**Study Title: XX**

**Data Sharing Agreement**

**Cover sheet**

***This page should be filed with the Data Sharing Agreement in the PCTU records but can be detached prior to sending to legal entities for signature if requested by these parties***

Version: x.x

Date: DD/MMM/YYYY

Data Sharing ID number DS XXX

**Approvals of the Data Sharing Agreement by on behalf of the PCTU and individual researchers**

|  |  |
| --- | --- |
| Position | **Chair of the Data Sharing Committee**  |
| Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Position | **Lead of the IT & Data Management team** |
| Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
|  Position | **Lead of the Statistics team** |
| Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Position | 1. **Chief Investigator**
 |
| Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Position | 1. **Lead recipient researcher**
 |
| Name |  |
| Signature |  |
| Date |  |

**Version control for the trial specific agreement**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Reason for Change** | **Author of change** | **Date**  |
| 0.1 |  |  |  |
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End of cover sheet

**Study Title**

If applicable, insert study logo here

**Data Sharing Agreement**

This data sharing agreement should comply with Queen Mary University of London (PCTU) data sharing policy.

**Research Project title:  *[Enter full title here]***

**REC Reference Number: [*Enter ref no. here]***

**Data Sharing ID number** **[*Enter ref no. here]***

1. Organisations

This Data Sharing Agreement is drawn up between:

The data owner [usually Study Sponsor]

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |

and the data custodian [usually Chief Investigator]

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |

and the data recipient [usually receiving organisation]:

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |

***[If the JRMO is the sponsor of the trial delete the following box]***

and

|  |  |
| --- | --- |
| **Name** | **Queen Mary University of London (“QMUL”)** |
| **Address** | Joint Research Management Office, Queen Mary Innovation Centre, Lower Ground Floor, 5 Walden Street, London, E1 2EF |

appointed to manage the Trial in accordance with the *Clinical Trials Management Agreement* signed and dated DD/MM/YYYY.

1. Period of agreement

This agreement commences on ***[DD-MMM-YYYY]*** and ends on ***[DD-MMM-YYYY]*** unless terminated by mutual agreement of both parties in writing, at which point an Amendment will be issued by Pragmatic Clinical Trial Unit (PCTU), Queen Mary University of London (QMUL) to replace this document. If a time extension to this agreement is required, beyond the date of termination stated above, and agreed by both parties, an amendment will be issued by Pragmatic Clinical Trial Unit (PCTU), Queen Mary University of London (QMUL) to complement this document.

1. Data required

3.1 Nature of the data:

***[Describe in detail the list of data required for sharing, highlighting any data which could be sensitive or identifiable). For large dataset include a summary here and full details in an accompanying technical document which should be dated and referenced here]***

|  |
| --- |
|  |

Upon approval of this agreement, Queen Mary University of London (PCTU IT & Data Management Team), will supply the above dataset to the defined recipient. Data will be anonymous /or pseudonymised [delete as appropriate], and no patient identifiable information will be shared.

1. Permissions

Approval to share data has been obtained on behalf of the PCTU and Study team from the Chair of the Data Sharing Committee, the lead of the Statistics team, the lead of the IT & Data Management team and the Chief Investigator.

***[Insert Name]* (Chair of Data Sharing Committee)**

***[Insert Name]* (Lead of Statistics team)**

***[Insert Name]* (Lead of IT & Data Management)**

***[Insert Name]* (Chief Investigator)**

***[Insert Name]* (Lead recipient researcher)**

Approval to share data has also been obtained from the following legal entities; the data owner, the data custodian, the data recipient and the JRMO for QMUL if not the study sponsor.

***[Insert Name]* (Data owner of *[Study name]*)**

***[Insert Name]* (Data custodian of *[Study name]*)**

***[Insert Name]* (Representative(s) of the JRMO for QMUL)**

***[Insert Name]* (Data recipient)**

1. Purpose for which the Data are to be used

The data will only be used for the ***[Enter study title here]*** Note that any other use or sharing of the data or addition of permitted users, will require an updated agreement to include further purposes and/or other parties involved. All users of the data must be listed by name below and the authority to use the data cannot be delegated to a third person.

***[Please add short summary of intended use here]***

***Table 1 - Individuals who will have access to and use of the data***

|  |  |
| --- | --- |
| **Permitted Users**  | **Job title – Organisation they work for – where they will store and access data** |
| *[Please add name(s) and emails here]* | *[Please add organisation and details of where data will be stored and accessed here]* |

1. User Obligations

Users of the data supplied are obliged to fully comply with The UK Data Protection Act 1998, together with all other relevant legislation and regulatory requirements covering handling and sharing of clinical research data.

1. Transfer of Data from the PCTU to ***[Insert name of Organisation receiving the data]***

 7.1 Anonymisation

Prior to transfer, the PCTU Data Sharing Committee (through its approval of this agreement) confirms that appropriate steps have been taken to anonymise the data , taking into account whether consent for data sharing was sought from the research participants, data security policies and procedures of the recipient.

Data will only be described as anonymised, for the purposes of this agreement, where the probability of identifying an individual from the data to be transferred is negligible. This may require some manipulation of the original data***.***

 7.2 Data Transfer & Security

Data will be transferred in a secured manner in line with PCTU procedures.

