

NHS Research Scotland (NRS) Diabetes Register **USER GUIDE FOR RESEARCHERS**

This guide is for researchers wishing to use the NHS Research Scotland Diabetes Network (NRS Diabetes) Register (Diabetes Register).

The Diabetes Register allows patients with diabetes, living in Scotland, to give their permission to be matched to and approached for diabetes-related research studies of all types.

For researchers, the Diabetes Register is a free resource to support:

1. Study feasibility by providing the number and location of potentially eligible subjects
2. Active recruitment by facilitating direct contact with patients

This guide explains the types of search request ([feasibility](#) or [active](#)) that researchers can apply for and what information and conditions are required to proceed.

The guide also aims to provide further information that may be important to consider when planning to use the Diabetes Register to support study participant recruitment.

[Contact NRS Diabetes](#)

To begin your application for the Diabetes Register or, if you have any questions, please contact NRS Diabetes at:

NRSDiabetesRegister@dundee.ac.uk

01382 383 595 or 01382 383 455

NRS Diabetes Network
University of Dundee
Diabetes Support Unit (Level 8)
Ninewells Hospital
Dundee
DD1 9SY

Study Feasibility Searches using the NRS Diabetes Research Register

What is a Feasibility Search?

Feasibility searches help both researchers and NRS Diabetes understand if and how the register may be used to support diabetes patient recruitment.

Feasibility searches

- are typically carried out during planning stages of a funding application or set-up of a research study
- provide the number of registrants on the Diabetes Register who fall within a study's inclusion criteria
- provide the location of potentially eligible registrants by NHS Scotland Health Board
- provide the number and type of contact preferences registrants have chosen (i.e. one or more of email, letter or phone)
- allow for prospective changes to be made to the inclusion and/or exclusion criteria while planning a study or an amendment. Additional feasibility searches can then be requested to observe any changes in the number and location of potentially eligible registrants
- can be requested by:
 1. Academic researchers
 2. Commercial research Sponsors

Is my study eligible for a Feasibility Search?

A study must require patients with a diagnosis of diabetes or pre-diabetes and be intending to have one or more research sites in any of NHS Scotland's Health Boards.

What do I need to provide for a Feasibility Search?

Researchers or Sponsors requesting this type of search must provide a study synopsis or protocol that includes the inclusion and exclusion criteria (drafts are acceptable), and/or (if missing from the synopsis/protocol) the following information is helpful:

- Study title
- Lead investigator details
- Sponsor
- Intended number of sites and NHS Health Board locations (if known)
- Planned cohort size
- Target patient population (inclusion and exclusion criteria)
- Objectives of the study
- Study duration and period

What happens after I provide the required information and request a Feasibility Search?

NRS Diabetes staff will review the information provided and confirm whether a study feasibility search can be carried out.

- If required, confirmation of which inclusion and exclusion criteria can and cannot be applied to the search will be provided as well as any potential modifications to the search criteria to suit similar available data fields.
- Results from feasibility searches are typically provided within 1-14 working days. Researcher's will be informed if this timeline cannot be met.
- Study feasibility search results are usually provided in a table showing the number, location(s) and contact preferences (if required) of patients who meet the study's target population. The specific criteria used in the search will also be reconfirmed.
- Feasibility search results contain no personal information and can be shared with any email address.
- At this stage, NRS Diabetes may also provide advice on optimising the set-up of the study and placement of the study sites e.g. advice on research site capability or equipment.

Active Study Searches of the NRS Diabetes Register

What is an Active Study Search?

An active study search of the Diabetes Register provides a list of potentially eligible patients to the study team for contact.

Active searches are carried out for studies that are eligible to use the Diabetes Register and have received all approvals, contracts and necessary documentation in place to commence recruitment.

Active search results contain each potentially eligible patient's personal information including: 1. Name 2. CHI number and 3. Contact information.

If required, multiple searches can be carried out throughout the course of the study. Many studies find it helpful to receive searches at intervals as patient criteria such as HbA1c and eGFR can change over time.

Is my study eligible for an Active Study search?

A study must require patients with a diagnosis of diabetes (includes remission from diabetes and some forms of pre-diabetes) and have one or more research sites in any of NHS Scotland's Health Boards.

In order to directly receive active search results study team members must have an NHS email account that can be accessed within NHS premises.

What do I need to provide for an Active Study Search?

- Research Ethics Committee (REC) Approval
- NHS Health Board Research and Development (R&D) Approval(s)
- Current Study Protocol (for non-commercial studies, intention to use the register should be included in the protocol. If this has not been detailed in the protocol, approval for use of the Diabetes Register should be sought from the study Sponsor)
- Location of the research sites
- Recruitment target information
- Study duration and period, if not in protocol
- Date(s), or expected period, during which active search results are required at the research site(s)
- Anticipated number of searches required and frequency

The following information about the Principal Investigator(s) and study team member(s) at the research site(s) is required:

- Name
- Role
- Location of the research site
- NHS email address

What happens after I provide the required information and request an Active Search?

- NRS Diabetes will review the information provided and confirm whether an active study search can be carried out.
- If required, confirmation of which inclusion and exclusion criteria can and cannot be applied to the search will be provided as well as any potential modifications or additions to the search criteria to suit similar available data fields.
- NRS Diabetes will endeavour to issue results on or near the specific dates requested during the application. For immediate searches, results will typically be issued within 1-14 working days. Researchers will be informed if any timelines cannot be met.

Receiving Active Search Results

Active search results will be provided in a Microsoft Excel spreadsheet. Data columns include each potential participant's CHI number, name and contact information.

Results will be sent from and received by NHSmail (or SWAN Secure File Transfer) and should be accessed entirely within the NHS network and NHS premises (at the research site). Further instructions and conditions are provided when results are issued to reinforce data security requirements.

Recipients of active study search results must ensure that the data is protected and managed in accordance with Caldicott principles, local Information Governance and Information Security Policies. It is the responsibility of the research team to appropriately manage information.

In addition to the search results, researchers will be issued with email and letter templates for making initial with contact patients.

First contact with potentially eligible participants

NRS Diabetes maintains ethically approved generic email and letter templates which can be used, by a study team, when making initial contact with patients.

Two contact template types are available:

1. For research concerning the patient
 2. For research concerning family members of the patient
- These templates have been approved by a Research Ethics Committee (REC) for use by any study that is eligible to use the Diabetes Register and therefore do not need to be included separately as part of a study's REC approved patient-facing material. However, individual studies may elect to generate their own materials in addition or instead of using the Diabetes Register templates ([see below](#)).
 - For initial telephone contact, researchers should be prepared to follow a similar format by conversation to the information provided in these templates. However, conversations do not need to be scripted beforehand.
 - The NRS Diabetes contact templates cannot be modified out-with the free-text sections and are required to be localised e.g. with an NHS Health Board logo.
 - NRS Diabetes also maintains templates for studies which allow patients to follow web links. These can be used for online-based questionnaire studies whereby patients can choose to participate immediately.
 - If the Diabetes Register contact templates are unsuitable the study team may draft new templates.
 - Any alternative template needs to be approved by NRS Diabetes before being submitted to the study's appointed REC for approval as part of the study's patient-facing material.

The Chief Scientist Office (CSO) publication acknowledgement for use of the Research Register

All publications arising from research that utilised the NRS Diabetes Register should acknowledge the support provided by CSO:



DIABETES

“[Research team or organisation] acknowledges the financial support of NHS Research Scotland (NRS), through Diabetes Network”