Training in GCP

The Trust provides GCP Training as part of its Participating in Clinical Trials / GCP workshop. This workshop covers all aspects of GCP when recruiting patients into multi-centre trials. There are also various companies that undertake in-depth GCP training. These courses are often expensive and aimed at staff working in commercial companies or the major research centers that are developing or managing clinical trials. Companies include

- Brookwood International       www.biahcr.co.uk
- Scope Educational Services www.scopect.com
- Liverpool Women's Hospital www.nwctognetwork.org.uk

Many pharmaceutical companies or other commercial companies undertaking clinical trials in the NHS offer their local investigators and their team training in GCP as part of their induction to the trial.

As from September 2006 NHS Staff undertaking research will have to show evidence of GCP Training before Trust approval is granted.

Other in-house research training
Introduction to research In-house training session covers the general principals of GCP, for further details please contact the R&D Office on 01895 279021 ext 3021 Email: gay.bineham@thh.nhs.uk

Further reading

- Declaration of Helsinki www.wma.net
- ICH Developments www.ich.org
- MRC Guidelines for GCP in Clinical Trials www.mrc.ac.uk
- Research Governance Framework 2nd ED 2004 www.nihr.ac.uk
- R&D Forum www.rdforum.nhs.uk
- Department of Health www.dh.gov.uk

For further information please contact Gay Bineham R&D Manager

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Research within Good Clinical Practice Framework

International Conference on Harmonisation (ICH) agreed standards for Good Clinical Practice for conducting clinical trials in the western world. The standards were based on the Declaration of Helsinki principles and have been adopted by Europe, Japan, the United States and much of the rest of the western world.

What is GCP?
A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of the subjects are protected.

Why do we need a code for Good Clinical Practice?
- Improve Patient Protection
- Encourage good science
- Ensure meticulous documentation
- Improve quality of trials
- Improve decision making reliability

Who does GCP affect?
- Sponsors / Funders of studies – This includes local NHS Trusts
- Investigators and all members of the study team
- Ethics committees – Multi Centre and Local

The Principles of Good Clinical Practice
- Clinical Trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject.
- The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
- The available non-clinical and clinical information on an investigational product should be adequate to support the trial.
- Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
- A trial should be conducted in compliance with the protocol that has received a favourable independent ethics committee opinion.
- The medical care given to, and medical decisions made on behalf of subjects should always be the responsibility of a qualified physician.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task.
- Freely given informed consent should be obtained from every subject prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules.
- Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP).
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.