An Introduction to the Basics of Good Clinical Practice (GCP)

What is GCP?

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality standards that must be adhered to when designing, conducting, recording and reporting clinical trials that involve people. GCP compliance provides assurance that the trial data and reported results are credible and accurate, and that the rights, safety, integrity and confidentiality of trial participants are respected and protected.

What are the 13 core GCP principles?

1) Clinical Trials should be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirements.

2) Before a trial is initiated, foreseeable risks and inconveniences should be weighed against anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3) The rights, safety and wellbeing of the trial subjects are the most important considerations and should prevail over interest of science and society.

4) The available non clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5) Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

6) A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB) / independent ethics committee (IEC) approval / favourable opinion.

7) The medical care given to, and medical decisions made on behalf of subjects should always be the responsibility of a qualified physician or when appropriate, a qualified dentist.

8) Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective tasks.

9) Freely given informed consent should be obtained from every subject prior to clinical trial participation.

10) All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

11) The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements.

12) Investigational products should be manufactured, handled and stored in accordance with applicable Good Manufacturing Practice (GMP). They should be used in accordance with the approved protocol.

13) Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Why complete GCP training?

Those involved in the management and conduct of clinical research must be competent to perform their tasks, qualified by training, education and experience. This is a requirement of the UK Policy Framework for Health and Social Care Research (2017) which applies to all research within the NHS in England for everyone working on clinical trials.

Who needs to complete GCP training?

It is important that everyone involved in research is trained and appropriately experienced to perform the specific tasks they are asked to undertake. Whilst GCP training is important and foundational for the majority of those involved in research, there are certain circumstances whereby completing a full GCP course may not be necessary. There are also situations where GCP training alone may not be enough. The NIHR's 'Delegation and Training Decision Aid' is a useful tool to help local research delivery sites consider what individuals are being asked to do in the context of an individual research project and what training and learning they need to be effective within their role. You must also liaise with the study Sponsor and NuTH R&D department when making decisions around what specific training is required.

If you have any queries around GCP training, please contact: nuth.genericqueries@nhs.net

How can I access GCP training courses?

GCP training can be provided in a range of formats, including face-to-face classroom sessions and web-based e-learning. The NIHR CRN GCP courses are available free of charge to the NHS, UK universities, and other publicly funded organisations conducting and supporting clinical research. To access the GCP e-learning courses or to book on to a classroom course, visit NIHR CRN Learn: https://learn.nihr.ac.uk/

Do I need to update my GCP training?

All staff working on NuTH FT Sponsored or NuTH FT hosted research must update their GCP training every 3 years. However, if you have recently participated in training and a regulatory change is made, you will need to be informed of these changes and understand their implications for your practice.

Useful Links

1) UK Policy Framework for Health and Social Care Research:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

2) NIHR CRN Learn

https://learn.nihr.ac.uk/

3) ICH GCP Website

http://www.ich.org/home.html