1. Introduction

1.1 Purpose

The purpose of this document is to guide members of the PCTU, core team and study teams to

- Decide whether data can be analysed entirely within the PCTU Safe Havens (PCTU_SOP_DM_11)
- Decide when a Data Sharing Agreement is required
- Prepare documents for submission to the Data Sharing Committee

This document aims to summarise and facilitate compliance with PCTU policies and SOPs and not replace these.

1.2 Background

Our policies and SOPs state that no participant data from trials should be shared with those outside the trial team without a data sharing agreement being in place and that all Data Sharing Agreements (DSA) should be reviewed by the Data Sharing Committee (DSC).

A formal Data Sharing Agreement is a contract drawn up between two institutions, which allows a copy of the data requested to be transferred to another institution. An alternative simpler approach is for the researcher to request access to the data from within the PCTU Safe Haven.

In addition, for the purposes of statistical analysis, all study data is accessed and processed only from within PCTU Safe Haven (ref PCTU SOP DM 05). These procedures have been drawn up in order to comply with Information Governance requirements.

A Data Sharing Agreement will only be agreed with organisations that have adequate data security policy and procedures in place. These will be clarified in the specific Data Sharing Agreement. (DS Policy)
All live study databases as well as data extracts are to be stored and managed from within the PCTU Safe Haven. (PCTU SOP DM 05)

This document also draws on the Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials. https://www.methodologyhubs.mrc.ac.uk/files/7114/3682/3831/Datasharingguidance2015.pdf

2. Trials which are open

For all open trials, data access should be discussed with the senior trial statistician or senior health economist in the first place.

This will ensure

- The most appropriate version of the data is accessed including derived variables where appropriate
- Appropriate quality checks have been carried out
- Workload and timelines for the stats team can be agreed.

Sometimes researchers from another institution will require access to trial data, in order to complete trial analyses as specified in the protocol. This will be most commonly for health economic analysis, but may also include sub analyses for specific purposes as described in the protocol or specialist advice on statistical modelling.

Giving external researchers’ access to the data whilst keeping it in the PCTU Safe Haven is the best way of achieving this. This is because

- This is in accord with current PCTU procedures (SOP DM 05)
- Drawing up the Data Sharing Agreement requires considerable effort to collect and describe required information (security of the destination environment and data to be shared)
- A DSA needs to be approved by the DSC
- Sign off depends on third parties (legal entities) over which the PCTU has little control.
- Data needs to be prepared for transfer requiring additional resources
- The PCTU Safe Havens allow remote access to data as well as most tools required for processing.

A DSA can be drawn up in exceptional circumstances but is not to be viewed as normal practice. Researchers requesting a DSA must explain to the DSC why it is not possible to carry out the analysis in the PCTU Safe Haven. Where the required data processing software is not currently available on the PCTU Safe Haven, it may be possible to install it.

To obtain access to PCTU Safe Haven for external researchers to complete trial analyses as specified in the protocol follows normal PCTU procedures (PCTU_SOP_DM_11). DSC approval is not required.

Where access to the data is required for purposes not described in the protocol, approval by the DSC is required, in the same way as trials which are closed. See section 5.

3. Trials which are closed.

A Data Sharing Agreement can be considered once the trial findings have been published, but it may be preferable because of reasons listed above to provide access to the data on the PCTU Safe Haven.
If the staff who analysed the data are still available they are best placed to give advice on the data fields including derived variables.

Wherever possible any data to be shared should be fully anonymised such that the risk of disclosing information referring to individuals is negligible (DS Policy). This is particularly important where data is to be shared outside the European Economic Area. In this case it should be discussed with the Lead of the IT & Data Management team, as additional steps may be required in order to comply with the Data protection Act and IG requirements.

4. Data Sharing Committee (DSC)

The Data Sharing Committee has been set up to consider access to all PCTU supported study data where a Data Sharing Agreement is required or where the study is closed and access is requested but the data remains on the PCTU Safe Haven. (DSC Terms of Reference). The DSC meets monthly, usually the week before the PCTU MGM meeting.

