Question 3.
To be eligible to use CRIS you must either be employed by SLAM, or have an honorary contract, KHP passport or research passport. If you are an NHS employee (but not part of SLaM) you do not require an honorary contract. Instead you will be issued with a letter of access (clear DBS check and evidence of substantive employment with your NHS Trust). For further details, please contact the CRIS administrator cris.administrator@slam.nhs.uk

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. Where objectives and rationale are not clear, the applicant may be asked to present the proposal to the oversight committee.

Question 6.
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.

Question 7.
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.

Question 8.
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.

Question 9.
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.

Question 11.
If you have any queries regarding whether you are covered by your research ethics and R&D approval for recruiting via CRIS please contact the R&D Governance Manager Jenny Liebscher (Jennifer.liebscher@kcl.ac.uk).

If you have not yet received ethics approval or SLaM R&D approval for your study, please indicate this and the expected approval date. This field can be updated post application approval, prior to the commencement of CRIS use.

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 www.maudsleybrc.nihr.ac.uk/facilities/clinical-record-interactive-search-cris/cris-data-linkages/.

Conditional approval:

As well as complying with the CRIS security model, in agreement with third party data controllers and other approvals (e.g. ethics) 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 generic research passport 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 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/CDLS 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 (CRIS BRCID removed and replaced with project specific patient anonym) in accordance with specific agreements.

Question 15.
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.

Question 18a.
Secondary analysis of CRIS data for research is covered by our Research Ethics approval. CRIS is also likely to be a useful tool for Trust audit, service evaluation or Quality Improvement (QI).

Non research use of CRIS requires confirmation of the relevant Trust approvals prior to use. Audit – please provide confirmation of approval and the directorate audit committee responsible for audit approval QI 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 19a.
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

write to Matthew Broadbent, matthew.broadbent@slam.nhs.uk or Andrea Fernandes, andrea.fernandes@slam.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)

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

"CRIS is supported by the NIHR Biomedical Research Centre for Mental Health BRC Nucleus at the South London and Maudsley NHS Foundation Trust and Institute of Psychiatry, King's College London jointly funded by the Guy's and St Thomas' Trustees and the South London and Maudsley Trustees."

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

Question 21.
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 Oxfordshire REC C National Research Ethics Service in September 2008 for a 5 year initial period and renewed in 2013. 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.

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 can only be saved on the CRIS shared drive on SLaM computers. CRIS data CANNOT be saved on personal or encrypted USB sticks. CRIS data CANNOT be emailed from SLAM machines to your personal email or King's email. Please be aware that all data also has to be analysed within the SLAM firewall. You are not allowed to analysis CRIS data using King's College or King's Hospital or your own personal statistical software on our personal computers. Please also note that currently STATA, SPSS and SAS are the only statistical programmes that are available at the Nucleus

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 8 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 BRC Stakeholder Participation theme 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.

The CRIS oversight committee 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.