
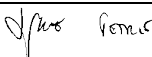


Completing the SDRN Research Register leaflet

Clinical S.O.P. No.: 11
Version 2

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Approved by:	
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DOCUMENT HISTORY

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

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

Giving all people with diabetes the chance to participate in research projects means populating a database, the 'Research Register', of those who would be interested in learning more about research projects with a view to participating in them.

3. Procedure

- The opportunity to join the Scottish Diabetes Research Network (SDRN) 'Research Register' becomes available when a person with diabetes is presented with the Research Register leaflet.
- When approaching people with diabetes to join the Research Register, the healthcare professional, or other individual trained in SDRN procedures and acting on behalf of SDRN will provide a Research Register leaflet and explain about joining the 'Research Register'.
- The person with diabetes should read the 'Research Register' leaflet and ask any relevant questions.
- The person should be made aware of the Frequently Asked Questions available to view at www.researchregister.info or on paper (upon request). The person should also be encouraged to speak to their family/friends about joining the 'Research Register', if they so wish.
- If the person with diabetes wishes to join the 'Research Register', they will complete the Research Register leaflet.
- The completed section of the Research Register leaflet should be retained by the individual who approached the person about joining the 'Research Register'. (Please refer to clinical SOP 25 for guidance on what actions are to be taken with the completed form)
- The top section of the Research Register leaflet should be detached where indicated and retained by the person who has completed the leaflet for them to keep for their records.
- The person with diabetes should be made aware of the 'Procedure for Withdrawal' from the 'Research Register'. (Please refer to clinical SOP 12)

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This procedure ensures that people with diabetes are given the opportunity to join the Scottish Diabetes Research Network (SDRN) Research Register and the process confirms to ICH GCP guidelines.