**NATIONAL PERINATAL EPIDEMIOLOGY UNIT CLINICAL TRIALS UNIT (NPEU CTU)**

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

Please complete this Data Sharing Request Form and submit by email. Please return to the NPEU CTU contact person for the relevant trial if known. Alternatively send to:

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| Email: ctu@npeu.ox.ac.ukTel: +44 (0)1865 289728 Fax: +44 (0)1865 289740 | NPEU Clinical Trials UnitNuffield Department of Population HealthUniversity of OxfordOld Road CampusHeadingtonOxford OX3 7LF |

All data sharing requests will be initially reviewed by the NPEU Data Sharing Committee which usually meets monthly. An initial position on the request will be communicated to you within 6 weeks of receipt of the Data Sharing request form. If the NPEU CTU have doubts over scientific validity of the proposal or the requestor's ability to analyse or interpret the data correctly, then additional information may be requested. If it is 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 (Data Controller). If the data sharing request is approved, then a Data Sharing Agreement from the sponsor will be drafted for you and your institution’s input and approval. If you have an urgent deadline, please liaise directly with the NPEU CTU.

*For the Applicant: please complete Sections 1 to 4 with as much detail as you are aware of and liaise with the NPEU CTU for help with the questions you are unsure about.*

**Section 1 – Details of Applicant**

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| **APPLICANT DETAILS** |
| **Name of person requesting data and role within the research team for the proposed project** |  |
| **Organisation name** |  |
| **Address** |  |
| **Telephone** |  |
| **Email** |  |
| **Date of application** |  |

**Section 2 – 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**  |  |
| **Ethical approval or other approval required** [e.g. Confidentiality Advisory Group] |  |
| **Details of collaborators and other personnel external to the CTU involved in the project** [please state their name, affiliation and role within the project] |  |
| **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?** |  |

**Section 3 – 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, population subset etc. can be attached to the application |  |
| **Do you require pseudo anonymised or anonymised trial data. If not, please give the reason** [see definitions at end of document] |  |
| **Will the data be combined or linked with any other source of data, and if so, what provision do you have in place to prevent 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.** |  |
| **How long do you require the dataset for?** |  |
| **Please provide details on preferred format for the data** e.g. .CSV or Stata 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 4 - Resource requirement for NPEU CTU**

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

**Section 5 – Details of Trial** *[to be completed by NPEU CTU]*

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| **TRIAL DETAILS: NPEU CTU trial from which data is requested** |
| **Trial Name** [acronym and/or full title of NPEU CTU Trial] |  |
| **Trial Sponsor** [please provide name and contact information] |  |
| **Commercial interests** [please provide detail] |  |
| **What does the head funding 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 patient information leaflet and informed consent form specify about data sharing; including the requirement for pseudo anonymised or anonymous data release** [please paste text or attach as pdf] |  |

**Section 6 - Definitions:**

**Pseudo anonymised data**

The aim of pseudo anonymisation is to obscure the identifiable data items within the participants records sufficiently that the risk of potential identification of the participant’s record is minimised to acceptable levels, this will provide effective anonymisation 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 participants across different data sets e.g. participant ID and this allows the linking of data sets and other information which is not available if the participant ID is removed completely. To effectively pseudo anonymise data each field of participant ID 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 NPEU CTU Data Sharing Committee, who may seek the opinion of the Trial Steering Committee 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 NPEU CTU, 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 by combining with another source of data
	2. Prohibits any attempt to contact trial participants
	3. Data must be destroyed to timelines stipulated by NPEU CTU
	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 NPEU CTU
	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. NPEU CTU will have exclusive use of this data up until this point.
6. The applicant must keep the contact person at the NPEU CTU 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 NPEU CTU trial(s) should be referenced and NPEU CTU should be represented on the authorship unless otherwise agreed. A reprint of the resulting publication should be provided to the NPEU CTU 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 NPEU CTU.

Applicants must undertake to provide to the Department, within a specified period, any derived data not requiring linkage to other studies.

1. The NPEU CTU, 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.
2. A Data Sharing Agreement may be required for the data to be released.