Oxford Health NHS
NHS Foundation Trust

CRIS Oversight Group

Terms of Reference

1 Background and purpose

1.1 The Case Records Interactive Search application (CRIS) enables researchers and clinical auditors to interrogate the Trust's clinical information for research, clinical audit and service evaluation purposes. CRIS has been designed primarily to support three types of usage.

Type 1: as a pseudonymised database for secondary analysis

Type 2: to identify potential recruits to research projects from the clinical population

Type 3: to provide contextual clinical information for existing OHFT approved research

1.2 Ethical approval for the use of CRIS for these purposes was given 29th June 2015 by NRES Committee Sough Centre, REC reference 15/SC/0247.

1.3 The CRIS Security Model and IG Framework has been developed to safeguard the legal and ethical rights of Trust service users, whose clinical information may be being accessed through CRIS. These terms of reference describe the specific role and responsibility of the CRIS Oversight Group, which has been set up to oversee the operational management of CRIS day-to-day usage following implementation.

2 Aim

2.1 The primary aim of the Group is to provide the oversight of the operational management of CRIS as identified in the CRIS Security Model and IG Framework. In so doing, the Group will promote the scientific and ethical principles that should govern the use of CRIS, and will represent stakeholders (who include CRIS users, service users and their carers) and reflect their views and interests.

3 Key responsibilities

3.1 To provide research oversight for projects intending to use CRIS that are covered by the Security Model and IG Framework, including ethically approved research and audits.

3.2 To oversee all elements of CRIS administration, including:

3.2.1 All applications for access to CRIS, will be presented to the Group for approval. In scrutinising requests the Group will consider whether the intended use of CRIS is feasible, realistic and appropriate, and whether it will unduly compromise confidentiality, e.g. seeking details of particularly

rare groups and therefore identifiable individuals. Initially, these applications will be granted for a maximum of one year only and will be subject to review. Applications to 'reverse search', i.e. reveal identifiable information (types 2 and 3 above), will need to include confirmation that users have had appropriate Human Resources checks and the individual has to access the Trust systems (i.e. research passport, letter of access, honorary contract (Clinical or research). These applications will need to be supported by the user's supervisor.

3.2.2 The scrutiny of CRIS audit logs. Reports on usage will be routinely submitted to the Group. The Group will compare intended use specified in initial applications with actual use recorded in audit logs. Users may be asked to report to the Group at any point during or at the end of their project's lifespan. Permission to use CRIS for a particular project may be withdrawn, with justification, by the Group at any point. Any significant security breaches identified, e.g. breaches of policy or unauthorised searching, will be dealt with according to disciplinary procedures specified in Trust and will follow accepted research governance practices,

3.2.3 Maintenance of the database of projects with ethics and R&D approval, for types 2 and 3 usage.

3.3 To monitor and formally review at least annually all elements of the Security Model, and recommend changes to improve this if necessary.

3.4 To act as a CRIS user group, providing users with advice on best use of CRIS*.

3.5 To monitor and review the effectiveness of the functional specifications and inform changes to improve these.

3.6 To receive and respond to complaints related to CRIS that are raised through the Trust complaints procedure, e.g. from service users, excluding issues relevant to research governance for ethically approved projects or Trust audit.

*Note – the Group will offer advice not only for type 1 use but also for users participating in types 2 and 3 projects which will be covered by separate research governance structures.

4 Deliverables

4.1 Written guidelines describing the application and oversight processes for projects intending to use CRIS.

4.2 Application forms to be completed for all projects seeking CRIS access.

4.3 A detailed CRIS Administrator 'job description', including the management of the access and reviewing of audit logs.

4.4 Written updates to the CRIS security model (as required).

4.5 Written specifications for CRIS functional improvements (as required).

4.6 CRIS training packages

5 Membership and organisation

5.1 Membership:

- Trust Caldicott Guardian –Chair
- CRIS Technology Lead
- CRIS administrator/Coordinator
- Head of Information Governance
- One clinical lead from each of the 3 Directorates
- Service user and carer/public representation – 2 places
- Clinical audit lead
- R&D lead
- Academic Lead
- Pharmacy Lead

5.2 The Group will be quorate when there are at least 6 members present

5.3 Initially the Group will meet monthly or as necessary. Where possible, the Group will conduct its business virtually, e.g. using e-mail communication to reach agreement

5.4 The Group will report to the R&D Governance Group but also provide assurance to the Information Management Committee of the Trust in relation to its information governance requirements

6 Approval

These terms of reference are approved by the CRIS Management Group and signed on behalf of the group by Prof John Geddes

Signed……  …… Date……27th March 2015