**REQUEST FOR DATA AND SAMPLE SHARING FROM SOUTHAMPTON CLINICAL TRIALS UNIT**

**Instructions for applicants:**

- For data sharing requests only: Please complete Sections 1- 3 and 5-6

- For sample sharing requests only: Please complete Sections 1- 2 and 4-6

- For data and sample sharing requests: Please complete Sections 1- 6

Please ensure you agree to the conditions for data sharing as described in section 6 before completing all relevant sections of this Data Sharing Request form in full. Please submit your completed request by email to the SCTU contact person for the relevant trial (if known) and/or to ctu@southampton.ac.uk.

All data and sample sharing requests will be initially reviewed by the SCTU Data and Sample Sharing Committee who will make a decision based on a review of the detailed description of the project and the feasibility of the data extraction and transfer\*. Furthermore, the SCTU Data and Sample Sharing Committee may seek the opinion of the Trial Steering Committee (TSC) and/or Trial Management Group (TMG) or Data Monitoring and Ethics Committee (DMEC). Approval for release of data/samples will also be sought from the sponsor and if appropriate a Sample and/or Data Sharing Agreement(s) from sponsor drafted for your input and approval. All data will be shared following the ICO code of practice.

\*An initial outcome of the request will be communicated within 6 weeks of request receipt and if the SCTU have doubts over scientific validity of the proposal or the requestor's ability to analyse/interpret data correctly, then additional information may be requested. If felt a refusal to share data in such circumstances is necessary, a justification for the decision will be provided. The final decision to release data rests with the sponsor.

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| **Data/Sample sharing request reference ID** | (For SCTU to add) |
| **Trial name(s) from which data/samples are being requested***(Please provide the acronym of SCTU trial)* |  |

**Section 1 – Details of Applicant**

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| **APPLICANT DETAILS** |
| **Name and role within research team***If you have not worked with the SCTU previously please link to or attach evidence of your research credentials (e.g. research profile, research CV, publication list)* |  |
| **Organisation name** |  |
| **Address** |  |
| **Telephone** |  |
| **Email** |  |
| **Date of application** |  |

**Section 2 – Details of project**

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| **PROJECT DETAILS**(please attach the protocol / grant proposal, if applicable) |
| **Project title / outline:** |  |
| **Background and reason for request:** |  |
| **Objectives and proposed methodology:** |  |
| **Funding sources:**Please describe any funding arrangements available for this project. |  |
| **Please provide details of ethical approvals (in place or pending) or other approvals required**Please provide REC and ISRCTN references or other appropriate reference(s) |  |
| **Details of collaborators:** |  |
| **Plans for publication of results:** |  |
| **Please specify any other intended use of the data requested or results generated:** |  |
| **Justification:** Please explain why the data/samples requested are the most appropriate to answer your research question and why it is required now |  |
| **What Intellectual Property (IP) will be generated from the proposed work?** |  |
| **SCTU have a publication policy for their managed trials:**Please detail how will you liaise with the SCTU to ensure appropriate acknowledgement and authorship from the SCTU on all outputs generated by the data and/or samples? |  |
| **Please list other personnel external to the SCTU involved in the project** (**e.g. statistician(s)), stating their name and responsibility within the project:** |  |

**Section 3 – Details of Data Requirements**

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| **DATA REQUIREMENTS** |
| **Details of data required** Please provide a template or empty data set of all required data including formats, variable names, subject id, meta data etc. |  |
| **Do you require pseudo anonymised or anonymised trial data?***(See definitions in section 7 of this document)*  | [ ] **Pseudo-anonymised** [ ]  **Anonymised** |
| **If Pseudo-anonymised:**Please detail how you will manage the risk of reidentification andwhat provision(s) you have in place to ensure this data is not combined with personal data or any other source of data that may support or lead to re-identification.*(A separate risk assessment can be attached if required)* |  |
| **Please provide details of how this data will be stored to ensure security of this data, no risk of loss, corruption or unintended access** |  |
| **Please provide details on preferred format for the data** e.g. excel listings, .CSV or SAS data sets |  |
| **Please provide a brief description of the intended statistical analysis for the data requested** |  |
| **Will this be a regular request for data?**If yes, please provide details and likely frequency. |  |
| **Please provide details of data destruction policy for this data** *(Please put process in place to inform the SCTU once data has been destroyed)* |  |

**Section 4 – Details of Sample Requirements**

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| **SAMPLE REQUIREMENTS** |
| **Details of sample(s) required** *(e.g. serum/plasma, aliquot size, volume required, maximum length of storage, minimum storage temperature, max number of freeze-thaw cycles)* |  |
| **Please detail processing requirements for samples prior to storage** *(e.g. for blood samples maximum clotting time, spin speed to pellet cells, pre-processing storage requirements etc.)* |  |
| **Please provide details of how and where the samples will be stored to ensure security and integrity** *(e.g. temperature controlled and monitored freezers)* |  |
| **Please provide details of which courier will be used for sample transfer**  |  |
| **Please provide details of shipping requirements** (*e.g. shipped ambient/on dry ice)* |  |
| **Please provide a brief description of the intended analysis/analyses for the sample requested**  |  |
| **Please provide details of where samples will be stored.** Please specify whether the facility is licensed by the HTA.  |  |
| **Does the laboratory performing the analysis hold accreditation?**  |  |
| **Is there an existing Material Transfer Agreement (MTA) in place?****If no, please provide details of a named contact with whom to liaise.**  |  |

**Section 5 – Details to help determine resource requirements**

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| **RESOURCE REQUIREMENTS** |
| **Summary of staff requirements**(*e.g. provision of clinical trial data, full anonymization of trial data, sample processing and packaging)* |  |
| **Are funds available to pay for staff time?** |  |
| **When do you need the data/samples**? Specify date(s) and whether this is flexible |  |
| **Name(s) of SCTU staff you have liaised with regarding this data request** *(if known)* |  |
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**Section 6 - Conditions for Sample and/or Data Sharing**

1. The applicant understands the approval of this sample and data sharing request:
	1. Prohibits attempts to re-identify participants using the results/data or combined with any other source of data
	2. Prohibits any attempt to contact trial participants
	3. Assumes after the trial has reached its primary analysis point (e.g the required number of events has been reached) and published, relevant information will be updated to EudraCT and available in the public domain. Open requests for IPD will be considered from this point. SCTU will have exclusive use of this data up until this point.
2. The research project must conform to relevant ethics and research governance requirements.
3. Any data transferred are confidential and must be stored in a secure location.
4. Any data transferred should not be used for any purposes other than those specified in the data sharing request and must not be discussed outside of the research team for the project nor provided to another third party.
5. The data transfer will be in a format acceptable to SCTU, including any necessary encryption and anonymisation.
6. The applicant must destroy any data transferred to timelines stipulated by SCTU.
7. A Material Transfer Agreement (MTA) may be needed before any samples can be transferred.
8. Any samples transferred are only to be used for the analysis/analyses described in this request. Samples should be held securely and where applicable in a temperature controlled and monitored environment.
9. If samples have been transferred and in the event of excess material being available following analysis described in this request the material continues to fall under the control of the original study. Any subsequent analysis would require a further Sample sharing request.
10. Excess material must either be returned to a holding facility identified by SCTU (courier costs to be borne by the requestor unless otherwise agreed) or destroyed with permission from SCTU.
11. The applicant must keep the SCTU informed of the development of the project and should provide any draft publication for review before it is used in any type of public presentation or submitted for publication. The SCTU trial(s) should be referenced and SCTU should be represented on the authorship unless otherwise agreed. A reprint of the resulting publication should be provided to the SCTU as soon as available.
12. Upon completion of the project or publication of the results, all copies of the data must be archived securely to required timelines and regulations or destroyed with agreement of SCTU.
13. **The SCTU, on behalf of the Trial Sponsor or Funder (according to individual trial contracts) is the Data Custodian of the trial data and Intellectual Property Rights. Any change from this position must be clearly stated.**

I have read and understood these conditions and agree to abide by them (please tick)

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| Applicant’s Signature |  | Date |  |

**Section 7 - Definitions:**

**Data Sharing Committee**

The committee is made up of Senior Clinical Trial Statistician (SCTS) or delegate Trial Statistician (TS) and a Public/Patient contributor in addition to a minimum of two of the following:

* Head of Trial Management [or delegate]
* Head of Quality Assurance [or delegate]
* Head of Data Management and Information Systems [or delegate]
* Associate Director of Operations

**Pseudo anonymised data:**

The aim of pseudo anonymisation is to obscure the patient identifiable data (PID) items within the persons records sufficiently that the risk of potential identification of the subject or a person’s record is minimised to acceptable levels, this will provide effective anonymization for analyses and reporting purposes. Although the risk of identification cannot be fully removed this can be minimised with the use of multiple pseudonyms. When pseudo anonymisation techniques are consistently applied, the same pseudonym is provided for individual patients across different data sets e.g. subject ID, and this allows the linking of datasets and other information which is not available if the PID is removed completely. To effectively pseudo anonymise data each field of PID must have a unique pseudonym e.g. variable name.

**Anonymous data:**

Anonymous data has all risk of re-identification removed by taking off the pseudonyms and normalising/minimising all dates/relevant data etc. It is also removing any data that when combined with other data may lead to re-identification and removing or categorising to < or > any extremes e.g. extremely low birthweight or excessively tall person etc.

