

**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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<b>SOP Date</b>	<b>Review</b> <b>August 2022</b>		<b>Effective date stamp</b> 21/08/2019

**Review History**

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	13-Oct-2016	Initial Version	21/10/2016
2	15/08/2019	V.2.0 Updated information on document locations, removal of redundant documents, and slight change in process.	21/08/2019

**STANDARD OPERATING PROCEDURE (SOP)****SOP Number: R&D 010****SOP Title: *Clinical Record Interactive Search Opt Out*****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. The Sharing Information about Research project is no longer used across the Trust although previously provided consent for contact from patients will be respected when considering patient approach for ethically approved research studies. Researchers are able to contact patients directly if they previously agreed to research contact under this project; de-identified data in CRIS (Type 1) can be reversed to reveal patient identifiable information for patients who have given consent (Type 2). For those who did not provide consent researchers will have to make contact with a patients care team instead to pass on information about the study or gain consent from the care team to make contact with the patient. These data will be provided to researchers via password protected spreadsheet, either through shared R&D folders or nhs.net to nhs.net email accounts.

- 1.7. The Review of Data Security, Consent and Opt-Outs has been reviewed by National Data Guardian and will inform future amendments to this SOP alongside future changes to legislation, although it is still being decided as to the Trust stand on this at the local level

## **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	<ul style="list-style-type: none"> <li>• To liaise directly with patients in regards to requests to opt out of CRIS</li> <li>• To remove the patient from the CRIS database</li> <li>• To ensure this decision is recorded for audit purposes and confirmation is provided to the patient via letter.</li> <li>• To report to the Monitoring group on a monthly basis</li> </ul>
CRIS Monitoring Group	<ul style="list-style-type: none"> <li>• To monitor the audit logs produced by CRIS Administrator and reports relating to opt-outs by patients</li> <li>• To review and action the Communication Strategy to ensure patients are aware of CRIS and opt out procedures.</li> <li>• To review this SOP as required in accordance with publication of new opt out legislation for data usage.</li> </ul>

- 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 procedure to "opt-out" from CRIS 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 [shft.cris@nhs.net](mailto:shft.cris@nhs.net) or via phone to the R&D Research Administrator (Appendix 1 and 2). 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 acknowledge receipt of request, address any concerns that may have arisen, and confirm they have been opted out on CRIS.

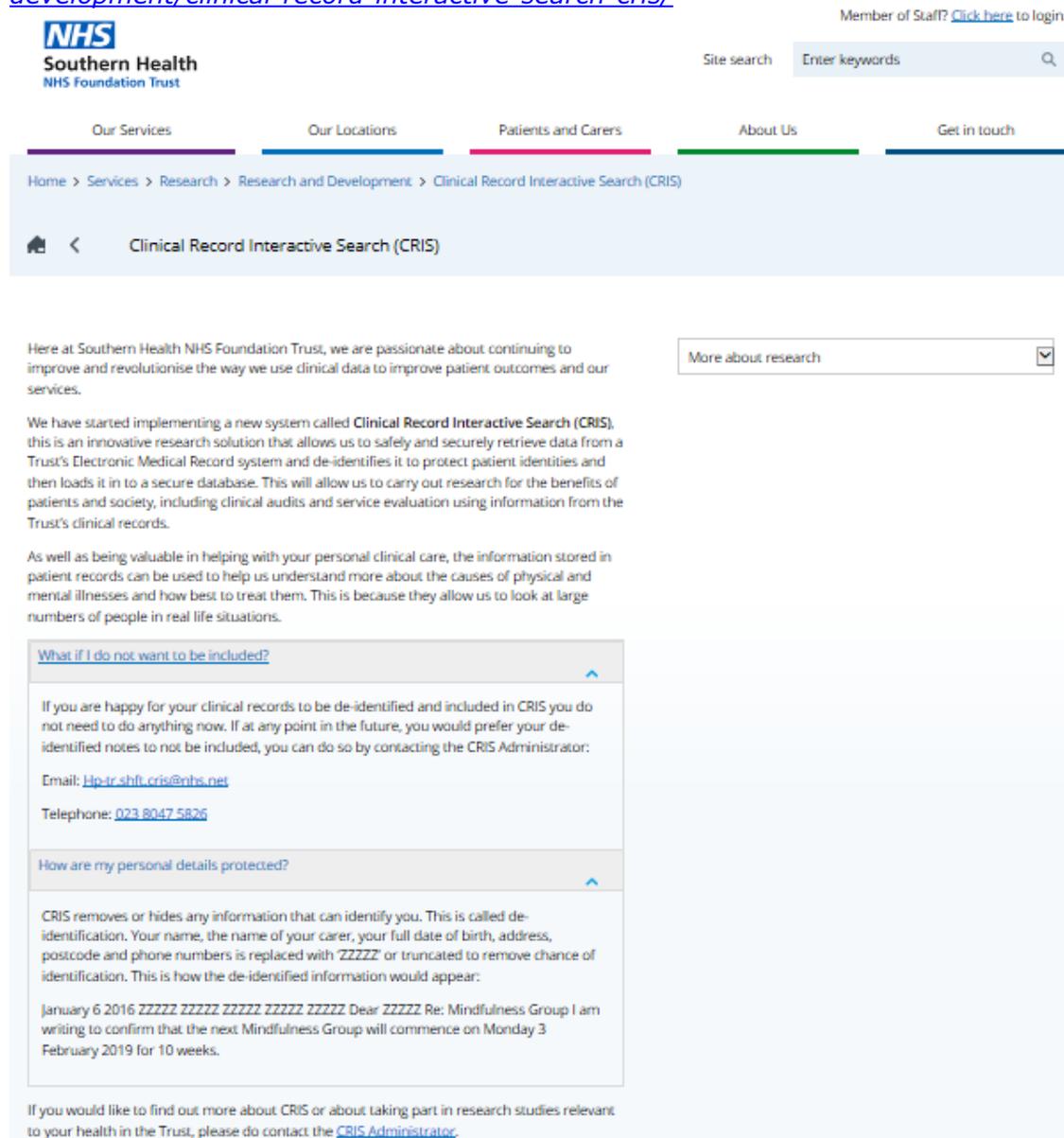
- 3.5. When the patient contacts the CRIS Administrator, the patient will be asked for their explicit consent to record the opt-out decision on their OpenRiO record. If the patient agrees, this will be documented in the progress note of the patient.
- 3.6. If the patient does not agree for the CRIS Administrator to record the opt out decision on OpenRiO, then the CRIS Administrator will make contact with the patient's last or active clinical team requesting they update the OpenRiO record and to further liaise with the patient if required. 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\R&D Admin Governance\UK-CRIS\Patient Opt-Out* under *CRIS Opt Out Database*. This is also logged on <https://ukcris.nhs.uk/>, viewable to the CRIS administrator under "Manage service-user opt-out from CRIS".
- 3.7. **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\R&D Admin Governance\UK-CRIS\Patient Opt-Out* under *CRIS Opt Out Database*
- 3.8. Once the patient is re-added to the CRIS database, the CRIS Administrator will send confirmation they have been re-added to the CRIS database via their preferred contact method.
- 3.9. 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.
- 3.10. If the patient does not agree for the CRIS Administrator to record the re-join decision on OpenRiO, then the CRIS Administrator will make contact with the patient's last or active clinical team. This will enable the clinical team to update the OpenRiO record.
- 3.11. 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.

