SDRN: Scottish Diabetes Research Network

Voluntary Withdrawal of Consent from a Clinical Trial

Clinical S.O.P. No. 37
Version 1

Compiled by:	Lauren M. Lynch
Approved by:	Shona Brearley
Effective date:	18 January 2016
Review date:	18 November 2016

CHIEF 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	

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1. Introduction

Clinical study subjects have the right to withdraw from a study at any time and for any reason, or no reason at all. Voluntary withdrawal of consent is the term given for a study subject deciding to withdraw from a clinical study.

2. Objective

The aim of this SOP is to describe the procedure to be followed if a patient who has initially given consent and taken part in research subsequently decides to withdraw.

3. Background

Section 2.3 of the ICH GCP guidelines states that the "rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society". This means that there must be a procedure for withdrawing a patient and their data from the research if they subsequently decide to do so.

4. Responsibility

All staff should know how to withdraw subjects from a clinical trial. It is the responsibility of the person taking consent to ensure that at the time of participation, as part of the consenting process, all patients are informed that it is their right to withdraw their information and tissue samples at any time without detriment to their diabetes care. Details on how this can be done should be discussed with the patient.

There is no legal requirement for subjects to communicate their withdrawal in writing, the participant may contact the study team directly by phone but the study team should encourage confirmation of withdrawal in writing.

5. Procedure

All procedures/processes should ensure that at all times the rights, safety and well-being of the trial subject are the most important consideration, over the interest of the study.

Should a patient subsequently decide to withdraw from the research, their baseline data must be removed from the database and the source data, including all tissue samples, should be destroyed. The participant may contact the study team directly by phone. The study team encourages confirmation of withdrawal in writing. (See appendix 1)

- The member of the study team who receives notification that a participant wishes to withdraw from the research should ensure that all partners involved in the study are informed of this decision so that any study data about this patient can be removed from their database.

- If required a member of the study team should contact the study technicians so that any samples from the patient can be removed from the database and destroyed.

- Any blood or urine samples which have been sent to different laboratories outside the study centres department for analysis should also be contacted and asked to destroy any tissue samples

- If patients notes are available and the patient was seen at a hospital clinic the participation sticker which goes on the front of the hospital notes indicating that the patient has taken part in the trial

should be identified by an asterisk in the right-hand corner to indicate that the patient has initially taken part in the trial but has now withdrawn.

- All requests for the destruction of samples should be recorded in writing, and documented in the study file and where possible the eCRF.

- All paper records that contain study data should be confidentially destroyed. The original signed consent form will be retained and archived

- Document any reason where follow up is required for post study safety monitoring. If follow-up monitoring is required for subjects who have withdrawn from a study then unless it is important for the subject's health and safety do not ask the subject to submit to any testing or data collection as a condition of withdrawal.

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Appendix 1

Insert study title here

Please initial box

I confirm that I wish to withdraw my anonymous information and blood samples from the (insert title here) study. I understand that this will have no effect on my future care. ☐

Date of Participation (if known)_____

Date of Birth_____

Print Name _____

Signature _____

Date_____

Please return to:
(Insert the study manager/co-ordinators details)
Name:
Address 1:
Address 2:
Address 3:
Address 4:
Address 5:
Tel:
E-mail: