Question 1:

Research
CRIS has been approved as an anonymised data source for secondary analysis.

Audit/ Service Evaluation/ Development/ Quality Improvement
As well as for research, CRIS may be used for Trust audit, quality improvement and service evaluation/ development projects. CRIS has not been developed to support service management. Applications to use CRIS to evaluate or monitor staff-level performance will not be granted.

Recruitment (Consent for Contact – C4C)
CRIS can be used as part of the Consent for Contact (C4C) recruitment process to identify patients who may be eligible for research trials. If you have any queries regarding whether you are covered by your research ethics and R&D approval for recruiting via C4C, please contact the R&D office on slam-ioppn.research@kcl.ac.uk

Question 2:

Applicant's ORCID
All applicants requesting access to CRIS for Research or Recruitment (C4C) projects are required to provide an ORCID. If you do not have an ORCID, please create one by registering for free here: https://orcid.org/register

Question 3:

To be eligible to use CRIS you must either be employed by the South London and Maudsley NHS Foundation Trust (SLaM), or have an honorary SLaM contract, a King's Health Partners (KHP) passport, or research passport/ letter of access. If you are an NHS employee but not affiliated to SLaM, you do not require an honorary contract; instead, you will be issued with an NHS-to-NHS letter of access. For further details, please contact the CRIS administrator CRIS.Administrator@slam.nhs.uk

Question 4:

Please provide the title of your project; the title should use language suitable for the general public to understand. Please do not use abbreviations or acronyms.

Question 5:

Please be as precise as possible. The lay summary should use language suitable for the general public to understand. Please do not use abbreviations or acronyms. Approved projects will have the lay summary displayed on the BRC website as part of the CRIS projects archive. For advice on writing a plain English summary, please see www.nihr.ac.uk/documents/plain-english-summaries/27363

Question 6:

The objectives of the analysis should be concise statements that describe what the project is aiming to achieve. Please be as precise as possible. Where the objectives

are not clear, the applicant may be asked to provide further information to the Oversight Committee.

Question 7:

The rationale for the analysis should provide justification for undertaking the project. It should state the reason(s) why the topic in question is being focused on and include what the significance is, what gaps the research intends to fill, and any anticipated benefits or useful knowledge that will arise from the results. Please be as precise as possible. Where the rationale is not clear, the applicant may be asked to provide further information to the Oversight Committee.

Question 8:

Include information on the variables that you intend to use to define your cohort of interest. Please be as precise as possible.

The CRIS Extraction Team have a role in facilitating extraction of variables from CRIS and will advise on how best to extract robust data. The information submitted in this application will be used to provide a basis for the data extraction specification. The data contained within CRIS is complex and users will be encouraged to collaborate and share expertise and hands-on experience.

Where variables are required that must be compiled manually by reviewing free text fields (e.g., case note entries or letters within the medical record), you will be required to complete a free text security review. The CRIS Extraction Team will support you with completion of this after the project is approved. A similar procedure will be followed where the project is focused on text reviewing to create a Natural Language Processing (NLP) algorithm/ application.

NOTE: Applications to use staff names for legitimate research/ audit purposes may be granted but additional mitigation may be put in place, e.g., encryption of staff names in CRIS extractions.

Question 9:

Include information on the variables that you require as outputs. Please be as precise as possible.

The CRIS Extraction Team have a role in facilitating extraction of variables from CRIS and will advise on how best to extract robust data. the information submitted in this application will be used to provide a basis for the data extraction specification. The data contained within CRIS is complex and users will be encouraged to collaborate and share expertise and hands-on experience.

Where variables are required that have to be compiled manually by reviewing free text fields (e.g. case note entries or letters within the medical record), you will be required to complete a free text security review. The CRIS Extraction Team will support you with completion of this after the project is approved. A similar procedure will be followed where the project is focused on text reviewing to create a natural language processing algorithm/app.

NOTE: Applications to use staff names for legitimate research/ audit purposes may be granted but additional mitigation may be put in place, e.g. encryption of staff names in CRIS extractions.

Question 10:

Ethics and research governance approvals for CRIS and associated (e.g., linked) data 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. Please consider whether this issue may occur and detail any strategies that will be used to avoid compromising anonymity (for example suppression of small cell sizes). The CRIS Extraction Team are happy to provide advice on this, drawing on previous experience with other projects.

Question 12:

The SLaM BRC Clinical Data Linkage Service (CDLS) hosts a number of third-party clinical data sets that have been linked to CRIS in a secure safe haven. Requests to include these data in your CRIS project should be detailed in this section.

A range of third-party data are held within the CDLS, including acute secondary care data for SLaM patients and controls (Hospital Episode Statistics [HES]) and local primary care data from Lambeth (Lambeth Data Net [LDN]). Details of all the data sets held by CDLS can be found at http://www.maudsleybrc.nihr.ac.uk/facilities/clinical-record-interactive-search-cris/cris-data-linkages/

Approval
As well as complying with the CRIS security model, in agreement with third party data controllers and other approvals (e.g. research ethics committee approval) specific and additional conditions may need to be met to include linked data from the various different data sets held in CDLS. For example:

To access HES data users are required to have a SLaM substantive contract, honorary contract or KHP passport. A research passport/ letter of access is not sufficient to access these data.

In addition to CRIS Oversight approval, access to LDN data linked to CRIS is dependent on an independent (non-SLaM) project specific LDN approvals process.

