

Access to Data

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Introduction

The ICH GCP (International Conference on Harmonisation of Good Clinical Practice) 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 Scottish public must feel assured that the data provided by them onto the SCI-DC database is secure and that access to this data is strictly controlled. This SOP explains the process a researcher would work through to gain access to anonymised data from SCI-DC and other supporting data sources.

Procedure

1. The researcher produces a hypothesis which asks a specific question from data that are to be linked.
2. The hypothesis is then submitted to the SDRN Epidemiology Studies Group for adoption. The SDRN Epidemiology Studies Group will be composed of both healthcare professionals and lay people. It will have its own constitution and SOPs for approving the use of anonymised data. This Committee will operate the same 60 day time constraints as an ethics committee. If a researcher is using data from a source other than SCI-DC e.g. Data from ISD, then they must also submit their hypothesis to the Privacy Advisory Committee as well as SDRN Epidemiology Studies Group.
3. The researcher applies for and obtains funding for the study and will ask the SDRN office to apply for Caldicott Guardian approval.
4. The researcher will submit the research project to MREC for ethical approval.
5. If the hypothesis now has the approval of the Epidemiology Studies Group, as well as ethical and Caldicott Guardian approval, a request for the data extraction can then be made to the SDRN programmers.
6. Anonymised linked data will then be released to the researcher, from each data source for the researcher to link.
7. The researcher will then do the statistical analysis on the linked dataset, answer their hypothesis and then submit the linked dataset to a designated archive store.
8. When publishing the data, the researcher must agree to acknowledge the contribution of SDRN within the research findings of the study.

This procedure ensures that access to data is controlled and the process conforms to ICH GCP guidelines.