



clinical  
research  
facility  
EDINBURGH

WTCRF  
Education  
programme



NHS  
Lothian

# Good Clinical Practice & the EU Directive

Tuesday 12<sup>th</sup> October 2010, 10.00am - 4:30pm

The Medicines for Human Use (Clinical Trials) Regulations 2004 now implement the EU Clinical Trials Directive (2001/20/EC) as law in the UK. This course is designed to provide an overview of the requirements of these regulations.

Research professionals involved in conducting clinical trials sponsored by NHS Lothian and the University of Edinburgh are required to demonstrate attendance at this course or demonstrate evidence of similar training.

## Who will benefit from this course?

This course is relevant to individuals who have no previous GCP training and those whose previous GCP training was more than two years ago. The course is appropriate for anyone conducting or supporting clinical research. It is particularly suitable for those who are conducting or supporting Clinical Trials of an Investigational Medicinal Product (CTIMPs) and, as such, are required to provide evidence of GCP training.

## Course Outline:

Through a mixture of lectures and workshops this course:

- 1) Provides a history of clinical trials and the development of GCP
- 2) Deciding what is a clinical trial as per EU Directive discussion of informed consent - the ethical and statutory imperatives with particular reference to vulnerable groups
- 3) Responsibilities of research personnel and the process for obtaining approvals to conduct clinical trials
- 4) Overview of the 14 principles of GCP
- 5) Pharmacovigilance - definitions and a series of case studies are discussed
- 6) 'Monitoring' exercise - group exercise to highlight examples of breaches of GCP and documentation discrepancies that can occur.

**Course Tutors:** Dr Allan Gaw (MD, PhD, FRCPath, FFPM)  
Director, Glasgow Clinical Research Facility  
Shona McDermott  
Education & Training Officer, Glasgow Clinical Research Facility

**Course fee:** £45 (academic rate)

**Venue:** Wellcome Trust Clinical Research Facility,  
Western General Hospital, Edinburgh

*This course is recommended by NHS Lothian and University of Edinburgh*

For more information, please contact:

Dr Jane Ilsley, Programme Manager, Wellcome Trust Clinical Research Facility, Western General Hospital, Edinburgh, EH4 2XU, Tel: 0131 537 3355,  
E-mail: [wctcrf.education@ed.ac.uk](mailto:wctcrf.education@ed.ac.uk)

<http://www.crts.org.uk/CRF/Edinburgh>