**CRIS Project Application Form**

**CRIS Project ID:** CRIS Admin to enter ID here

**CRIS User ID**: CRIS Admin to enter ID here

1. **Details**

|  |  |  |  |
| --- | --- | --- | --- |
| First Name:  | **Enter first name here** | Last Name: | **Enter last name here** |
| Department: | **Enter department here** |
| Email address | Please use Oxford Health or Psych email address for any communications regarding CRIS |
| **Enter your email address here** |

1. **Contract details**

|  |
| --- |
| Do you have a substantive or honorary contract with Oxford Health? [View Guidance Notes](#Q3Guidance) |
| **Choose an item** |
| * 1. If Yes contract type
 | **Choose an item** | * 1. If No, do you have a valid Research Passport?
 | **Choose an item** |

1. **Project details**

|  |  |
| --- | --- |
| Project Title | **Enter project title here** |
| Chief Investigator Name (**essential**) | **Enter CI name here** |
| Research Team | **Enter research team name here** |

1. **Student CRIS searches**:

|  |  |
| --- | --- |
| Is this a Student CRIS search?  | **Choose an item** |
| If yes please provide details of your supervisor below. Please note we would like the details of the supervisor for the project you’ve detailed in this application (This may not necessarily be your line manager) |
| Supervisor name |  |
| Profession |  |
| Department |  |
| Work address |  |
| Contact number |  |

1. **Lay summary** (Max 1000 characters) [View Guidance Notes](#Q5Guidance)
2. **Objectives of the analysis**
	1. **What are the primary objectives?** *Please put this in language comprehensive to a lay person.*
	2. **What are the secondary objectives if applicable?** *Please put this in language comprehensive to a lay person.*
3. **Rationale for the analysis** (i.e. anticipated benefits / useful knowledge which will arise from the results)
4. **Types of variable you envisage using to define groups.** *Please specify the data fields including the parameters e.g Age:18-45, Gender: M/F or both, Diagnosis: Alzheimer’s, Dementia, Depression* [View Guidance Notes](#Q8Guidance)
5. **Types of variable you envisage needing as outputs** [View Guidance Notes](#Q9Guidance)
6. **Are there any variables / combinations of variables which might identify individuals on the database?**

|  |
| --- |
| **Choose an item** |
| * 1. If yes: what steps will be taken to avoid de-anonymisation?
 |

1. **Will your project use CRIS to identify potential participants for study recruitment?**

|  |
| --- |
| **Choose an item** |
| * 1. If yes please provide the Research Ethics Committee approval number below
 |
| **Enter REC approval number here** |
| * 1. Date of REC approval
 | **Click here to enter a date.** | * 1. REC Expiry Date
 | **Click here to enter a date.** |
| * 1. OHFT Research and Development (R&D) reference number
 | **Enter OHFT R&D ref num here** |
| * 1. Date of OHFT R&D approval
 | **Click here to enter a date.** |

* 1. Quote the statement which explicitly states that your project is covered to approach clients who have given consent to be approached for recruitment purposes
1. **Names of anyone else who will be involved in CRIS use for this project** (or state ‘None’). Please provide the roles and email address (They must have an OHFT honorary contract, valid Research Passport or be a OHFT member of staff)

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role in project** | **Email Address** | **Contract Type** |
| **Enter name here** | **Enter project role here** | **Enter email address here** | **Enter contract type here** |
| **Enter name here** | **Enter project role here** | **Enter email address here** | **Enter contract type here** |
| **Enter name here** | **Enter project role here** | **Enter email address here** | **Enter contract type here** |

All users will be required to complete an ‘Additional user for a CRIS Search’ form to acknowledge the usage regulations. This form will be emailed to each user above by the CRIS Coordinator, cc’ing you in.

1. **How long do you envisage requiring use of CRIS for this project?** [View Guidance Notes](#Q14Guidance)

|  |  |  |
| --- | --- | --- |
| **Phases of the study** | **Start date** | **End date** |
| Data collection | **Click here to enter a date** | **Click here to enter a date** |
| Analysis | **Click here to enter a date** | **Click here to enter a date** |
| Data report / publication | **Click here to enter a date** | **Click here to enter a date** |

1. **Would you class your project as Research or Audit or Service Development?**

|  |
| --- |
| **Choose an item** |

1. **Audit applications**

If audit, please confirm the project has received appropriate OHFT Clinical Governance approval and email the approval to the CRIS administrator along with this filled out application. [View Guidance Notes](#Q16Guidance)

|  |  |
| --- | --- |
| * 1. State the Directorate responsible for this approval
 | **Enter Directorate here** |
| * 1. Give the title of the approved project if different from above
 | **Enter different project title here** |

1. **Research Output**

Oxford Health NHS Foundation Trust expects all CRIS research to be published. If this CRIS research is not going to be published please explain your reason for this below. [View Guidance Notes](#Q17Guidance)

When publications are produced the following entities need to be acknowledged as part of using CRIS.

**“*This study was supported by the Case Record Interactive Search (CRIS) system funded and developed by the National Institute for Health Research (NIHR) Mental Health Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London using the system within Oxford Health NHS Foundation Trust.”***

* 1. Please give an indication of where you are intending to publish, from higher to lower impact for example, The Lancet, PMAS, The Journal of Neuroscience.
1. Use of CRIS requires adherence to the **Case Records Interactive Search (CRIS) Usage Regulations**. Please note here that you have read and understood these requirements. [View Guidance Notes](#Q18Guidance)
	1. **Case Records Interactive Search (CRIS) Usage Regulations** read and understood [ ]

By submitting this project application, you agree to treat CRIS data confidentially and in adherence to the guidelines stated above. You confirm to have the necessary research passport or an honorary or substantive contract with Oxford Health NHS Foundation Trust to be authorised to access CRIS. Your searches will be audited to ensure that all searches are within the remit of the project you specify in this application form. Any searches performed outside the remit of the application form will be queried with the user and where found in breach of CRIS terms and conditions, CRIS access may be withdrawn subject to discussions with the CRIS Oversight Committee. You agree and confirm that this project has the relevant audit approvals or if a research project has an official research supervisor.

