York and Scarborough Teaching Hospitals NHS Foundation Trust
R&D Unit
Standard Operating Procedure
R&D/S77

Identification of Potential Research Participants to Ensure Compliance with the National Data Opt-out Policy

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Author:	Mags Szewczyk & Cate Laven
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	Date:	13th of April 2022
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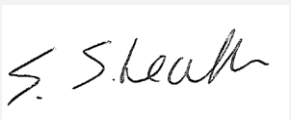
	Signature:	
	Date:	13th of April 2022

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	30th April 2012	
2.0	7th June 2013	
3.0	6th March 2014	Removal of reference to GP records, clarification of text, correction of typographical errors
4.0	20th June 2016	Changes to sequence, minor revisions of terms and punctuation. Some re-writing for clarity and to remove contradiction.
5.0	24th August 2017	Change of Author to Hilary Campbell Addition of staff with letter of access/ honorary Contract
6.0	13th April 2022	Change of author. Change of link to R&D website. Wording added re NHS Constitution. Information added to ensure compliance with the national data opt-out policy.

Contents

1 Introduction, Background and Purpose

It is in the interests of patients that they should be made aware of opportunities to consider participating in suitable clinical research. The NHS Constitution also advises all patients should be offered the chance to become involved in research studies.

For compliance with Data Protection legislation, the NHS Confidentiality Code, and the National Data Opt-Out Policy, potential participants in research studies should be identified by members of their immediate clinical team. These patients have not yet been informed about the research and have not consented to research use of their data. The Caldicott Guardian for the Trust has determined that it is appropriate for staff employed by York and Scarborough Teaching Hospitals NHS Foundation Trust (the Trust) as specialist Research Nurses, Midwives or other appropriately delegated research staff belonging to a trial team, to be regarded as part of the clinical team for the purpose described in this SOP, and to be involved in identifying and approaching potential participants using this procedure. This also includes staff who have been issued with a letter of access or an honorary contract by the R&D Unit (see SOP/S20 for details).

As from the 1st of April 2022, health and care organisations must comply with the national data opt-out policy for all activities, including clinical research. The national data opt-out allows a patient to choose if they do not want their confidential patient information to be used for purposes beyond their individual care and treatment - for example for clinical research purposes. Patients can register their data opt out on the NHS.UK website (https://www.nhs.uk/your-nhs-data-matters/manage-your-choice/) or by contacting NHD Digital via email or telephone.

The national data opt-out has no impact where a patient has consented to participate in a research study and has agreed for their data to be used in that study. Nor will it affect studies that use anonymised data. However, the data opt out applies to procedures for identifying potential research participants (pre-screening/ screening/ participant identification activities). Therefore, the relevant Chief or Principal Investigators and research staff must ensure compliance with the national data opt out policy when searching for potential research participants by following the procedures outlined below.

2 Who Should Use This SOP

- Chief or Principal Investigators wishing to recruit participants to research studies;
- Research Nurses, Midwives and other appropriately delegated staff working on research studies.

3 When this SOP Should be Used

This SOP should be used when potential research participants are being identified and approached, following issue of the R&D Unit's Confirmation of Capacity and Capability to deliver a research study in the Trust; as well as when the Trust is set up as a Participant Identification Centre (PIC) for a research study (see SOP/S67).

The issuing of Confirmation of Capacity and Capability is required for all studies as part of the Health Research Authority (HRA) approval process for the NHS in England. It comprises a review by an NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff (see SOP/S14). The Trust standard Confirmation of Capacity and Capability email will contain information for the study CI/PI and their research team to consider the procedures for participants' identification specific to their project and to ensure compliance with the national data opt-out policy.

Depending on the mechanism used to identify potential research patients - please see the table below- **the data opt-out choice must be checked on CPD prior to approaching patients with research information**.

