
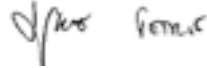


# Withdrawal From The SDRN Research Register

**Clinical S.O.P. No.: 12**  
Version 2.0

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| Approved by: |                 |
| Review date: | November 2016  |

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S.O.P. No. 12  
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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            | Addition of SDRN in the SOP title   | Louise Greig       | June 2012   |
| 2.0            | Changes made to reflect the use of the Research Register leaflet and 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. Objective

The purpose of this SOP is to describe the procedure regarding how patients can withdraw from the SDRN Research Register.

## 3. Background

All patients who join the Research Register must be informed of the Withdrawal Procedure.

When a healthcare professional, or other trained person acting on behalf of the SDRN, approaches a patient regarding the SDRN Research Register they must explain the procedure on how to withdraw from the register.

Once a patient has completed the SDRN Research Register leaflet they must detach the top section, where indicated, and retain that part for their records. The section the patient retains explains how a patient can withdraw from the Research Register.

Patients can withdraw from the SDRN Research Register temporarily and join again at a later date.

## 4. Procedure

- Patient decides to withdraw temporarily/permanently from the Research Register.
- Patient sends an email, phones or sends a letter to the SDRN Office to notify his/her withdrawal. The withdrawal email address, SDRN office telephone number and address are available on the retained section of the Research Register leaflet.
- On notification of a patient's wish to withdraw from the Research Register, the SDRN Administrator will change that person's status accordingly in the SCI-Diabetes database.

This procedure, together with the procedure for completing the SDRN Research Register leaflet will ensure that there is a robust mechanism for patients joining or withdrawing from the Research Register and satisfy ICH GCP requirements.