

Clinical S.O.P. No.: 25 Version 2.0

Compiled by:	Shova Breakley Lomei M. Juis Jat Man Jake
Approved by:	am
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### **DOCUMENT HISTORY**

Version	Detail of purpose / change	Author / edited	Date edited
number		by	
1.0	New SOP	Louise Greig /	
		Paul McIntosh /	
		Shona Brearley	
1.1	Minor change to SOP title	Louise Greig	June 2012
2.0	Changes made to reflect the use of the Research Register leaflet and updates to SCI-Diabetes,	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 used.

### 2. Background

The Research Register is a national SDRN initiative set up to give people with diabetes the opportunity to sign up to a register that allows research staff to contact them about research projects with a view to participating in them. (The 'Research Register' leaflet contains the registration form and shows that the patient has had the opportunity to volunteer to be approached about research studies).

### 3. Objectives

To describe the steps that should to be followed by the individual entering data onto the SDRN function in SCI-Diabetes and how to process the Research Register documentation.

#### 4. Procedure

The following describes the process for entering patient details into the SDRN/SCI-Diabetes Research Register.

Please refer to 'SDRN/SCI-Diabetes Research Register Data Entry – User Guide' (APPENDIX 1) at the end of this SOP for a step-by-step guide to the pages you will see throughout the whole data entry process -

- Please note it is necessary to enter all responses Yes and No into the SDRN/SCI-Diabetes Research Register.
- The SDRN Research Register pages of SCI-Diabetes are restricted to specific staff. In order to access the SDRN Permission to Contact pages of SCI-Diabetes you will have to make a request to the SDRN Office by email (admin@SDRN.org.uk) or telephone.
- Once you have been granted access you can login from the main SCI-Diabetes System Login page to access the SDRN/SCI-Diabetes Research Register pages.
- Once you have logged in you should select the 'Main Menu' option on the left-hand side
  of the toolbar wherein you can navigate to 'SDRN Admin' before clicking on 'Find and
  Select a Patient'.



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- You can now search for a specific patient's details using the CHI or Surname, Date of Birth and/or Postcode (or a combination of the three). This information can be obtained from a completed Research Register leaflet form.
- Once you have entered the relevant information into the appropriate fields click on the 'Search' button to return the Patient List.

(If a patient's details cannot be found by using the CHI or Surname and D.O.B. then please highlight the name on the white spreadsheet and a member of the SDRN Administration team will carry out a search at a later date and enter the details. If you require a copy of the white spreadsheet please contact the SDRN Office by telephone or email (admin@SDRN.org.uk). Alternatively, make a note detailing the patient/s that cannot be found and return this with the completed Research Register leaflet forms.

- The Patient List will display the results of your search and you should be able to match the D.O.B. with the name of the patient for whom you are searching.
- To select a patient, place the cursor over the patient information. The patient details will then be highlighted in red. Click on the highlighted line to select the patient.
- When the Patient has been selected, the 'Manage Patient Consent' page will be displayed and you should now proceed to complete the relevant fields.
  - o If the patient is to be added to the register:
    - Enter the patient's telephone number and/or email (if provided) into the appropriate field(s).
  - Proceed to the 'Recording Consent' section and click each section as appropriate.
  - Proceed to the 'Patient Preferences' section and click each section as appropriate before selecting the patient's preferred method of contact.
  - If several methods of contact have been indicated, and this includes telephone, select telephone as the preferred method of contact.
  - If the preferred method of contact is unclear then 'letter' has to be selected as the method of contact.
     (Our preferred default order is 1. Phone, 2. Email, 3. Letter.)
- When the correct data has been entered click 'Save'. (Click 'Reset' if you want to edit or revise the information.)
- You will now be redirected to the Find and Select a Patient screen where you can begin to enter the details of another patient or exit/log-out the system.
- Once you have entered a patient's details into the system please make a record of this on the white spreadsheet by placing a tick in the relevant box next to their name.



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### The following provides guidance on how to Process the Research Register documentation -

- Start a new white spreadsheet every month and all patients should be entered onto the spreadsheet in date order.
- Collate the completed Research Register leaflets in the order patients are listed on the white spreadsheet(s).
  - When storing patient identifiable data (PID) held on paper (i.e. Completed Spreadsheets & Research Register leaflets) must be securely stored in locked filing cabinets within secure offices/areas.
- Return the completed Research Register leaflets and the white spreadsheets to the SDRN central office on the 1st day of every month.
  - When returning completed Research Register Spreadsheets & completed Research Register leaflets to the SDRN, please make sure the package is securely taped to prevent the contents from moving in transit and tearing the envelopes/ packaging. It is required to be double wrapped in stout envelopes/packaging with recipient and sender name and address written/printed on both layers. Envelopes/packages must be sent by Royal Mail Special Delivery or a similar signed for service.

(For further details of SDRN PID Procedures please see SOP 26 - SDRN & Personal Identifiable Data (PID) in Clinical Use)

 No copies of the Research Register spreadsheets or the completed Research Register leaflets are to be retained at the site/hospital/clinic where the patients joined the register.

#### Address for returns -

Administrator
Scottish Diabetes Research Network
SDRN Office
Diabetes Support Unit
Level 8
Ninewells Hospital
Dundee
DD1 9SY



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(APPENDIX 1)



SDRN/SCI-Diabetes Research Register Data Entry – User Guide

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