the ICO website [10]

9. Documentation

Third parties must sign an agreement before they can access data held by the PCTU. Where data are to be removed from the PCTU Safe Haven this will take the form of a Data Sharing Agreement signed by the legal entities representing Queen Mary University of London and the recipient organisation. Where data is remaining on the

PCTU Safe Haven this will take the form of a Data Access Request form signed by researchers and PCTU representatives only.

9.1 Agreement to data sharing by 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 NHS Digital (previously the Health & Social Care Information Centre) Data Sharing Framework, which can be referred to for more guidance. [11]
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.

9.2 . Agreement to data sharing by Data Access Request

Where third parties will access data on the PCTU Safe Haven a written Data Access Request based on the PCTU Data Access Request template will detail items 1-6, 8, 12–14 above.

9.3 Review and 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 Systems and Data Management , the lead recipient researcher and the Chief Investigator (for ongoing or recently closed studies).

9.4 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 (usually the sponsor), 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.

10. 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 [7].

Associated documents:
PCTU_SOP_IG_01 Data Sharing SOP v 1.0 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
References:
[1] General Data protection Regulations https://www.gov.uk/government/publications/guide-to-the-general-data-protection-

regulation
[2] Data Protection Act https://www.gov.uk/data-protection/the-data-protection-act
[3] Data sharing code of practice https://ico.org.uk/media/for-organisations/documents/1068/data_sharing_code_of_practice.pdf
[4] Good Clinical Practice Guidelines https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
[5] MRC Policy and Guidance on Sharing of Research Data 1 from Population and Patient Studies https://mrc.ukri.org/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies see page 24 for definition of bona fide research
[6] Health Research Authority http://hra-decisiontools.org.uk/consent/content-sheet-support.html#three
[7] Information Commissioners Anonymisation Decision making Framework which can be accessed http://ukanon.net/wp-content/uploads/2015/05/The-Anonymisation-Decision-making-Framework.pdf
[8] PCTU_GUI_IG_05 Patient identifiable vs anonymised data
[9] EU Commission decisions on the adequacy of the protection of personal data in third countries https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en
[10] Information Commisioner's Office International transfers https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/international-transfers/
[11] NHS Digital Data Sharing Framework Contract Guidance Version 1.0 : https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process

[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. anonymisation section	**Sally Kerry**	21st March 2016

	3. Data Sharing Committee 4. International Sharing 5. References on the above		
2.1	Annual review. Data Sharing through Data Access Request	**Sally Kerry**	13th 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**	15th March 2017
2.3	Invitation of CI to committee. Response to Comments by Natasha Stevens and Domenico Giacco	**Sally Kerry**	22nd March 2017
3.0	Reversion from 2.3	**Sally Kerry**	22nd 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**	6th 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**	28th Feb 2018
4.0	Reversion from 3.3	**Sally Kerry**	28th Feb 2018
4.1	Major revision. Addition of GDPR; clarification about purpose and commercial organisations, clarifications on anonymisation and charging, inclusion of 'data sharing pack' DSC committee composition	**Sally Kerry**	30th January2019
4.2	Additional review and edits on v4.1	**Arouna Woukeu**	20th February 2019
4.3	Response to review from Sandra Eldridge (sections 2 and 5) and Arouna Woukeu	**Sally Kerry**	6th March 2019
4.4	Response to review from Sarah Thomas to align wording of purpose more closely with PCTU IG policy	**Sally Kerry**	11th March 2019
4.5	Checked all references on 11th March 2019. Edited section 4 as no longer quoted on HRA website. Relabelled as new section on information to participants. Renumbered sections.	**Sally Kerry**	11th March 2019
4.6	Minor edits in response to review by	**Sally Kerry**	26th March

	Rupert Pearse, Steph Taylor and Sandra Eldridge		2019
5.0	As version 4.6	**Sally Kerry**	26th March 2019