STANDARD OPERATING PROCEDURE (SOP)

SOP Number: NCP/R&D_010

SOP Title: Clinical Record Interactive Search Opt Out

Role	Name	Signature	Date
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SOP Authoriser	Dr Shanaya Rathod – R&D Director		21/10/16
SOP Review Date			

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	13-Oct-2016	Initial Version	

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1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes "the opt out" process that should be followed when a patient's request for their data to not be included within the Clinical Record Interactive Search (CRIS) system is received. The purpose of this document is to describe the procedures and methods that will be used by Southern Health NHS Foundation Trust CRIS team to ensure that a patient's decision to opt out of CRIS is processed fairly and legally.

1.2. CRIS allows authorised staff (see CRIS SOP NCP-R&D_011) with regulated access to compare and search an extensive amount of pseudonymised clinical data, linked to the OpenRiO patient record for audit, service evaluation and research purposes. It is a tool that identifies relevant records based on search terms (e.g., a particular diagnosis and/or a particular word or phrase in a clinical assessment or event).

1.3. The Trust CRIS Monitoring Group is responsible for overseeing and monitoring the use of CRIS and will include representation from patients. The CRIS Monitoring Group is comprised of key Trust roles (e.g. Caldicott Guardian Representative, Information Governance, Director of Research, etc.). The Monitoring Group will ensure relevant stakeholders, including Trust patients and staff, are able to access relevant information about CRIS, including the right to opt-out.

1.4. The CRIS Administrator acts on behalf of the Monitoring Group on a day-to-day basis, including managing CRIS applications, users' accounts and access to audit logs, and Monitoring Group meetings. The CRIS Administrator is responsible for processing a patient's request to opt out of having their data processed and de-identified for use in CRIS.

1.5. CRIS works on an implied consent model; all patients are included in CRIS unless the patient explicitly opts out of having their records de-identified. This de-identification process is known as Type 1 use of CRIS, to de-identify electronic care records to enable approved staff and researchers to run queries on the de-identified data.

1.6. If a patient has agreed to take part in research as part of the Sharing Information about Research project, Researchers are able to contact patients directly to take part in ethically approved research studies. Type 2 use of CRIS refers to these patients who have provided prior consent to take part in research. The de-identified data in CRIS (Type 1) can be reversed to reveal patient identifiable information for those patients who have given consent (Type 2). This enables researchers to identify and contact the patient.

1.7. The Review of Data Security, Consent and Opt-Outs is under review by National Data Guardian and will inform future amendments to this SOP alongside future changes to legislation.

2. DEFINITIONS

2.1. SOP Author - Any person who is familiar with the activity covered by the SOP and who is competent to carry it out.

2.2. SOP Reviewer – A person who is appropriately qualified or experienced to review the procedure covered by the SOP

2.3. CRIS – Clinical Record Interactive Search

2.4. Pseudonymised- refers to data in which the most identifying fields within a data record are replaced by one or more artificial identifiers, or pseudonyms.

2.5. De-identified- refers to data in which any identifiable information has been removed. Within this SOP it is used interchangeably with Pseudonymised.

3. PROCEDURE and RESPONSIBILITIES

Table 1. To show responsibilities of staff members in relation to patient opt out of CRIS.

Staff Role	**Responsibility**
CRIS Administrator	• To liaise directly with patients in regards to requests to opt out of CRIS • To remove the patient from the CRIS database • To ensure this decision is recorded for audit purposes and confirmation is provided to the patient via letter. • To report to the Monitoring group on a monthly basis
CRIS Monitoring Group	• To monitor the audit logs produced by CRIS Administrator and reports relating to opt-outs by patients • To review and action the Communication Strategy to ensure patients are aware of CRIS and opt out procedures. • To review this SOP as required in accordance with publication of new opt out legislation for data usage.

3.1. As part of the CRIS implementation, a Communications Strategy has been developed in conjunction with the Trust Communications Team and Information Governance. The purpose of which is to ensure that patients are informed of the "opt-out" procedure outlined below.

3.2. The Communication Strategy will continue to be reviewed by the CRIS Monitoring Group to ensure patients continue to be informed of CRIS. CRIS will be publicised in numerous formats for example, posters, leaflets, open events and electronically via the website and social media.

3.3. CRIS communications will direct patients towards the CRIS Administrator via secure **hp-tr.shft.cris@nhs.net** or via phone to the R&D Research Administrator. The patient can directly discuss any queries regarding the CRIS process and report if they would like to be removed from the database. The CRIS Administrator will then remove the patient from the CRIS database.

3.4. Following the patient's request and removal, the CRIS Administrator will send a confirmation letter to the patient; the template is located in *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Opt Out Patient Confirmation Letter*

3.5. When the patient contacts the CRIS Administrator, the patient will be asked for their explicit consent to record the opt out decision on their OpenRiO record. If the patient agrees, this will be documented in the progress note of the patient.

3.6. If the patient does not agree for the CRIS Administrator to record the opt out decision on OpenRiO, then the CRIS Administrator will send a letter of notification to the patient's last or active clinical team. This will enable the clinical team to update the OpenRiO record and to further liaise with the patient if required. A template letter is located in *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Opt Out Clinician Confirmation Letter*

3.7. For audit purposes the CRIS Administrator will maintain a log of opt-out requests to include patient details and date of opt out on working document "CRIS Opt out Database" located in *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Opt Out Database.*

3.8. **Re-joining CRIS**
If at a future date the patient decides to re-join the CRIS database, they can do so by re-contacting the CRIS Administrator. The CRIS Administrator will then re-add the patient to the database to be included in future extractions. The CRIS Administrator will record the decision to re-join via *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Opt Out Database*

3.9. Once the patient is re-added to the CRIS database, the CRIS Administrator will send a confirmation letter to the patient; the template is located in *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Rejoin Patient Confirmation Letter*

3.10. When the patient contacts the CRIS Administrator, the patient will be asked for their explicit consent to record the re-join decision on their OpenRiO record. If the patient agrees, this will be documented in the progress note of the patient.

3.11. If the patient does not agree for the CRIS Administrator to record the re-join decision on OpenRiO, then the CRIS Administrator will send a letter of notification to the patient's last or active clinical team. This will enable the clinical team to update the OpenRiO record. A template letter is located in *S:\ResearchandDevelopment\CRIS Confidential* under *CRIS Rejoin Clinician Confirmation Letter*

3.12. The CRIS Administrator is responsible for the auditing of CRIS searches and

reporting to the CRIS Monitoring Group. The CRIS Administrator will report the number of opt-out and re-joins to the Monitoring group at each meeting to ensure this can be monitored accordingly.

3.13. The CRIS Administrator will ensure there is a back-up member of staff within the R&D Team to provide support and cover for procedures and responsibilities should the CRIS Administrator be on leave or absent from work.