A Data Sharing Agreement needs to be approved by the Data Sharing Committee before being approved and signed off by legal entities.

The Data Sharing Committee needs 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 to be removed from PCTU Safe Haven, data security policies and procedures of the recipient, including country of data recipient (if sharing abroad), and any other applicable regulatory requirements are adequate.

In addition the committee may make recommendations to the PCTU Management Group concerning the resource implications of any data sharing requests. (See DSC Terms of Reference)

The Data Sharing Committee will consider the following when making a decision as to whether the risk of patient identification has been appropriately minimised and any remaining risk justified.

1. The purpose for which the data will be used
2. The nature of the data and risk of identification of participants posed by the data
3. Whether the patient consent and PIS covers the use requested.
4. Who will have access to the data
5. Security measures at the destination (if applicable)

In addition to the completed Data Sharing Agreement or Data Access Request Form please supply supporting documentation such as the PIS and unfilled consent form or description of the security measures at the destination, as applicable.

Consent Forms
Anonymised individual patient data can be shared without specific consent, as anonymised data are not covered by the Data Protection Act 1998 (DS Policy). Where data to be shared is not fully anonymised, such that the risk of identification is negligible, the requester should provide a copy of the patient information sheet and the unfilled consent form.
Applying to the Data Sharing Committee

Contact DSC administrator using pctu-data-sharing@qmul.ac.uk for DS number and a list of meeting dates. Please include the P number of the study, whether data is to be removed from the PCTU Safe Haven, brief description of the reason for the request.

Once completed, documents should be sent two weeks before the meeting to pctu-data-sharing@qmul.ac.uk so that the DSC has time to review them. Please quote the DS number in all correspondence with the DSC.

5. Preparing a Data Sharing Agreement

Please complete the PCTU DSA template (PCTU_TEM_IG_01) and provide supporting documentation

5.1 Structure of the DSA

The template has three sections. The first section is researchers and PCTU representative’s approval None of these people can sign the legal document and in some cases the legal entities may request this page is removed. In this case the approval page should be stored in the PCTU records with the DSA. This section also contains the trial specific document control.

The second section is the main part of the DSA, which should be signed by representatives from the institutions involved. Queen Mary’s Joint Research Management Office (JRMO) should sign in addition to the sponsor, where the sponsor is another institution. The data recipient in section 4.0 and 12.0 should be the representative from the institution not the recipient researcher.

The final section is the sign off page for the template which can be removed prior to use but the version number of the template should be retained in the footer.

5.2 Completing the DSA

Summary

1. Describe the purpose for which the data is requested. It should be clear that the data requested is relevant and necessary to fulfil the stated purpose
2. Describe the data. The data needs to be sufficiently well described so that the risk of identification can be assessed by the DSC. Steps should be taken to reduce unnecessary risk by deleting fields, recoding or banding variables (see 5.2.2 below). There may be a valid scientific reason for including some fields without change but this should be given along with any applicable consent from participants. Where ever possible the PCTU will fully anonymise any data to be shared outside the EEA (see DS Policy for more details).
3. Describe the data security measures at the destination. This is particularly important if high risk fields are included in the dataset.
4. Identify the signatories. The DSA needs to be signed by representatives from the institutions involved.

5.2.1 Describing the purpose
The purpose can be described on a separate document or within the DSA. If on a separate document this document must reference the DSA ID, be version controlled and contain a signature box with date. It should be clear how the purpose relates to the fields requested.

5.2.2 Describing the data

The data can be described on a separate document or within the DSA. If on a separate document this document must reference the DSA ID, be version controlled and contain a signature box with date.

1. Description of data fields
   It should be clear what each field refers to. It may be helpful to include an annotated copy of the CRF.

