

<b>POLICY FOR GOOD CLINICAL PRACTICE TRAINING FOR PERSONNEL INVOLVED IN CLINICAL RESEARCH</b>		
Responsibility: Research & Development Manager	Last Update: March 2009	Review date: August 2010

## 1. Policy Objectives

This policy has been developed to ensure that:

- Personnel involved in clinical research are qualified and trained to comply with Good Clinical Practice (GCP)
- Clinical Trials of Investigational Medicinal Products are conducted in compliance with the regulations governing clinical research
- Patient safety and well-being are maintained at all times when participating in a clinical trial

The policy applies to all staff who hold substantive or honorary contracts with NHS Greater Glasgow and Clyde, and those who have a letter permitting access for research.

## 2. Background

The Medicines for Human Use (Clinical Trials) Regulations Amendment 2006 (SI 2006 1928) specifies that

“each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks”

To comply with this legislation NHS Greater Glasgow and Clyde (GG&C) has formulated the following policy for personnel involved in Clinical Trials of Investigational Medicinal Products (CTIMP). The policy defines a stepped approach to training requirements according to the level of involvement of the personnel in clinical research.

## 3. Definitions

The following definitions for the terms used in this policy are:

Chief Investigator: the investigator who has overall responsibility for the trial

Principal Investigator: the Authorised Health Professional who has responsibility for the conduct of a trial at a particular site

CTIMP: a clinical trial of an investigational medicinal product.

Delegation Log: the record of delegated responsibilities filed in the Study Site File and/or the Trial Master File

Good Clinical Practice: the set of rules and regulations for conducting a clinical trial involving human subjects.

External Contractors: an external organisation which provides a service to the NHS

## 4. Training Requirements

### 4.1 Category 1A Research Staff working within NHS GG&C and Partner Institutions

This includes all research personnel conducting clinical trials sponsored, co-sponsored or hosted by NHS GG&C and who have responsibilities for procedures to secure the quality of every aspect of the trial:

- Chief Investigators and Principal Investigators
- Staff recorded on the trial responsibility and delegation logs in Trial Master Files and Study Site Files
- All staff whose principal role is clinical research (this includes all staff in the Glasgow Clinical Trials Unit)

### 4.2 Category 1B Research Staff at Remote Sites in trials Sponsored / Co-sponsored by NHS GG&C

The Principal Investigator and research staff recorded on the trial responsibility and delegation logs will be required to provide evidence of the level of training documented below or undergo the required GCP training. The training requirements will be documented in the formal clinical trial agreement between the PI institution/employer (e.g. HEI or NHS) and NHS GG&C

#### Level of Training:

All staff in Categories 1A&B are required to provide evidence (usually a certificate) of attendance at the Glasgow Clinical Research Facility's one day GCP training course or an equivalent course and to have attended a half-day GCP Update course every two years.

An equivalent GCP training course will be either one from an approved list located on the CTU website ([glasgowctu.org](http://glasgowctu.org)) or one which is a minimum of 6 hours duration and which after submission of the course agenda is approved by the CRF Education and Training Officer (appendix 1 – Approved list).

### 4.3 Category 2 Research Staff

This includes all staff that have contact with subjects of CTIMPs as part of their routine clinical work and who are responsible for delivery of protocol directed interventions and treatment.

This group of staff are not required to provide evidence of full GCP training but are required to read and sign a short document (Appendix 2) which details:

- a) The importance of complying with the regulatory and legal framework surrounding the conduct of CTIMPs
- b) Where they can access a current version of the study Protocol

- c) The named Investigator with whom they should discuss any questions about the study.

Two copies of the document will be required. The original signed document will be given to the member of staff and a copy will be filed in the Study Site File as evidence of the discussion.

It should be noted that all staff in this category are eligible to attend regular GCP training courses offered by the Glasgow CRF and should be encouraged to do so, in the interests of best practice, even though the policy does not make this mandatory.

#### **4.4 NHS GG&C Staff exempt from GCP training requirement**

While all are encouraged to attend GCP training as part of Continuing Professional Development, staff whose contribution to a study protocol is limited to routine care (that is, the procedures they undertake are the same as in regular patient care and are not specific to the research protocol) do not require GCP training, do not need to be listed on the staff responsibilities log, and are also not required to sign the short document.

Staff in this category include nurses who conduct patient examinations as they would if the patient was not in a research project, or those who administer prescribed an investigational medicinal product as part of 'routine care' (note that the prescriber would fall into Category 1A above).

#### **4.5 Category 3 External Contractors**

These groups do not need to provide evidence of GCP training to NHS GG&C. It is the Principal Investigator's responsibility to ensure all external sites and associated staff are appropriately trained and complying with the regulations governing CTIMPs. This will be documented in the contract between the External Contractor and NHS GG&C.

### **5. Sponsorship by GG&C**

Evidence of approved GCP training for all research personnel in Category 1 is a mandatory requirement for sponsorship and co-sponsorship of CTIMPs by NHS GG&C. Failure to meet this requirement will result in withdrawal of sponsorship / co-sponsorship by NHS GG&C or non-approval of new submissions for sponsorship / co-sponsorship by NHS GG&C.

Any Chief Investigator or Principal Investigator at a NHS GG&C sponsored or participating site who refuses GCP training will not receive R&D management approval for the study.

### **6. Dissemination**

The current version of this policy will be published on the Research & Development departmental site. There will be a link to it on the Clinical Trial Unit website.

The current version of this policy will be made available to all relevant personnel involved in clinical research in a hard copy by the R&D department.

**Appendix1:**

Approved GCP courses (of at least 6 hours duration)

- Infonetica
- Tower Mains
- UKCRN
- ICR
- Epigeum
- Symons limited

**Appendix 2**

**See attached**