Introduction to Good Clinical Practice (GCP):  
A practical guide to ethical and scientific quality standards in clinical research

Aims  
This course is designed to provide a basic introduction to ICH Good Clinical Practice (GCP) and the EU Directives, UK Regulations and Research Governance Framework requirements covering clinical trials and other NIHR Portfolio studies conducted within the NHS. The session has a practical focus with the key aim being that participants know what to do to practice excellent GCP when they return to their workplace to ensure that the rights, safety and well-being of patients are always protected.

Expected Learning Outcomes  
Following the course, participants will have a demonstrable understanding of the background and practical implications of GCP. This understanding is intended to be a foundation for action about translating principles into practice and give participants the confidence to take a proactive role in improving processes and standards within their own work area.

Following the workshop participants should be able to:
- Describe the principles and standards of GCP and why they are important
- Describe the relevant UK legislation and understand how it applies to different kinds of clinical research
- Have a clear understanding of the research process pathway
- Demonstrate an understanding of the roles and responsibilities of different individuals and organisations in clinical research
- Identify the fundamentals of study set up to ensure an understanding of what should be in place before work on the study begins, including essential documents
- Understand the process of receiving informed consent and the roles and responsibilities of those involved
- Demonstrate the ability to correctly and accurately complete case report form and other relevant documentation and understand the process for data query resolution
- Ensure patient safety by correct reporting of Adverse and Serious Adverse Events
- Understand the role of audit, monitoring and inspection in clinical research
- Know where to go for further advice and support and how to keep updated.

Further information  
The course is aimed at site staff involved in the conduct of studies once they have been accepted onto the NIHR Portfolio. Individuals involved in the design and management of portfolio studies are able to access this course but should be aware that it will not address their specific needs.

To book your place visit http://www.crncc.nihr.ac.uk/index/training.html
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Facilitators: Kelly Waller & Arlene Lee

09:00  Arrival and Registration with Tea/Coffee
09:15  Welcome, Introduction and Quiz
10:00  The Clinical Research Process and NIHR CRN
10:30  GCP: the standards and why we have them
11:10  Tea/coffee
11:25  Study set up: Responsibilities, approvals and essential documents
12:40  Lunch
13:20  Receiving consent and who should do it
14:10  Source Data & Case Report Form Completion
15:10  Tea/coffee
15:25  Safety reporting – responsibilities and timelines
16:10  Quiz and evaluation
16:30  Close