2. Format of the fields
   a. Any free text fields should be removed unless a clear justification is given.
   b. The type of data fields used should be specified in the data description (text, categorical, number).
   c. Coding should be given for categorical variables.

3. Patient identification number or code
   a. The format of the patient identification number or code should be described and whether any letters/numbers are included that would either relate to the patient or the site e.g. patient or site initials. It is preferable to replace this with an unlinked patient identifier, or failing that a linked identifier that is simply a number.

   These may pose a risk in conjunction with other variables
   An example list is given in the MRC Good Practice Guidelines at https://www.methodologyhubs.mrc.ac.uk/files/7114/3682/3831/Datasharingguidance2015.pdf.
   Those most likely to be present on PCTU pseudonymised datasets are
   - Year of Birth (for pregnancy studies this includes mother and baby)
   - Other dates relating to an individual
   - Age
   - Sex
   - Ethnicity
   - BMI
   - Multiple pregnancies
   - Small denominators
   - Very small numerators
   - Recruitment/treatment site and/or GP practice

   The following steps should be considered for these fields, and more techniques are described in the ICO Anonymisation code of practice at https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf
   - Removal of fields which are unnecessary for the stated purpose
• Grouping of age, BMI
• Grouping of ethnicity, multiple pregnancies to avoid small categories and number in each category should be given.
• Converting all dates to time since recruitment or similar reference point so that dates can be removed.
• Removal of field specifying treatment site or GP practice. If it is required for analysis remove labels so that sites cannot be identified.

Where data needs to remain unaltered, provide justification for doing so.

5.2.3 Describe the data security measures at the destination

Provide details of storage, access control and security arrangements in place at the recipient site for handling sensitive and Patient Identifiable Data (PID) study data. These could be copies of relevant local data security documentation and should also clarify how pseudonymised datasets are stored and handled, as well as how access to data will be restricted to those listed in the DSA. This is particularly important where high risk fields are included in the data.

Describe where the identifiable data for the study is kept and who has access to this data.

5.2.4 Identify signatories

The PCTU approval signatories are

- Chair of Data Sharing Committee
- Lead of Statistics team
- Lead of IT & Data Management

This section can be completed by the DSC

For the trial

The data owner will be the sponsor of the study. For a QMUL sponsored study the signatory will be the JRMO contracts manager.

The custodian of the data will be the chief investigator. The chief investigator signs the front page but the main document will be signed by a representative of the chief investigator’s organisation. If QMUL this is the JRMO contracts manager.

If the JRMO is not the sponsor then they also need to sign the legal document on behalf of the PCTU.

For the recipient

The lead recipient researcher will sign the front page, but the main document will be signed by a representative of the lead recipient researcher’s organisation. It will be the lead recipient researcher’s responsibility to find out the name of the appropriate person.

6. Preparing Data Access Request form

Where data access only is required please complete the PCTU Data Access Request template (PCTU_TEM_IG_04) and provide supporting documentation as required (see section 4). The Data Access Request form is a simplified version of the DSA.
Summary

1. Describe the purpose for which the data is requested. It should be clear that the data requested is relevant and necessary to fulfil the stated purpose.

2. Describe the data. The data needs to be sufficiently well described so that the risk of identification can be assessed by the DSC. Steps should be taken to reduce unnecessary risk by deleting fields, recoding or banding variables. There may be a valid scientific reason for including some fields without change but this should be given.

See section 5.2 for more details about describing the data and potential identifiers.

Document History

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<td>Sally Kerry</td>
<td>13th Oct 2016</td>
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<td>0.2</td>
<td>Review</td>
<td>Arouna Woukeu</td>
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<td>0.3</td>
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<td>0.4</td>
<td>Clarified Data Access to include minimising risk of identification. Clarified consent form request. Changed deadline to 2 weeks Explanation of signatories</td>
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<td>Reordering to create new section 4 about DSC and how it makes decisions. Section 6 moved up to new section.</td>
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