**Case Records Interactive Search (CRIS) Terms and Conditions – Local Oxford Health searches**

**Background**

CRIS provides a means of analysing de-identified data from the Oxford Health NHS Foundation Trust (OHFT) electronic case records. Access to clinical information is clearly a sensitive issue and a security model was developed which has been considered and approved by the Oxford Health NHS Foundation Trust Caldicott Guardian and the Trust Executive as well as forming part of the original ethics application.

**Security Requirements of CRIS use**

CRIS can only be accessed from either the OHFT network or via the CRIS Virtual Desktop Environment (VDI) at Amazon Web Services (AWS). CRIS Data must remain within this secure environment and not saved on personal or encrypted USB sticks or emailed to an external email. CRIS researchers must only access their own CRIS Project files and folders either on the Oxford Health CRIS Projects folder or AWS.

Please be aware additional permission is required for derived data to be analysed outside of the OHFT firewall, from the CRIS Admin Team. See Appendix 1 regarding the removal of data from the AWS environment

The security model includes regular audits of searches carried out using CRIS. Audits are recorded and a random sample are audited monthly. For this to be possible, we record all CRIS project details along with a data plan to indicate the type of searches which will be conducted.

Ethics and research governance approval assume anonymity of the data analysed. As with any dataset, there is the potential within this database to compromise anonymity by generating unique variable combinations or rare categories. CRIS users are asked to consider whether this issue may occur and strategies to avoid compromising anonymity. Alternatively, they may wish to obtain specific ethics approval for an analysis where this risk is likely to be significant. Searching under clinician’ names are a sensitive issue; this type of information in research would need to be justified and approved.

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| ***I have read, understood and agree*** | ***Please check box to confirm*** |
| *CRIS project data is required to remain within the OHFT firewall or AWS VDI and files saved to either the designated project OHFT CRIS Projects folder or the CRIS Virtual Desktop Environment (AWS)* | [ ]  |
| *CRIS data must not be saved onto a personal or encrypted USB sticks or manually extracting data (typing into another file) outside of the OHFT firewall or the AWS VDI environment* | [ ]  |
| *CRIS data must not be emailed from OHFT machines to an external email.*  | [ ]  |
| *Additional permission is required from the Oxford CRIS Admin Team for derived data to be analysed outside of the OHFT firewall – I have read Appendix 1 regarding the removal of data from the AWS environment.* | [ ]  |
| *CRIS researchers are only permitted to access their own CRIS Project files and folder located within either the AWS VDI or the OHFT CRIS Projects folder.*  | [ ]  |

**Reporting potential data issues within CRIS**

CRIS users have a responsibility to ensure Patient Identifiable Information (PII) is not available within the system. There are processes in place to make sure that this does not happen, but there may be instances where you feel the system contains information that could be used to identify a patient and you need to report any such instances where you feel this may be the case. The **Report Data Issue** screen allows you to raise potential data issues within the CRIS data for review by a CRIS Trust Administrator.

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| ***I have read, understood and agree*** | ***Please check box to confirm*** |
| *Instances where I feel the system contains information that could be used to identify a patient must be reported to CRIS Admin via the inbuilt CRIS reporting system of ‘Report Data Issue’* | [ ]  |

**Rationale for Application Process**

The CRIS Oversight Group, led by the Trust Caldicott Guardian will review all requests to use CRIS as a de-identified research database. It is important for the Trust to demonstrate that OHFT clinical data are used responsibly and for projects with demonstrable research and clinical importance.

The future of CRIS, as with other aspects of OHFT research, depends on successful bids for future funding. This in turn requires evidence of use of the database, hence the need to keep a record of individual projects.

The CRIS Oversight Group has a role in facilitating CRIS analyses and to advise on how best to extract robust data. The database is potentially complex and users will be encouraged to collaborate and share expertise and hands-on experience. The information submitted in the project application form will be used to provide a database for this purpose to assist future researchers.

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| ***I have read, understood and agree*** | ***Please check box to confirm*** |
| *The role of the CRIS Oversight Group in the approval process and the retention and sharing of project application data for the benefit of future CRIS researchers* | [ ]  |

**Collaborations and Grant or Research Applications for use of CRIS data**

All work conducted using CRIS must be reviewed and approved by the CRIS Oversight Group. It is a requirement to inform the CRIS Oversight Group of any grant or research application, including all external collaborations, which require the use of CRIS data, either prior to initial submission, or immediately via a change request to an existing CRIS application.

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| ***I have read, understood and agree*** | ***Please check box to confirm*** |
|  *To inform the CRIS Oversight Group immediately of any grant, research application and collaborators on the project* | [ ]  |

**Publication of results**

All CRIS research projects are required to publish their results, preferably in a peer reviewed journal. This is an integral part of the CRIS application process. Once you complete your CRIS research you are required to keep the CRIS Admin team informed of the progress of your publication. Please inform them of the title and journal you plan to publish in. Please send a copy of the manuscript before submission to the journal to CRIS.Admin@oxfordhealth.nhs.uk

You are also required to acknowledge the NIHR Oxford Health Biomedical Research Centre and the relevant CRIS team member(s) who supported you with your data plan, extraction and/or analysis.

The standard acknowledgement text is as follows: -

“**This study was supported by the UK Clinical Record Interactive Search (UK-CRIS) system funded by the National Institute for Health Research (NIHR) and the Medical Research Council, with the University of Oxford, using data and systems of the NIHR Oxford Health Biomedical Research Centre (BRC-1215-20005**)”

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| ***I have read, understood and agree*** | ***Please check box to confirm*** |
| *All CRIS research projects are required to publish their results and that failure to do so may restrict my access to CRIS in the future. This excludes Clinical Audit and Service Evaluation Searches* | [ ]  |
| *The CRIS Admin team are to be kept informed of the progress of my publication and that the above CRIS BRC acknowledgement text must be included* | [ ]  |
| A copy of my publication must be sent to the CRIS Admin team for approval prior to publication | [ ]  |
| *I have read and understood each section of the Terms & Conditions outlined above and agree to adhere to these.* | [ ]  |

**Signed**

Click or tap here to enter text.

**Date**

Click or tap to enter a date.

**Appendix 1 - Releasing Files from AWS to Users**

Extraction of individual patient level data from AWS is not permitted. Analysis of patient-level data can take place within AWS using one of the available statistical analysis packages.

Release of aggregated information from AWS is permitted. Although the risk of re-identification from aggregated data is lower than that of individual patient-level data we will apply restrictions to sensitive personal data to further reduce the risk of re-identification.

The Information Commissioner’s Office (ICO) defines sensitive personal data as:

1. the racial or ethnic origin of the data subject,
2. their political opinions,
3. their religious beliefs or other beliefs of a similar nature,
4. whether they are a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
5. their physical or mental health or condition,
6. their sexual life,
7. the commission or alleged commission by them of any offence,
8. any proceedings for any offence committed or alleged to have been committed by them, the disposal of such proceedings or the sentence of any court in such proceedings.

We will review aggregated files for data and/or graphs relating to any of these categories. If there is aggregated data which contains numbers *less than 10* in any of these sensitive categories, the file will be rejected, and the user will be asked to re-submit with these numbers suppressed. For example, users could suppress small numbers by either a) combining categories within variables or b) rounding figures up. The user would then re-submit the file for approval at which point it would be reviewed again.