Mechanism for identifying research study participants:	**National data opt-out applies?**
The researcher gains the explicit consent of every patient with a record in the population pool being assessed.	NO
The search is conducted by a health or social care professional who has a 'legitimate relationship' with the patient, such as a social worker or a clinician who has a reason to view the patients ' records because they are directly involved in the patient's care at that point.	NO
The search is conducted by a researcher who is part of the immediate clinical team.	NO
The search is conducted by a researcher who is NOT considered a part of the immediate clinical team or is NOT directly involved in the patient's care at the time of searching.	YES * (opt-out choice must be checked on CPD)
Support under Section 251 regulations* is granted for researchers to contact suitable patients to seek their consent - for such studies checking for data opt-outs will be required. This will be possible when the CPD process for checking for data opt-outs gets implemented. *Section 251 approval provides a reliable basis in law to permit the disclosure and temporary use of identifiable NHS patient information for those wishing to obtain identifiable NHS patient information without consent; or for data controllers who are asked to supply identifiable patient information without consent. Section 251 approval is considered by the Confidentiality Advisory Group (CAG) and granted if there is a sufficient justification to access data without consent.	YES *(opt-out choice must be checked on CPD)

This is strictly an opt-out process (all patients are opted in by default). When a patient sets an opt-out choice; it is recorded against their NHS number on the 'Spine' system. Information from the 'Spine' system are also linked to the Trust Core Patient Database (CPD):

*To check if a patient has opted out, use the CPD screen **NDOP_CHK** via

(Forms → Patient Administration →NDOP_CHK).

Please see Appendix 1 for complete instructions.

4 Authorising the Identification of patients

The Chief / Principal Investigator and the research team should first check that the proposed methods to be used for identifying and approaching potential participants are consistent with the protocol, the terms of the favourable ethical opinion and compliant with the national data-opt out policy.

The identification of candidate research participants may commonly include the following:

- attending multi-disciplinary team (MDT) meetings or clinics
- encouraging patients' interest using the Sponsor's ethically approved advertising material
- inviting members of the immediate clinical team, or those with 'legitimate relationship' currently involved in the patient's care, to suggest suitable patients in meetings or correspondence
- searching patient records and reports to identify candidate participants
- following up leads to exclude unsuitable patients and to include those with a reasonable chance of being interested and eligible
- approaching candidate trial patients at their clinic visits to introduce the trial
- giving or sending the Sponsor's ethically approved recruitment information to candidate participants, to introduce and explain the research
- noting in patients' medical records that trial information has been provided to patients, and the outcome of any conversation or correspondence

The Chief/Principal Investigator is responsible for consulting and informing his / her colleagues about the research protocol and gaining their agreement. The research study team members who are to identify potential participants should be named on the delegation log and considered as a member of the immediate clinical team.

Delegated trial team members should be trained by the Investigator on any conditions or limits placed on the recruitment activity. R&D/T29 may be used as a template file note to document the immediate clinical team's agreement and the relevant conditions. Alternatively, the relevant email correspondence can be filed as a documented evidence of the immediate clinical team's agreement.

5 Pre-screening, screening and PIC site actions

Following authorisation as above, the Research Nurse, Midwife or other delegated research staff, is regarded as a member of that clinical team and may then carry out identification activities such as those listed above.

Data opt out choices must be checked prior to approaching the identified candidates if the approach is to be made by someone from outside the immediate clinical team, or NOT currently involved in the patient's care.

A candidate trial participant has not yet agreed to participate in the study at this stage. Therefore, two important principles have to be balanced: to minimise approaches made to candidates with no prospect of eventual enrolment, and to limit the access of extraneous personal data while exploring candidates' prospects.

6 Data handling

It must be remembered that during this process the patient has not agreed to participate in the study. This activity is, meant to lead to the point where the patient can be consented and enrolled according to the Protocol. No study data collection or other study procedures should take place until full informed consent has been given.

A record of approaches to potential participants should be retained in the Investigator Site File and in medical records, noting the dates of approach and outcomes. If there is a requirement for a screening log with patient identifiable information allowing the research team to track patients over a period of time, care should be taken not to generate lists, notes or other data that are uncontrolled and give rise to data security risks. Any lists with patient identifiable information should be kept in restricted access folders on Q-drive/ R&D Clinical Research Projects with access restricted to the R&D research teams only.

- The patient's medical record should be treated as the secure depository of clinical data, compiled to support patient care
- The patient's trial data should be recorded only with informed consent and according to Protocol, to support reliable science

7 Related SOPs and Documents

R&D/T29 File Note Identification of Research Participants

Appendix 1- How to check CPD to see if a patient has opted out of data sharing

Communications Document

The national data opt-out is a service that allows patients to opt out of their confidential patient information being used for research and planning. This is strictly an opt-out process (all patients are opted in by default).

