SDRN: Scottish Diabetes Research Network

Caldicott Guardian Approval

Epidemiology S.O.P. No.: 4

Version 1

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Approved by:	
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CHIEF SCIENTIST OFFICE

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

Any research involving the use of routinely collected patient data must be approved by the Caldicott Guardian of that particular dataset. At present, there are 14 Caldicott Guardians in Scotland and SDRN will keep a list of which Caldicott Guardian should be approached for each analysis of SCI-DC data. The SDRN office will apply for Caldicott Guardian approval for each analysis once the researcher has gained MREC approval for the study, and the SDRN Epidemiology Studies Group has provided a favourable opinion on the linkage.

Procedure

1. SDRN Manager/Administrator will complete the standard form (Appendix 1) to apply for Caldicott Guardian approval for each hypothesis.

2. SDRN office, will contact appropriate Caldicott Guardian(s) to seek approval for the analysis.

3. Once Caldicott Guardian has approved the use of the data for that particular analysis, researcher then moves to the next step of the approval process.

This procedure ensures that Caldicott Guardian approval is obtained and the process conforms to ICH GCP guidelines.

(APPENDIX 1)

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Caldicott Guardian Approval 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 Office:

SDRN Use Only

Date Received in SDRN Office:	
Date sent to Caldicott Guardian:	
Name of Caldicott Guardian:	
Caldicott Guardian Approval:	❑ Granted / ❑ Not Granted (Date: _ _ / _ _ / _ _ _ _)
Decision Communicated to Researcher:	Caldicott Guardian