

SDRN Adoption

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Epidemiology S.O.P. No.: 2
Version 1

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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.

Background


In order for a researcher to have access to anonymised linked data from SCI-DC, they must have their request for data linkage approved by the SDRN Epidemiology Studies Group. This committee is composed of healthcare professionals and lay people and will maintain oversight of epidemiological research in order to avoid duplication of studies and to identify research gaps.

Procedure

1. All bona fide researchers will be encouraged to ask research questions and work with SDRN
2. The researcher should complete the standard SDRN data extraction form (see Appendix 1).
3. This form is then sent to the SDRN Epidemiology Studies Group which will examine the hypothesis and give/refuse a favourable opinion on the study. In forming this opinion the group will also take advice from experts on each source of data to be used.
4. Once approval for the data linkage is granted by the SDRN Epidemiology Studies Group, the researcher will be informed and can then apply for MREC.
5. The researcher will ask the SDRN office to apply for Caldicott Guardian approval for the study.
6. SDRN Epidemiological Studies Group will keep a comprehensive list of all studies submitted to the group and the outcome of the group’s decision. This will avoid unnecessary duplication of linkage and may help to identify gaps within this research area.
7. If the researcher submits a second hypothesis to the SDRN Epidemiology Studies Group, the group will decide whether the existing linkage should be used or a new linkage created. In most cases, a new linkage will be created for each hypothesis.
8. The SDRN Epidemiology Study Group will not authorise release of data that addresses an identical or similar research question for four months from data release.

This procedure ensures that SDRN approval is given in all requests for linked data and the process conforms to ICH GCP guidelines.

(APPENDIX 1)

 **SDRN:** Scottish Diabetes Research Network

Data Extraction Form

Name of Investigator:

Address:

Title & Qualifications:
(Please attach 1 page CV)

Data Required: *(Please attach a copy of the protocol)*

Field	Source

Date submitted to SDRN Epidemiology Studies Group:

SDRN Use Only

Date Reviewed:	<input style="width: 100%; height: 20px;" type="text"/>
SDRN Epidemiology Study No.:	<input style="width: 100%; height: 20px;" type="text"/>
Data Extraction:	<input type="checkbox"/> Approved / <input type="checkbox"/> Not Approved
Data Released to Researcher:	<input style="width: 100%; height: 20px;" type="text"/>