

Ethical Procedure

Epidemiology S.O.P. No.: 3

Version 1

Compiled by:	Shava Breatley
Approved by:	RUh
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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

As with the use of any data for research purposes, each hypothesis created by the researcher must be ethically approved by an independent ethics committee.

Procedure

- 1. Researcher completes a COREC form for each new study. The researcher must set up a COREC account for him/herself before he/she can access the COREC form. Web address: www.corec.org.uk
- 2. Once the COREC form is completed and the relevant documents attached, the researcher submits form to an MREC committee.
- 3. MREC committees have a standardised 60 day turnaround time, so the researcher will have a date to look for an outcome to this part of the approval process.
- 4. Once a favourable opinion on the study has been obtained from the MREC, the researcher will then move onto the next step of the approval process.

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