**ERIN Data Access Application form**

**Instructions to applicants**

The EHR Research and Innovation database (ERIN) includes de-identified routinely collected Electronic Health Record (EHR) data at CUH. The ERIN Data Access Committee (DAC) will consider applications for research projects, technological innovations and other data driven projects. Please note that only applications for limited datasets with scientific justification will be considered.

All applicants must complete this Application Form. In addition to review by the ERIN DAC, applications may be reviewed by the ERIN Patient Involvement Panel (PIP). Please ensure the application is comprehensible to a lay person.

The text highlighted in yellow provides a guide on how to complete the application form. Please delete the highlighted text prior to submitting the application.

Prior to submitting their application, applicants should discuss their application with the ERIN team to ensure that arrangements for Cambridge studies meet local standards and any queries can be addressed in advance. The ERIN DAC meets monthly and completed applications will be reviewed at the next available meeting. Applicants will be informed of the outcome of their application as soon as possible thereafter.

Please submit completed applications to cuh.dataresearch@nhs.net

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| **Applicants may make a request to analyse de-identified EHR data in the following ways. Please indicate the relevant option.** [ ]  **A limited subset of EHR data will be analysed within CUH** [ ]  **A limited subset of EHR data will be analysed at the University of Cambridge. For example, where the research team are based at the University of Cambridge and additional computational resources are required.**[ ]  **A limited subset of EHR data will be transferred outside of Cambridge.** **This would usually be where CUH is collaborating with a third party or for a project led by a third party with its own regulatory approvals.**  |

**1. Primary Applicant:**

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| **Applicant name** |  |
| **Employing organisation and address** |  |
| **Department** |  |
| **Do you hold an honorary or substantive contract with CUH?** | *Please indicate if this is a clinical contract (you work clinically at the Trust) or a research contract (you obtained your contract through the research passport system).*  |
| **Email address** | *Institutional email address required.*  |

**2. Project details**

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| **Project title** |  |
| **Funding** | [ ]  **No funding at CUH is required. Please justify:** [ ]  **Yes – funding held at CUH**[ ]  **Yes – funding held at University of Cambridge. Please provide grant G number:**  |
| **Collaborators** | *Please list collaborators involved in the project design and their employing organisations. For external studies, the Chief Investigator should be listed here.*  |
| **Planned study duration and end date** |  |
| **Estimated patient sample size** |  |

**3. Proposed project**

**(If an existing protocol exists, this may be referenced in answer to these questions.)**

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| **Abbreviations** | *Please list all relevant abbreviations not defined in texts below.* |
| **Background and rationale** | *Please place the analysis in context, to justify the proposed analysis, what new information the proposed analysis will provide and how it will contribute to the knowledge base. Please write your answer in a way that is easy to read and can be understood by lay audiences and other readers with a basic sense, but not expertise in the topic. Technical terms and concepts are likely to benefit from an explanation.*  |
| **Project aim(s) and objective(s)** | Please state the research question(s) the proposed study is attempting to answer. This section should exclude methods. |
| **Patient inclusion criteria** | Please state the criteria that will limit which data points/patient data are extracted (e.g. Males, aged 45-60). Please include the data collection time range. |
| **Patient exclusion criteria** | *Please state the criteria that will determine which data points/patient data are not extracted (e.g. taking concomitant medication). It is not necessary to state the converse of the inclusion criteria.* |
| **Planned analyses** | *Please provide an overview of the methods that will be used to obtain the results and the main statistical tests to be used. This can include how the data is extracted, coded, de-identified and accessed.* |
| **Outcome(s)** | *Please state how all objectives of the study will be determined through analyses of the extracted data. If the analyses are exploratory, without a predefined outcome, then please specify this.* |