**Section 8 - Details of Trial (for SCTU to fill out)**

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| **TRIAL DETAILS: SCTU Trial from which data is requested** |
| **Trial Sponsor** *(Name and contact information)* |  |
| **Commercial interests**  |  |
| **What does the contract with sponsor and (if applicable) funder specify about data sharing?**  |  |
| **What is the definition for ‘End of contract’?****Are there any surviving clauses?** *(Please paste text or attach as pdf)* |  |
| **What does the current version (or previous relevant versions) of the Informed Consent Form (ICF) or Patient Information Sheet (PIS) specify about data sharing; including the requirement for pseudo anonymised or anonymous data release** *(Please paste text or attach as pdf)* |  |
| **If the ICF is inconclusive, has Health and Social Care Act common law duty of confidence Section 251 been authorised or has REC been contacted to request permission for this or future data sharing requests with third parties?** *(please confirm and append pdf copy of request)* | Yes / No / Not applicable |

**Section 9- Assessment of request - (for SCTU Data and Sample Sharing Committee to fill out)**

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| **Approval from Chief Investigator?**If yes please file approval with this Data/Sample Sharing Request | Yes / No |
| **Approval from Sponsor?**If yes please file approval with this Data/Sample Sharing Request | Yes / No |
| **Approval from Data Custodian?**If yes please file approval with this Data/Sample Sharing Request | Yes / No |
| **Data/Sample sharing request in line with lawful basis of Public Task (UK GDPR Article 6 (1)(e))\*** | Yes / No |
| **Contract and ICF/PIS allow for proposed data sharing?** Or **Health and Social Care Act common law duty of confidence Section 251 in place?** | Yes / No |
| **Consent issues (is further consent required from trial participants?)** If yes, what is required?Has it been actioned, if so by who? | Yes / No |
| **REC approval required?** | Yes / No |
| **Does this trial have an embargo period?** | Yes / No |
| **CTU resource required** (type and number of staff needed to respond to request) |  |
| **Does the request require full anonymization of trial data?**If yes resource requirements: | Yes / No |
| **Timeline** (approximate time required to complete request) |  |
| **Is there any NHS England (formally NHS Digital) data included in this transfer?**If Yes is data aggregated or derived as per NHSE definition\* or manipulated as per NHSE definition\* with permission from NHSE to share?If No is there a valid NHS England (formally NHS Digital ) Data Sharing Agreement or sub licence in place, to be reviewed/updated every 3/5 years? **If not DO NOT SEND NHS Digital Data** | Yes / NoYes / No |
| **Is there any PHE data included in this transfer?**If Yes has it been aggregated or derived and anonymous?If No is there a valid NHS England (formally NHS Digital) Data Sharing Agreement in place to be reviewed / renewed every 5 years? | Yes / NoYes / NoYes / No |
| **Oversight committee approval required?**If yes, specify which committee and date of approval | Yes / No |
| **Date of SCTU Data/Sample Sharing Committee meeting:** |  |
| **SCTU Data/Sample Sharing Committee meeting attendees:** | *Add/Delete as necessary:* Trial Statistician:Head of Trial Management [or delegate]:Head of Quality Assurance [or delegate]:Head of Data Management and Information Systems [or delegate]:Associate Director of Operations:Public contributor: |
| **Data/Sample sharing approved?** | Yes / No |

**\*** **GDPR Article 6 Lawfulness of processing 1(e):**  processing 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.

\* **NHS England (formally NHS Digital) definition of derived and manipulated data:**

*‘*The data’ is the data supplied by NHS Digital and this includes manipulated data.  Derived data is not ‘the data’ and its retention or use is not subject to a Data Sharing Agreement and not controller nor constrained by NHS Digital.  The definition of derived data (in NHS Digital’s Data Sharing Framework Contract) is: any Data (wholly or in part) that is Manipulated to such a degree that it:

(a) cannot be identified as originating or deriving from the Data and cannot be reverse-engineered such that it can be so identified; and

(b) is not capable of use as a substitute for the Data; and

(c) has not at any time been verified by NHS Digital as not fulfilling the criteria (a) and (b) above

Based on this definition, it is probable that patient level data would be ‘manipulated’ rather than ‘derived’.

Manipulated data is defined as: any Data that has been Manipulated, unless and until it qualifies as Derived Data (to be determined at the sole discretion of NHS Digital);

‘Manipulate’ means:

• combine (wholly or in part) with other data or information; or

• aggregate (wholly or in part) with other data or information; or

• adapt (wholly or in part); (and "Manipulating" and "Manipulated" shall be construed accordingly)

As far as ‘the data’ is concerned, it cannot be kept beyond the point where there is an active Data Sharing Agreement in place between the data controller (in this case, the CTU) and NHS Digital.  That Agreement would specify the purposes for which the data can be used including where it can be processed in what format in what manner for what reasons and by whom (at organisational level).  The Agreement is for a fixed term which is likely to be shorter than the CTU’s intended data usage period but the Agreement can be extended on request prior to expiry or amended, subject to application, should the purpose(s) for processing change beyond those covered in the Agreement. On expiry or termination of the Data Sharing Agreement then the data would need to be destroyed.  If date of death was supplied, then typically it would need to be destroyed.  There are scenarios where this would not be the case but this would depend on the specifics of the case such as whether the data was verified by another source.