**Study Title**

**Data Access Request**

**This form is to be used where researchers who are not part of the study team require access to data held and remaining on the PCTU Safe Haven**

Version: 0.1

Date: DD MMM YYYY

Data Sharing ID number DS XXX

**Approvals**

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

|  |  |
| --- | --- |
| Position | **Senior Statistician**  |
| Name |  |
| Signature |  |
| Date |  |

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

|  |  |
| --- | --- |
| Position | 1. **Chair of Data Sharing Committee**
 |
| Name |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Position | 1. **PCTU Information Governance Lead**
 |
| Name |  |
| Signature |  |
| Date |  |

**Version control for the trial specific agreement**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Reason for Change** | **Author of change** | **Date**  |
| 0.1 | NA |  |  |
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1. Introduction

This form is only for use for data sharing requests by external researchers where data does not leave the PCTU data safe havens.

1. Period of access

Please specify dates for which access is required

1. Data required

***[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 appendix]***

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1. Permitted users and Purpose for which the Data are to be used

The data will only be used for the following purpose:

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| *please add short summary of intended use here, adding study name if relevant* |

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.

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

|  |  |
| --- | --- |
| **Permitted Users** ***Please give name and email address in this column*** | **Job title – Organisation they work for**  |
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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. Dissemination

The Users shall have the right to use a) the analyzed, 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 Users shall not include any personally identifying information in any publication or presentation. The contribution to the study by the original study team 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. Agreement Signatures
2. I agree that I will use the requested data for the purposes specified in this Data Access Request and in accordance with the principles and conditions set out in the Data Protection Act 1998, the Research Governance Framework, and all other relevant legislation and regulatory requirements covering handling and sharing of clinical research data
3. I accept that I will not attempt to establish the identity of, or communicate with, any of the research participants
4. I will not remove the data from the secure storage environments
5. I will require the permitted users listed above 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 access to the 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.

 **PCTU Document control and approval for the Data Access Request template**

To be detached prior to completing the template

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| --- | --- | --- | --- |
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|  |
| Author: | **Sally Kerry** |
| Reviewed by: |  **Arouna Woukeu, Anitha Manivannan** |
|  |
| Authorisation: |
| Name / Position | **Arouna Woukeu, PCTU Information Governance Lead** |
| Signature |  |
| Date |  |

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| **Version** | **Reason for Change** | **Author of change** | **Date**  |
| 0.1 | Initial draft from EMPIRE Data Access Agreement  | Sally Kerry | 7th Nov 2016 |
| 0.2 | Addition of conditions adapted from DSA sections 5.0 to 7.0 | Sally Kerry | 13th Dec 2016 |
| 0.3 | Minor edits in DSC meeting | Sally Kerry | 15th Dec 2016 |
| 0.4 | Review and minor edits  | Arouna Woukeu | 16 February 2017 |
| 0.5 | Response to edits suggested by AWEdits to footer to match DSA template | Sally Kerry | 22 February 2017 |
| 0.6 | Minor edit to footer DS not DSA ID following review by Anitha Manivannan | Sally Kerry | 28 February 2017 |
| 1.0 | Clean version of 0.6 for sign off | Sally Kerry | 28 February 2017 |