

Implementing the SDRN Research Register in General Practice

Clinical S.O.P. No.: 24
Version 2.0

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Louise Greig / Barbara Brett / Shona Brearley	
1.1	SDRN added to SOP title and other minor changes	Louise Greig	June 2012
2.0	Changes made to reflect the use of the Research Register leaflet and new processes.	John Kerr	May 2013

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1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'. This SOP details the procedure to be followed to continue to develop the expansion of the Research Register into primary care.

2. Background

The purpose of this SOP is to describe the process that SDRN staff should follow when contacting GP practices in order to expand the geographical distribution of the Research Register and to encourage collaboration with the Primary Care Community. By following the directions in this standard operating procedure it is expected that practices will be assured that the letters being sent to their patients will not be a source of anxiety or unease to the practice or patients.

3. Objectives

To describe the steps that should be followed when a SDRN member of staff contacts a GP practice to implement / promote the Research Register.

4. Procedure

The appointed SDRN members of staff will identify practices to be contacted in their area.

The identified practices will then be contacted by telephone, email or letter. The communication will include an overview of the Research Register and a summary of what steps are required for a practice to implement the Research Register. If appropriate, a meeting with all relevant practice staff should be arranged.

In the communication with practices and/or at any meeting the following subject matter will be discussed in order to ensure practices are aware of the function of the network –

- Provide an overview of the purpose of the network.
- Tell the practice about the Research Register.
- Advise the practice as to the minimal level of involvement they would need to provide in order to support the distribution of Research Register documentation.
- Review and discuss the Research Register leaflet and cover letter that is to be sent to patients – see Appendix 1.

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Ask the practice to generate a list of all their patients with diabetes – the list should be screened and patients not considered appropriate for contacting should be removed from the list.

Select from the following two options:

Option 1: If the member of staff in contact with the practice has arranged to carry out all printing and envelope packing at their respective NHS site, the practice should be asked to email the screened list of their patients along with a copy of their practice headed paper to an NHS clinical inbox or NHS email address.

Option 2: Alternatively, the member of staff should arrange to visit the practice to print the letters and pack the envelopes for sending to patients.

The SDRN Research Register GP letter should be printed on practice headed paper and will have local SDRN contact details included.

The SDRN Research Register GP letter should be auto signed by one of the General Practitioners within the practice if this is normal practice to do so.

The letters to be sent to patients should include the following:

- Cover letter (on practice headed paper)
- Research Register leaflet

The time between generation of the checked list of suitable patients and the sending of the letters should be as small as possible to minimise the possibility of a change in patients circumstances and the inappropriate sending of the letter.

Before posting out the documents please check the bottom of the GP letter to ensure that the bottom statement, that explains how to say no to being on the research register, is included on the page.

To ensure data protection the letters that contain patient identifiable information should either be:

1. sent directly from the NHS site where the patient listing was received,
2. sent directly from the practice where the printing and envelope packing was carried out
3. or transferred immediately by a member of the SDRN team from one secure NHS site to another secure NHS site. Letters should never be left in a car or house of a member of staff. (Sites may prefer to use the hospital franking service as it is more convenient.)

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Appendix 1 – Example of letter to be sent from a GP practice to a patient

Please print letter on GP practice headed note paper

<PATIENT' NAME>
<PATIENT'S ADDRESS 1>
<PATIENT'S ADDRESS 2>
<PATIENT'S TOWN/CITY>
<PATIENT'S POST CODE>

Date:

Dear [Sir / Madam](#),

Scottish Diabetes Research Network – Diabetes Research Register

Diabetes is becoming much more common in the Scottish population. It is because of this that research into the causes, treatment and prevention of diabetes is very important.

The Scottish Government, aware of how important diabetes is becoming to the people of Scotland, initiated the Scottish Diabetes Research Network (SDRN). The SDRN has a Scottish-wide diabetes research register that contains information on all those patients with diabetes who are willing to be contacted about diabetes research. We, as your GP practice, have been asked to help with the continued development of this important resource.

The Research Register requires a form to be completed to say that you would be happy to be contacted regarding any research study that you may be eligible to join. Please note that this permission is only to allow your GP or SDRN staff to approach you to consider taking part in any research project. You are not under any obligation to take part and your diabetes care will not be affected whether or not you agree to this contact or to any of the studies.

If you complete the form, and are then contacted, you can choose whether or not to take part in the study once all your questions have been fully answered by a healthcare professional.

If you wish to join the national research register, please follow the instructions provided in the enclosed leaflet.

If you have any questions, or would like further information before deciding whether to join, please contact [Jackie Lindsay, Diabetes Specialist Research Nurse on 01382 660 111 ext. 35169](#) or email JacquelineLindsay@nhs.net **(NB Please change to reflect local contacts.)**

Thank you for taking the time to read this and we look forward to hearing from you.

Yours sincerely,

(GP Signature)

[Jacqueline Lindsay, Diabetes Specialist Research Nurse, SDRN](#) **(Please change to reflect local changes.)**

PLEASE NOTE: If you do not want to join the Research Register at this time, no further action is required. However, if you wish to be recorded as having chosen not to join the Research Register please add your full name, postcode and date of birth where indicated before drawing a large cross through the permission to contact section. Please then seal the leaflet and return it by post.