**4. Data extraction and de-identification**

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| **Methods of EHR data extraction and de-identification** | [ ]  **Manual extraction will be undertaken by a member of the clinical care team**[ ]  **Automated extraction will be undertaken by eHospital analysts** |
| **Type of data required** | [ ]  **Clinical data will be extracted**[ ]  **Medical images will be extracted** |
| **De-identified data for analysis** | **Please indicate if any of the following are included in the requested data set:**[ ]  **Age – Date of Birth should be converted to age bands and, if necessary, age in years may be acceptable depending on other variables.****Details:**[ ]  **Specific dates - should be removed where possible unless justified. Where sequencing is imperative, lapsed time or offset dates may be a suitable alternative.****Details:**[ ]  **Outliers - Potentially identifying outlying values such as height, weight, age should be avoided. Upper/lower bands may be appropriate.****Details:**[ ]  **Rare/small groups - including patients with rare diseases, or receiving unusual treatments and medicines.** **Details:**[ ]  **Particularly sensitive data - such as information related to sexual health, mental health or HIV status.** **Details:**[ ]  **Genetic data – please provide further detail on whether the information is unique to an individual and whether individuals may be identifiable from the data, either alone or in combination with any publicly available database or other background information.****Details:**[ ]  **Free text – please indicate if any free text data fields will be included. Please provide detail of how this will be redacted manually and converted to structured data to ensure anonymity. The e-hospital team do not currently have the capability of redacting free text data.****Details:** |
|  | **Including the data outlined above, please provide a full list of the de-identified data to be analysed or provide a separate list if necessary.** |
| **Pseudonymisation key** | *Please note: Where data are extracted by the eHospital team, they will retain a pseudonymisation key.***For manually extracted data, is it necessary for the care team to keep a pseudonymisation key** [ ]  **No**[ ]  **Yes - Please explain why this is necessary:** |
| **Please outline the secure storage arrangements for the key and how access will be limited.***Any pseudonymisation key must be stored separately from the de-identified clinical data, in a password protected CUH environment with limited and controlled access.* |
| **Please detail who will have access to the key and their role.***Only members of the care team may have access to the key.* |

**5. Data storage and deletion**

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| **Data access** | **Please list all members of the project team who will have access to the de-identified data. Please detail employing organisation and honorary contract status for any members not substantively employed by CUH.** |
| **Data Transfer (If applicable)** | **Please outline the method of secure transfer out of CUH.** *This should comply with local policies and procedures. Please discuss with ERIN team for current secure options.*  |
| **Data Storage** | **Please outline the details of the storage of the data. This should include security and access arrangements.** *For local studies, please discuss with ERIN team for current secure options.* |
| **For external projects, please outline any relevant cybersecurity standards in place at the receiving institution.****Will any cloud storage systems be used?** [ ]  **No** [ ]  **Yes - Please specify the location of the server:** |
| **Long term data storage and use** | Please outline how long the data will be stored after end of study and what will happen to the data after the retention period.Please justify any retention period over 5 years, without reference to guidelines. Consider that the analysis can be replicated in the future due to the retrospective nature and consider how you will ensure that data is deleted at the end of the retention period. |
| **For external studies, please outline any terms for future use.** |

**6. PPI and Communications**

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| **Please provide details of any PPI conducted in the design of the proposed project and any plans to communicate with patients and the public about the project and results of the analyses. Please justify if no PPI or dissemination of results are planned.***Please note: Applicants will be given the opportunity to present the results to the ERIN Patient Involvement Panel.* |

**7. Researcher Training and Experience**

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| **Please outline below any data protection training you have undertaken. Please confirm you have completed the mandatory training for your institution.**  |
| **Please outline below your expertise, training and experience to conduct the proposed analysis and provide a brief CV.**  |

**8. Project summary**

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| **Please provide a lay summary of your study in no more than 250 words in plain English, understandable to a lay audience. This summary will be seen by patients and the public.** *Please ensure that the lay summary has sufficient readability. See link for guidance: https://readabilityformulas.com/* |

**9. Other supporting information**

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| **Please provide any other relevant information in support of your application.**  |
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**In signing the below the signatory confirms that the contents of the application are correct and if the application is approved that the analysis will be conducted in accordance with the contents of this application and any conditions set out by the ERIN Data Access Committee.**

**Principal Investigator**

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| **Signed By:** |  |
| **Print Name:** |  |
| **Date:** |  |

**(If applicable) Educational supervisor or line manager**

Where the primary applicant is a student or a non-medical member of staff, the educational supervisor or line manager must sign below.

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| **Signed By:** |  |
| **Print Name:** |  |
| **Date:** |  |

**CUH Speciality Lead, Clinical Director or Divisional Director**

For all projects, sign off from the Speciality Lead (or above) responsible for the clinical area(s) and patient population detailed in this application is required. By signing, the Speciality Lead or above confirms their knowledge of, and support for, the proposed use of patient data from their clinical area, as detailed in this application. The specialty lead must not be part of the study team.

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| **Signed By:** |  |
| **Print Name:** |  |
| **Role and Clinical area responsible for:** |  |
| **Date:** |  |