For further information on specific requirements, constraints, and conditions for accessing any data held within the CDLS please contact the CDLS Lead directly or via CRIS.Administrator@slam.nhs.uk

Access
Users will not be given direct access to CDLS data repositories. Linked data held within CDLS will be extracted by the CRIS Extraction Team against agreed specifications and stored within the BRC_CRIS network drive, in accordance with the CRIS Security Model. In some cases, patient-level data may need to be fully

anonymised at point of extraction (i.e., CRIS BRCID removed and replaced with a project specific patient anonym) in accordance with specific agreements.

Question 13:

Please give the details of anybody else who will be working on the project, please only include those who will require access to CRIS data directly. All those accessing CRIS data must have a contract with SLaM or a Research Passport/ Letter of Access and provide proof of Information Governance Training completed within the past 12 months.

If you do not know an individual's ORCID, it can be searched for here: https://orcid.org/

Details for up to 10 additional users may be added.

Question 14:

Please provide the details of your supervisor for the project, this is the person who will take overarching responsibility for the project and the conduct of those working on the project.

If you do not know your supervisor's ORCID, it can be searched for here: https://orcid.org/. If they do not have an ORCID, they will need to create one by registering for free here: https://orcid.org/register

If you are applying as the supervisor, then please indicate your level of clinical and/or academic seniority.

Question 15:

It is a requirement of all CRIS projects that a least one person named on the project is an employee of King's Health Partners (KHP), i.e., King's College London, South London and Maudsley NHS Foundation Trust, King's College Hospital NHS Foundation Trust, or Guy's and St Thomas' NHS Foundation Trust. As well as providing local knowledge and perspective, this person will also take responsibility for the project and the conduct of those working on it alongside the project supervisor.

Question 16:

Please give an indication of how long you will require use of CRIS for. Approved applications will be followed up on an annual basis by the CRIS Administrator.

Question 17:

Non-research use of CRIS requires confirmation of the relevant Trust approvals prior to use. All confirmation of approval should be emailed to the CRIS Administrator CRIS.Administrator@slam.nhs.uk.

Audit
Please provide confirmation of approval and the directorate audit committee responsible for audit approval.

Quality Improvement Projects
Please provide written confirmation of SLaM Quality Centre approval.

Service Evaluation/ Development
Please provide written confirmation of approval and name the approving clinical or service director.

Question 18:

The continuation and further development of CRIS will depend to a large extent on demonstrable research activity. Therefore, 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.

Question 19:

If any text is quoted from CRIS (whether for internal or external use), this will need to be reviewed and approved by the CRIS Oversight Committee prior to any dissemination.

Please write to CRIS.Administrator@slam.nhs.uk clearly indicating what text will be quoted – ideally in the proposed format (e.g., draft manuscript). Please also state the context of where the text will be used (e.g. presentation slide, journal article, other audit publications etc).

Question 20:

Please indicate if all or part of the project will be used for an MSc project. Before offering the study as an MSc project, please ensure that you have sufficient time to acquire CRIS project approval and obtain the necessary data.

If you have any concerns over the time frame or would like to discuss the feasibility of the project before submitting a CRIS application, please contact: CRIS.Administrator@slam.nhs.uk

Question 21:

Please indicate who the main funder is for this project

Question 22:

Projects which may result in commercially relevant intellectual property will require further discussion with the CRIS Team, please contact: CRIS.Administrator@slam.nhs.uk for more information.

Question 23:

Overview of BRC Clinical Records Interactive Search (CRIS) Usage Regulations:

Background
CRIS provides a means of analysing anonymised data from the South London & Maudsley Foundation NHS Trust (SLaM) electronic case records. Ethical approval for such analyses was provided by South Central - Oxford C Research Ethics Committee (REC) in September 2008 for an initial 5-year period and renewed in 2013, 2018, and 2023. Access to clinical information is clearly a sensitive issue and a security model was developed which has been considered and approved by the SLaM Caldicott Guardian and the Trust Executive, as well as forming part of the ethics application, this is available to view here.

Security requirements of CRIS use
CRIS can only be accessed from the SLaM network. Data from CRIS must be kept within the Trust firewall and must only be saved on the CRIS shared drive on SLaM computers. CRIS data **MUST NOT** be saved on personal or encrypted USB sticks.

CRIS data **MUST NOT** be emailed from SLaM machines to your personal email or King's email.

Please be aware that all CRIS data must be analysed within the SLaM firewall. You are not allowed to analysis CRIS data using another organisations or your own personal statistical software on non-SLaM computers.

Please also note that currently STATA and R are the only statistical programmes that are available with SLaM.

The CRIS Security Model includes regular audits of searches carried out using the CRIS Front End and CRIS SQL database - all searches by all users outside of the CRIS Extraction Team are recorded and can be audited. To enable this. we keep a record of all projects submitted to the CRIS Oversight Committee along with data extraction specifications and other related documentation (e.g. free text security reviews).

Breaches of the CRIS Security Model will be considered a serious matter potentially resulting in disciplinary action.

Rationale for this application process
The CRIS Oversight Committee will review all requests to use CRIS as an anonymised database. It is important for the BRC to demonstrate that SLaM clinical data are used responsibly and for projects with demonstrable research and clinical importance.

The future of CRIS, as with other aspects of BRC 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.