The received data will be stored and processed from agreed secure locations at the ***[receiving organisation]*** as described in Table 1, section 5.0 above. The Receiving Party shall use appropriate safeguards (including, without limitation, with respect to encrypting identifying numbers, linking files, storing and retrieving files from secured locations) to prevent any unauthorized use or disclosure of the Data and shall promptly report to the Disclosing Party any unauthorized use or disclosure of which Receiving Party becomes aware.

1. Dissemination

The Receiving Party shall have the right to use a) the analysed, de-identified data derived from the use of the Data; and b) information and results arising out of analysis of the Data, as part of a publication or presentation of the results of the Study. The Receiving Party shall not include any personally identifying information in any publication or presentation. The Contribution to the study by the Disclosing Party’s investigator shall be acknowledged appropriately in any such publication or presentation in accordance with academic standards. Publication of research findings resulting from the use of the Data will not be prevented or delayed if the terms of this Agreement are fully met.

Anticipated dissemination outputs include presentations of abstract and series of publications.

QMUL reserve the right to audit the use of the shared data at any time to ensure that it complies with this agreement

1. Data Retention

The user will keep the data until the purpose of the data sharing has been completed or shall continue in effect until the termination of this agreement whichever is sooner. (For details see section 2.0 Period of Agreement.)

1. Data Destruction

In situations where the shared data is to be taken out of QMUL (PCTU) secure data storage environment, upon completion of analysis or at agreement termination date, any copies of the data in any format will be destroyed in an appropriately secure manner. The user will confirm in writing to the PCTU and data custodian(s) that data is destroyed safely and securely.

1. Data usage limitation

Data supplied by the data custodian(s) via the QMUL (PCTU) must only be used for the purpose described in section 5.0 of this data sharing agreement.

1. Agreement Signatures
2. I agree that I will use the requested data according to the terms specified in this Data Sharing Agreement and in accordance with the principles and conditions set out in the Data Protection Act 1998, the Research Governance Framework, and all other applicable regulations as outlined in section 6.0
3. I accept that I will not attempt to establish the identity of, or communicate with, any of the research participants
4. I accept that my access is limited as described in section 11.0 of this agreement, and that I will destroy all supplied data and any copies made thereof, as described in section 10.0 of this agreement. I will confirm to QMUL (PCTU) in writing once this has been done.
5. I will require anyone on my team who utilises these data to comply with the terms of this agreement.
6. I agree that I will ensure use of appropriate administrative, physical and technical safeguards to prevent use or disclosure of the data other than as provided for by this Agreement.
7. I accept that if I knowingly disregard the conditions relating to the release of data as per the terms in this agreement that this will be considered a serious offence and could result in action being taken against me and my organisation, as well as the termination of this agreement.

For and on behalf of

***[Enter name of the data owner here as in section 1.0]***

|  |  |
| --- | --- |
| Signed |  |
| Name |  |
| Post/Title |  |
| Date |  |

For and on behalf of

***[Enter name of the data custodian here as in section 1.0]***

|  |  |
| --- | --- |
| Signed |  |
| Name |  |
| Post/Title |  |
| Date |  |

For and on behalf of

***[Enter name of the data recipient here as in section 1.0]***

|  |  |
| --- | --- |
| Signed |  |
| Name |  |
| Post/Title |  |
| Date |  |

***[Delete the text and box below if the JRMO is one of the parties above]***

For and on behalf of JRMO, Queen Mary University of London

|  |  |
| --- | --- |
| Signed |  |
| Name |  |
| Post/Title |  |
| Date |  |

**PCTU Document control and approval for the DSA template**

To be detached prior to completing the template

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| --- | --- | --- | --- |
| PCTU Template number | **PCTU\_TEM\_IG\_01** | Version | **2.0** |
| Publication Date: | **16 February 2017**  |
|  |
| Author: | **Michael Waring, Arouna Woukeu, Anita Patel** |
| Reviewed by: |  **Sally Kerry** |
|  |
| Authorisation: |
| Name / Position | Arouna WoukeuHead of Information Systems and Data Management |
| Signature |  |
| Date |  |

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| **Version** | **Reason for Change** | **Author of change** | **Date**  |
| 0.1 | First draft of DSA Template based on PCTU’s BELLA, PREP and HabSelect data sharing agreements. | Mike Waring, Arouna Woukeu, Sun Poon, Carolina Quintero-Paulsen  | 28th January 2016 |
| 0.2 | Clarification of* sign off process
* data to be shared
* anonymisation procedures

Changes to formatting to be consistent | Sally Kerry | 14th March 2016 |
| 0.3 | Added data recipient sign off  | Sally Kerry | 17th March 2016 |
| 0.4 | Update of document control to reflect history and minor changes to text | Arouna Woukeu | 18th March 2016 |
| 1.0 | As 0.4. Document history simplified  | Sally Kerry | 21st March 2016 |
| 2.0 | Addition of DS number and change of footer to include DSA version number and template version number. Section 7.2 edited as per current PCTU data transfer requirements. | Sally Kerry, Arouna Woukeu | 14th Feb 2017  |