# The School of Medicine (SOM)/

Data Request No.

*(office use only)*

# Keele Clinical Trials Unit (CTU)

# External data request form

##### To be completed by the Researcher of the proposed study

(The researcher should complete this form in conjunction with the Principal Investigator of the study from which data are requested)

|  |  |
| --- | --- |
| Proposed Study Title: |  |
| Key Words: |  |
| Date study proposal submitted: |  |

STUDY STAFF DETAILS

Lead External Researcher:

|  |  |
| --- | --- |
| Name and title: |  |
| Position: |  |
| Organisation: |  |
| Address: |  |
| Telephone number: |  |
| Email: |  |

Study Team:

*This section of the form will also be used to support decisions on authorship of papers generated from this secondary analysis*

|  |  |  |
| --- | --- | --- |
| *Name* | *Department / Institution* | *Role within study team* |
|  |  |  |
| For researchers & members of the study team external to the Keele School of Medicine please enclose a short CV (1 side of A4) including up to five recent relevant publications & full contact details. | | |

|  |
| --- |
| **Reason for request (tick all that apply):** |
| Publication Meta analysis Presentation |
| Other (please specify)………………………………………………………………………………… |

|  |  |  |  |
| --- | --- | --- | --- |
| Is this a student study? | | YES  NO | |
| If YES: | Please state level (e.g. MPhil, PhD).. | |  |
|  | At which Institution(s) is the student registered?…………… | |  |
|  | Student name………………….. | |  |
|  | Names of student supervisor(s)…… | |  |
|  |  | |  |

PROPOSED STUDY DETAILS

|  |  |  |
| --- | --- | --- |
| Research Question / Objective: | | |
| OUTLINE DESIGN OF THE INVESTIGATION – DOCUMENT TO BE ENCLOSED  *(Up to four A4 sides in length including references)*  *Include scientific background and justification, study design, plan of* investigation, methods of data collection (if applicable) and *analysis, publication and dissemination strategy, key references*, ethical approval letters. | | |
| Why is the requested dataset appropriate to answer this research question? | | |
| STUDY PLAN | | |
| Study start date: |  | |
| Study end date: |  | |
| Study Management Plan with timescales: | | |
| Is the study funded or will funding be applied for? | | |
| Has the proposed study undergone a scientific review? | | |
| Study (or studies) from which data are requested: | | |
| Study population required *(e.g. age range, gender):* | |  |
| Precise data required *(please be specific on survey wave (e.g. baseline data) and list all variables required):* | |  |
| Does the current proposal fit with the original aims of the study from which data are requested? (*Please give details*) | | |
| Is new data collection required? | | YES  NO |
| If YES, please justify | |  |
| Would any of the data required be deemed as sensitive or identifiable? | | YES  NO |
| If YES, please justify its use | | |
| At which location(s) and how will the data be stored (e.g. University server requiring password for access)? | | |
| Level of support required from School staff *(e.g. input on project design / methods, informatics, statisticians, clinicians):* | | |
| Is new REC approval required? | | YES  NO |

DECLARATION

1. *I agree to comply with any conditions for data access required by School of Medicine (the School).*
2. *The data and outputs supplied to me will be used only for the approved Research Project identified above.*
3. *The data and outputs will not be released to any other individual(s) or organisation(s) not named on the application.*
4. *The data and outputs will only be processed at the location(s) stated above, in accordance with the principles and conditions set out in the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018, the Research Governance Framework, and with proper safeguards to ensure confidentiality.*
5. *All data and outputs supplied, and any copies or information derived from them will be destroyed or returned to the School on or before the end date specified above. At the end of the access period, for any data or analysis not returned to the School, I agree to destroy all copies of the data, including temporary copies, CDs, printed copies, personal copies, back-ups, derived datasets and all electronic copies.*
6. *The focus of the project is research / analysis and the data will not be used for any other purpose, including personal or commercial gain.*
7. *I understand that these data are provided in good faith and, to the best of the School's knowledge and ability, are free of error at the time of supply. The School will not be responsible for any errors, omissions or mistakes contained in the outputs or for any consequences or liabilities arising there from.*
8. *I confirm that the School of Medicine and the study from which data is requested (including funding source) will be fully attributed in any publications or reports resulting from analysis of this data.*
9. *I confirm that co-authorship agreements for any publications arising from analysis of this data set will reflect the list of study team members as set out in this form.*
10. *I understand that any publications resulting from analysis of this data will be placed in journals with open access publication policies. If the original grant which funded this cohort data requires immediate full open access publication, then I agree to take responsibility for meeting these requirements in relation to any publication(s) which I initiate and which arise from the analysis of this data.*

*………………………………………………………………….. ……………………………..*

Name of Main External Researcher Date

*…………………………………………………………………..*

**Signature of Main External Researcher**

|  |
| --- |
| Main External Researcher co-authorship agreement with School of Medicine, Keele University *(please state level of agreement):* |

|  |  |  |
| --- | --- | --- |
| Main External Researcher | | |
| Signature: |  | Date: |
| Study team member | | |
| Signature: |  | Date: |
| Study team member | | |
| Signature: |  | Date: |
| Study team member | | |
| Signature: |  | Date: |
| Study team member | | |
| Signature: |  | Date: |

Please return an electronic version of the completed form together with an outline design of the investigation and a short CV for all study team members external to the School of Medicine to [medicine.datasharing@keele.ac.uk](mailto:primarycare.datasharing@keele.ac.uk)

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| --- | --- | --- |
| School of Medicine Principal investigator(s) of study (or studies) from which data are requested | | |
| Study name : |  | |
| Principal Investigator: |  | |
| Signature: |  | Date: |
| Study name : |  | |
| Principal Investigator: |  | |
| Signature: |  | Date: |
| Study name : |  | |
| Principal Investigator: |  | |
| Signature: |  | Date: |

|  |  |  |
| --- | --- | --- |
| Reviewed by | | |
| Reviewer 1 name: |  | Date : |
| Reviewer 1 comments: |  | |
| Reviewer 2 name: |  | Date : |
| Reviewer 2 comments: |  | |
| Reviewer 3 name: |  | Date : |
| Reviewer 3 comments: |  | |

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| --- | --- | --- | --- | --- | --- |
| FORMAL RELEASE OF DATA | | | | | |
| Approved by Data Custodian and Academic Proposals Committee? | YES |  | NO |  |  |
| Name of DCAP committee member: | |  | | | |
| Signature of DCAP committee member: | |  | | | |
| Date of data release: | |  | | | |
|  | | | | | |
| Name of data custodian: | |  | | | |
| Signature of data custodian upon data release: | |  | | | |
| Name of person data sent to: | |  | | | |
| Date data issued: | |  | | | |
| Format of data issued: | | Tab delimited txt  STATA file  SPSS file  Other (please specify)  ……………………………………….. | | | |
| Method data was transferred to recipient: | | OneDrive  Microsoft Teams Chat  Microsoft Team private Channel  Other (please specify and justify)  ……………………………………….. | | | |
| Date of confirmation data received: | |  | | | |