

Linkage & Anonymisation Procedure

Epidemiology S.O.P. No.: 5
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

The anonymisation and linkage procedure adopted seeks to enhance patient privacy and research governance in the construction of linked datasets and conforms to the spirit, as well as the letter, of the Data Protection Act 1998. The anonymisation procedure must be clearly defined so as to ensure it conforms to all data protection legislation governing the use of data for research purposes.

Procedure

1. Once all the approvals for data linkage are in place, the independent institution linker will produce random subject identifiers for the requested linkage.
2. The independent institution will be the only place where all unique subject identifiers for all studies will be kept for SCI-DC patients. This includes the CHI number. No source data, or patient details are held by the independent institution.
3. The independent institution will then deliver these random subject identifiers, along with identifiable data to the SCI-DC data source and other data sources to be linked eg. ISD
4. The data sources - SCI-DC and others - will then deliver their dataset to the researcher, in which identifiable data have been replaced with the new study specific identifier, when the researcher makes a request.
5. The researcher will receive only data with the random subject identifier attached.
6. When the linked data is delivered, the SDRN Epidemiology Studies Group will receive notification from the SDRN computer programmers that the linkage has been completed and data has been released to the researcher.

This process ensures that the data is correctly anonymised for each study and that the procedures for dealing with anonymisation conform to ICH GCP guidelines.