**SOUTHAMPTON CLINICAL TRIALS UNIT**

**REQUEST FOR DATA SHARING FROM SCTU MANAGED TRIALS**

Please complete this Data Sharing request form in full and submit by email (alternatively you may fax or post it but this may delay the review process). Please return to the SCTU contact person for the relevant trial if known. Alternatively send to:

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| Email: ctu@southampton.ac.ukTel: +44 (0)23 8120 5154 Fax: +44(0)844 7740621 | Southampton Clinical Trials UnitMail Point 131Southampton General Hospital Tremona RoadSouthampton SO16 6YD  |

All data sharing requests will be initially reviewed by the SCTU Data Sharing Committee which usually meets monthly. An initial position by SCTU on the request will be communicated to you within 6 weeks of receipt of the Data Sharing request form and if appropriate a Data Sharing Agreement from sponsor drafted for your input and approval. If you have an urgent deadline, please liaise directly with SCTU.

**Data sharing requests**

When SCTU are contacted with a request to share their data, they will ask the requestor to complete the Data Sharing request form [template located on the SCTU web site] to provide a brief research proposal on how they wish to use the data. It will include the objectives, what data are requested, timelines for use, intellectual property and publication rights, security preservation, data release definition in the contract and participant/patient informed consent etc. If 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.

*For the Applicant: please complete Sections 1,3 and 4 with as much detail as you are aware of and liaise with SCTU for help with the questions you are unsure about and sign Section 6*

**Section 1 – Details of Applicant**

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| **APPLICANT DETAILS** |
| **Name of person making request and role within the research team for the proposed project**Please attach your research CV |  |
| **Organisation name** |  |
| **Address** |  |
| **Telephone** |  |
| **Email** |  |
| **Date of application** |  |

**Section 2 – Details of Trial**

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| **TRIAL DETAILS: SCTU Trial from which data is requested** |
| **Trial Name** (acronym and/or full title of SCTU Trial) |  |
| **Trial Sponsor** [please provide name and contact information] |  |
| **Commercial interests** [please provide detail] |  |
| **What does the contract specify about data sharing** **What is the definition for ‘End of contract’?****Are there any surviving clauses? If yes please provide**[please paste text or attach as pdf] |  |
| **What does the current version [or previous relevant versions] of the Informed consent or patient information 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 yes or no and append pdf copy of request] | Yes / No |

**Section 3 – Details of project and data sharing request**

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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 attach evidence of the funds available] |  |
| **Evidence of ethical approvals or other approval required**  |  |
| **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 requested is 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; how will you liaise with the SCTU to ensure appropriate acknowledgement and authorship from the SCTU on all outputs generated by the data?** |  |
| **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 4 – Details of Data Requirements**

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| **DATA REQUIREMENTS** |
| **Details of data required** (please provide specific details of the data requested)A template or empty data set of all required data including formats, variable names, subject id, meta data etc. can be attached to the application |  |
| **Please detail whether you require pseudo anonymised or anonymised trial data [see definitions at end of document]. Detail what provision 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.** |  |
| **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** |  |

**Section 5 - Resource requirement for SCTU**

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| **SCTU INVOLVEMENT** |
| **What do you require from SCTU?** (e.g. provision of clinical trial data, full anonymization of trial data) |  |
| **Are funds available to pay for SCTU time?****If so, how much?** |  |
| **When do you need the data**? (Specify date/s and whether this is flexible) |  |
| **Name of SCTU person you have liaised with regarding this data request** (if known) |  |
| **Other SCTU staff involved** (if applicable) |  |

**Section 6 - Definitions:**

**Pseudo anonymised data:**

The aim of pseudo anonymisation is to obscure the identifiable data 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 data sets 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 7 - Conditions for Data Sharing**

1. The research project must conform to relevant ethics and research governance requirements.
2. Any request for data sharing must first receive approval from the SCTU Data Sharing Committee, who may seek the opinion of the Trial Steering Committee and/or Trial Management Group or Data Monitoring and Ethics Committee and final release of data will be at the approval of the sponsor.
3. A decision on approval will be based on a review of the detailed description of the project and the feasibility of the data extraction and transfer.
4. The data transferred are confidential, must be stored in a secure location, must not serve 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. The transfer should be in a format acceptable to SCTU, including any necessary encryption and anonymisation.
5. As a minimum the applicant also understands the approval of this data sharing request:
	1. Prohibits attempts to re-identify participants using this data or combined with any other source of data
	2. Prohibits any attempt to contact trial participants
	3. Data must be destroyed to timelines stipulated by SCTU
	4. Addresses any requirements regarding planned outputs of proposed research e.g., publication and acknowledgement requirements
	5. Prohibits non approved uses or further distribution of the data, observing disclosure controls set by SCTU
	6. 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.
6. The applicant must keep the contact person at 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.
7. 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.
8. **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.**
9. A confidentiality agreement may be required for the data to be released.

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

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| Applicant’s Name |  |  |  |
| Applicant’s Signature |  | Date |  |

**Section 8 - SCTU Information and Resources**

*[Completion of this section coordinated by SCTU Trial Management or Senior Clinical Trial Statistician/Trial Statistician]*

NAME OF SCTU MAIN CONTACT PERSON for this request: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Who ensures:

* a copy of the data sent is located with this form in J: drive with an optional paper/disc copy
* a copy of the form is filed in:

\\soton.ac.uk\Resource\Medicine\CTU\Trials\014 Data Sharing requests\Data sharing request forms

* the request is updated to the Data Sharing Catalogue located:

\\soton.ac.uk\Resource\Medicine\CTU\Trials\014 Data Sharing requests

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| **For SCTU use only:** |
| Approval from Data Custodian?If yes please file approval with this Data Sharing Request | Yes / No |
| Approval from Sponsor?If yes please file approval with this Data Sharing RequestIf no, has applicant been informed? | Yes / No |
| Contract and Informed consent or patient information allow for proposed data sharing? Or Health and Social Care Act **common law duty of confidence Section 251** in placeIf No, why? | 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 Digital data included in this transferIf Yes is data aggregated or derived as per NHSD definition\* or manipulated as per NHSD definition\* with permission from NHSD to share?If No is there a valid 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 transferIf Yes has it been aggregated or derived and anonymous?If No is there a valid PHE 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 |
| Data sharing approved by SCTU Data Sharing Committee If no, has applicant been informed?Date approved / not approved [delete as appropriate] | Yes / NoYes / No |
| Signed by HOG on behalf of Data Sharing Committee (name & signature, with date) |  |
| Name & signature (with date) of person(s) who prepared the data for sharing [Trial Statistician or DM] |  |
| Name & signature (with date) of person who checked the data before release (Statistician, Data Manager or Quality & Regulatory Team) |  |
| Date data sent: By [recommended to be Sponsor]:Name and position in organisation |  |
| Name and contact details of Applicant or person data sent to |  |
| Format of data released (.xls, .docx, .csv, SAS, other) plus accompanying information e.g. data set specifications, meta data standards, dictionaries, blank PDF of eCRF forms, limitations and anomalies in the data to allow accurate interpretation by a third party etc |  |
| File names and location  | [\\soton.ac.uk\Resource\Medicine\CTU\Trials\014 Data Sharing requests\](file:///%5C%5Csoton.ac.uk%5CResource%5CMedicine%5CCTU%5CTrials%5C014%20Data%20Sharing%20requests%5C) xxxxPaper Y/N Location:Disc Y/N Location: |
| How was the data sent (e.g. via Dropoff, by post) |  |
| Password (if applicable) |  |

**\**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.*