To check if a patient has opted out, use the CPD screen **NDOP_CHK** via

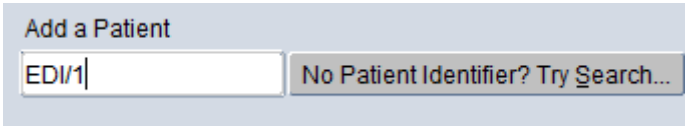
- (Forms → Patient Administration →NDOP_CHK).

Start by either:

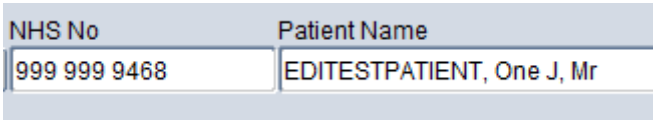
- Entering the patients' identifier into the **Add a Patient** box and pressing enter key

Or

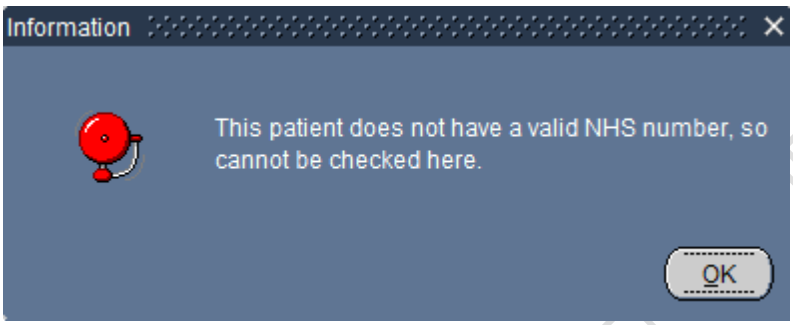
- Search for the patient using the **No Patient Identifier? Try Search…** button



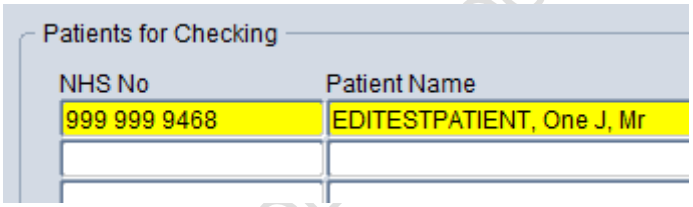
At this point the patients' details will be populated in the **NHS No** and **Patient Name** boxes.



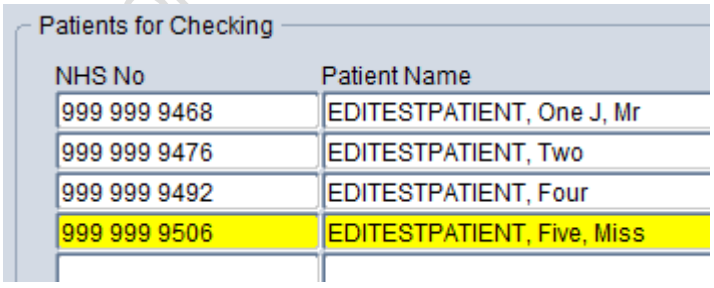
A patient must have a verified NHS number to be checked against. If the patient does not have one, an error will show on the screen.



Once you have confirmed the patient details are correct, press the **Confirm** button to add the patient to the **Patients for Checking** list below.



You can repeat this process as many times as required to add the patients you want to check to the list.



If you need to remove a patient from the list, highlight the patient to be removed and press the red cross in the toolbar. 

If you need to clear the list of all patients, press the **Clear** button.

Once you have added the patients you want to check, press the **Validate** button, or if you would like to extract the output to a CSV file, press the **Validate and Extract** button.

The validation process will remove any patients from the list that have opted out. The patients that remain in the list are patients that have not opted out, whose data can be shared for this purpose.

It can take up to 5 days for any opt out changes to be reflected in this screen.

Further information on national data opt-out can be found on the NHS Digital website: https://digital.nhs.uk/services/national-data-opt-out