Please email this completed form to CRIS.Admin@oxfordhealth.nhs.uk

**Application Guidance Notes**

**Q2** **Contract details** - To be eligible to use CRIS you must either be employed by Oxford Health NHS Foundation Trust (OHFT), or have an honorary contract or letter of access from the Trust. If you are an NHS employee (but not part of OHFT) you do not require an honorary contract. Instead you will be issued with a letter of access (clear CRB check and evidence of substantive employment with your Trust). For further details, and to obtain an honorary research contract or letter of access, contact the research governance team in the R&D office: research @oxfordhealth.nhs.uk)

**Q5** **Lay summary** - Please be as precise as possible. The lay summary should use language suitable for the general public to understand. Approved projects will have the lay summary displayed on the BRC website as part of the CRIS projects archive. Where objectives and rationale are not clear, the applicant may be asked to present the proposal to the oversight committee.

**Q8 Variables to define groups** – Please be as precise as possible. This will be used to determine the parameters / inclusion criteria for your search and will be used to assess the searches you are ‘covered’ for when audits of CRIS usage are carried out. If different searches become necessary, please re-submit a further form clarifying the reasons for this.

Examples of parameters are:-

Age – specify the age range of your search

Gender – M or F or both

Diagnosis – Alzheimer’s, Dementia, Depression for example

**Q9** **Variable output types** - Please be as precise as possible. This will be used to identify what types of search you will carry out and will be used to assess the searches you are ‘covered’ for when audits of CRIS usage are carried out. If different searches become necessary, please re-submit a further form clarifying the reasons for this.

**Q13 Length of time for CRIS project** - Please indicate the planned CRIS use time. We don’t anticipate that there will be many specific analyses which require more than 12 months CRIS access. When you log on to the system it will also ask you about duration of CRIS use and there is a maximum of 3 years. If your project is likely to need longer than this then re-approval of the project will be required after that time. We require date ranges for the expected project time lines.

**Data collection** - when the CRIS searches will take place, this will provide an indication of dates that the system will be used to search for the data.

**Analysis** – the CRIS data file will require access and will be used to analyse the data. Searches would not be expected to take place during this period

**Data report / publication** – All CRIS research is expected to be published unless otherwise agree, see point 16 in the application form. This will provide the CRIS Oversight Group with an indication of when they can expect the details of the CRIS research and also details of the publication.

**Q15 Audit searches** - Secondary analysis of CRIS data is covered by our Research Ethics approval. CRIS is also likely to be a useful tool for Trust audit – however, audit projects need to go through the normal Oxford Health NHS Foundation Trust Clinical Governance processes and receive approval prior to CRIS use. If your study does not fall under research or audit, please state the type of study you are trying to conduct using CRIS and please provide official approval of your study from the appropriate department and department head.

**Q16 Research output** - The continuation and further development of CRIS will depend to a large extent on demonstrable research activity. Therefore it is likely that projects and their applicants will be followed up regarding research output (i.e. primarily international peer reviewed publications). However, it is envisaged that there may be some CRIS uses for research where publication is not envisaged (e.g. to inform power calculations for funding applications) so please explain if this is the case. If any text is quoted from CRIS (whether internal or external), this will have to be checked by the CRIS Oversight Committee. Please contact Tanya Smith at CRIS.Admin@oxfordhealth.nhs.uk, clearly stating the contents of the text. Please also state the context of where the text will be used (e.g. presentation slide, journal article, other audit publications etc)

When publications are produced the following entities need to be acknowledged as part of using CRIS.

**“*This study was supported by the Case Record Interactive Search (CRIS) system funded and developed by the National Institute for Health Research (NIHR) Mental Health Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London using the system within Oxford Health NHS Foundation Trust.”***

Please note that CRIS does not provide access to patient identifiable information (e.g. NHS Numbers).

**Q17** **Case Records Interactive Search (CRIS) Usage Regulations**

**Background**

CRIS provides a means of analysing anonymised data from the Oxford Health NHS Foundation Trust (OHFT) electronic case records. Ethical approval for such analyses was provided by Oxfordshire REC C National Research Ethics Service in July 2015. 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 ethics application.

**Security Requirements of CRIS use**

CRIS can only be accessed from the OHFT network. Data from CRIS must be kept within the Trust firewall and can only be saved on the CRIS shared drive on OHFT computers. CRIS data CANNOT be saved on personal or encrypted USB sticks. CRIS data CANNOT be emailed from OHFT machines to your personal email or Oxford University email. Please be aware that all data also has to be analysed within the OHFT firewall. You are not allowed to analysis CRIS data using University of Oxford or your own personal statistical software on our personal computers. Please also note that currently SPSS and R are the only statistical programmes that are available at the Research Team.

The security model includes regular audits of searches carried out using CRIS (all searches by all users are recorded and can be audited). For this to be possible, we keep a record of all projects carried out involving CRIS analysis along with general specification of the type of searches which will be required.

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 (Question 9 will provide scope to cover this). 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 have to be justified.

**Rationale for Application Process**

An oversight committee led by the Trust Caldicott Guardian will review all requests to use CRIS as an anonymised 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.