



SDRN: Scottish Diabetes Research Network

Requesting a Search of the SDRN Research Register

Clinical S.O.P. No.: 29

Version 3

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SCIENTIST
OFFICE**

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Louise Greig	
2.0	Additional information added to SOP	Louise Greig	June 2012
2.1	Additional information in relation to the search criteria added	Louise Greig	June 2013
3.0	Additional information to reflect updated registration leaflet	John Kerr	October 2014

1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'.

2. Objective

To describe the process of how NHS and University research staff request a search of the SDRN Research Register Database.

3. Background

The SDRN Research Register is a national project developed for patients wishing to take part in research.

Patients who wish to become involved in research are asked to complete a 'Permission to Contact' leaflet and this allows staff to contact them directly about studies they may be interested in participating in. The information is securely stored and accessed through the SCI-Diabetes system. The aim of the register is to make the recruiting of patients to research studies more focused.

The following SOPs are related to the Research Register and should be viewed in conjunction with this SOP:

- SOP 11 Completing the SDRN Research Register Leaflet
- SOP 12 Withdrawal from the SDRN Research Register
- SOP 25 Entering Patient Data into the SDRN/SCI-Diabetes Research Register

4. Process

- Access to the search facility of the SDRN Research Register is restricted and can only be done centrally through the SDRN office. To request a search to be carried out please contact us by e-mail or letter:-

admin@sdrn.org.uk

or

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

- In the e-mail/letter it is important to provide the following information:
 - Your full name
 - Your position/role within the NHS/University
 - Your full address, including postcode, for the institution/organisation where you are based
- Your study will need to be recorded by the network before a search can be activated - this involves completing a '[SDRN Minimum Dataset Form](#)' that can be downloaded from our website.
- The network requires a copy of the R & D approval letter for a study. Ensure the approval letter covers whether the study is single or multi-centre.
- On receipt of your request, along with the completed 'Minimum Dataset Form', the SDRN team will consider your request in order to make a decision if you can have access to the dataset you requested.
- If your request for a search of the SDRN Research Register is refused then a reason as to why the request was denied will be provided.
- If the SDRN Research Register is used to provide eligible patients for your study you must comply with any reasonable requests for recruitment numbers from the SDRN team.

5. Management of Search Results

Search results show 'Patient Identifiable Information' therefore all results are required to be sent from, and to, a secure NHSmail address.

Search results will be sent in the form of an excel spreadsheet and it will be the responsibility of all recipients of search results to take all the necessary steps to protect patient confidentiality.

*(For further details of how to control PID please refer to **SOP 26**: [SDRN & Personal Identifiable Information \(PID\) in Clinical Use](#))*

Results will only be as current as at the time the search is carried out. **DO NOT** store search results for use at a later date.

If you require an updated search for an existing study, or if you need a search for a study where the criteria are similar, please submit a new request to the SDRN office.

A record should be kept of all patients contacted. (Searches do not filter out the names of patients who have appeared on recent search lists therefore it is important that you check with colleagues to ensure they have not recently made contact with a patient. This will avoid patients being contacted by more than one member of staff within a 6 month period of time.)

Results do not indicate the source of the search information e.g. hospital, clinic, GP practice etc...

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A record will be kept at the SDRN office of all requested searches.

A condition of getting access to the SDRN Research Register is that we ask you to record the following and send the information to the SDRN office:

- Keep a record of the number of patients you contact from the search results
- Keep a record of all responses from the patients you contact from the search results provided
- Record the number of patients contacted who say 'Yes' to participating in the study
- Record the number of patients contacted who say 'No' to participating in the study

Please include the following information in your search request e-mail/letter.

- **Information Required for a Search**

- Name of Applicant
- Address of Applicant (Name of Hospital/University & Health Board)
- Telephone number
- E-mail address
- Study title

- **Search Criteria Descriptors – please include all that apply:**

General criteria

- Type of diabetes -Type 1, Type 2 or T1 and T2
- Patient's gender – Male, Female, Other specific or Not specified
- Patient's age range - Upper and Lower limit
- Enrolled in hospital clinic - if possible state where the patient was recruited to the SDRN Research Register e.g., Angus dietetic clinic, Perth and Kinross Diabetes Clinic Domain, Western General Hospital Lothian, Royal Infirmary Edinburgh etc.

Biochemistry criteria

- Blood pressure between – systolic upper and lower and diastolic upper and lower values
- BMI between – upper and lower values
- Cholesterol between – upper and lower values
- Creatinine between – upper and lower values
- HbA1c between – upper and lower values
- eGFR between – upper and lower values
- ALT between – upper and lower values
- AST between – upper and lower values
- Alkaline phosphatase between – upper and lower values

Lifestyle criteria

- Treatment type
 - No drugs found
 - Insulin
 - Insulin via pump
 - Oral Agents
 - Metformin
 - Sulphonylurea
 - Glitazone
 - Gliptin
 - Glinide
 - Glucosidase inhibitor
 - Other injectable agent
 - Other therapy

- Smoking status
 - Patient declined
 - Not known
 - Never smoked
 - Ex-smoker
 - Current smoker
 - Current non-smoker

- Alcohol status
 - Non drinker
 - Ex-drinker
 - Current non drinker
 - Currently within recommended daily and weekly limits
 - Currently exceeds daily recommended weekly limits
 - Currently exceeds both weekly and daily recommended limits
 - Not disclosed
 - Not known

- Cardiovascular criteria
 - MI record
 - In the last 6 months
 - In the last 12 months
 - In the last 15 months
 - In the last 18 months
 - Ever

 - CVA record
 - In the last 6 months
 - In the last 12 months
 - In the last 15 months
 - In the last 18 months
 - Ever

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- PVD record
 - In the last 6 months
 - In the last 12 months
 - In the last 15 months
 - In the last 18 months
 - Ever

- OR any record of the above options (MI, CVA or PVD) which have has this value recorded
 - In the last 6 months
 - In the last 12 months
 - In the last 15 months
 - In the last 18 months