## 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. Appendices

### 1. Public CRIS Website.

The Trust public website including information on CRIS can be found here:

<https://www.southernhealth.nhs.uk/services/research/research-and-development/clinical-record-interactive-search-cris/>



The screenshot shows the public website for the Clinical Record Interactive Search (CRIS) service. At the top, there is the NHS logo and Southern Health NHS Foundation Trust branding. A search bar is present with the text "Site search Enter keywords". Navigation tabs include "Our Services", "Our Locations", "Patients and Carers", "About Us", and "Get in touch". The breadcrumb trail reads: Home > Services > Research > Research and Development > Clinical Record Interactive Search (CRIS). The main heading is "Clinical Record Interactive Search (CRIS)".

The content area includes:

- A paragraph stating: "Here at Southern Health NHS Foundation Trust, we are passionate about continuing to improve and revolutionise the way we use clinical data to improve patient outcomes and our services." A dropdown menu labeled "More about research" is visible to the right.
- A paragraph explaining: "We have started implementing a new system called Clinical Record Interactive Search (CRIS), this is an innovative research solution that allows us to safely and securely retrieve data from a Trust's Electronic Medical Record system and de-identifies it to protect patient identities and then loads it in to a secure database. This will allow us to carry out research for the benefits of patients and society, including clinical audits and service evaluation using information from the Trust's clinical records."
- A paragraph explaining: "As well as being valuable in helping with your personal clinical care, the information stored in patient records can be used to help us understand more about the causes of physical and mental illnesses and how best to treat them. This is because they allow us to look at large numbers of people in real life situations."
- A section titled "What if I do not want to be included?" with an expand/collapse arrow. The text below reads: "If you are happy for your clinical records to be de-identified and included in CRIS you do not need to do anything now. If at any point in the future, you would prefer your de-identified notes to not be included, you can do so by contacting the CRIS Administrator: Email: [Hp-tr.shft.cris@nhs.net](mailto:Hp-tr.shft.cris@nhs.net) Telephone: 023 8047 5826".
- A section titled "How are my personal details protected?" with an expand/collapse arrow. The text below reads: "CRIS removes or hides any information that can identify you. This is called de-identification. Your name, the name of your carer, your full date of birth, address, postcode and phone numbers is replaced with 'ZZZZZ' or truncated to remove chance of identification. This is how the de-identified information would appear: January 6 2016 ZZZZZ ZZZZZ ZZZZZ ZZZZZ Dear ZZZZZ Re: Mindfulness Group I am writing to confirm that the next Mindfulness Group will commence on Monday 3 February 2019 for 10 weeks."
- A final paragraph: "If you would like to find out more about CRIS or about taking part in research studies relevant to your health in the Trust, please do contact the [CRIS Administrator](#)."

## 2. CRIS Poster

This is located in <S:\ResearchandDevelopment\R&D Admin Governance\UK-CRIS\Communications\FINAL COMMS\CRIS poster v2>



Acrobat Document

## 3. CRIS Leaflet

This is located in <S:\ResearchandDevelopment\R&D Admin Governance\UK-CRIS\Communications\FINAL COMMS\CRIS leaflet-2>



Acrobat Document

## 4. National opt-out patient hand out

Available online at: <https://digital.nhs.uk/services/national-data-opt-out-programme/supporting-patients-information-and-resources>



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nal+v1.0+web.pdf

## 5. National opt-out poster

Available online at: <https://digital.nhs.uk/services/national-data-opt-out-programme/supporting-patients-information-and-resources>



Patient+poster+Fina  
l+v1.0.pdf