

Good Clinical Practice (GCP)	
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Document History

Version	Description of Update	Date Effective
2.0	Periodic Review	02/04/2024
1.0	First Release	01/03/2021

1. Purpose

1.1 To document the requirement for GCP training for those undertaking clinical research within GCU SHLS.

2. Scope

2.1 All GCU SHLS staff and students involved in clinical research.

3. Responsibilities

- 3.1.1 The SCRGM is responsible for overseeing the administration of the centrally held GCP database. Ensuring staff and students are reminded to inform the SCRGM of GCP training at twice yearly intervals.
- 3.1.2 Those undertaking clinical research are responsible for obtaining and maintaining their GCP certification

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4. Procedures

4.1 Definitions

- 4.1.1 Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance and reporting of clinical trials. It serves to protect the rights, integrity and confidentiality of trial subjects.

GCP training is a key requirement for individuals involved in clinical research, and is designed to ensure that those involved in conducting a trial are qualified by education, training and experience to perform their respective tasks.

Clinical Research is research that is undertaken under the approval of NHS REC involving NHS participants, staff and/or premises.

4.2 Researcher Responsibilities

- 4.2.1 All GCU staff and students conducting clinical research must be able to demonstrate adherence to GCP. GCP training must be in place prior to initiation of a research project. Training can be done online through the [NIHR training site](#).
- 4.2.2 GCP certificates are to be sent on to the SCRGM for filing.
- 4.2.3 GCP certification must be renewed every 2 years.

4.3 SCRGM Responsibilities

- 4.3.1 The SCRGM will maintain a database of GCP certificates and provide research staff and students with a 2-month notice when their certification is due to expire.

5. Referenced and Related Documents

EMA: GCP E6 R2

Joint HRA/MHRA Statement on the Application of Good Clinical Practice to Training for Researchers (v1.1 12/10/2017)

UK Policy Framework for Health and Social Care Research

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6. Abbreviations and Definitions

GCP - Good Clinical practice

GCU - Glasgow Caledonian University

SCRGM – Senior Clinical Research Governance Manager

SHLS - School of Health and Life Sciences

SOP - Standard Operating Procedure

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