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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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Trial Specific Good Clinical Practice (GCP) Training Module

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Purpose of Training

- To provide an overview of what Good Clinical Practice (GCP) is
- To provide a brief explanation of the 13 principles of GCP
- To provide important information on GCP and safety

GCP and care home staff

One of the key points of GCP is to ensure that the staff working on the trial are suitably trained. Without the help and support of care home staff we would not be able to conduct the trial.

This success of this research will require the knowledge and expertise of all care home staff who contribute to the trial.

What is Good Clinical Practice?

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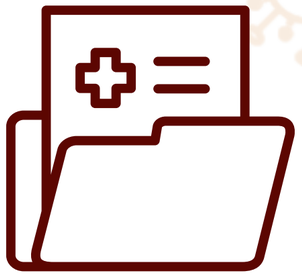
- Compliance with GCP provides the public with reassurance that:
    - The rights, safety and wellbeing of research participants are protected
    - Research data collected is reliable

GCP covers the following areas within research:

Design & Conduct

Performance & Recording



Analysis

Monitoring & Auditing

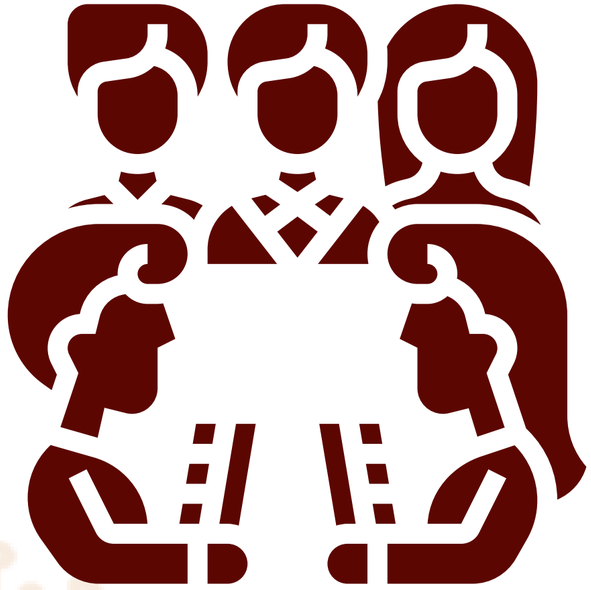
The following slides will briefly explain the 13 principles of GCP.

However, it is important to remember that GCP is:

- An internationally agreed set of principles
- Mandated in law in the UK for clinical trials of medicines
- GCP covers what the trial team do as well as the staff at care homes working on the trial

1. Ethics

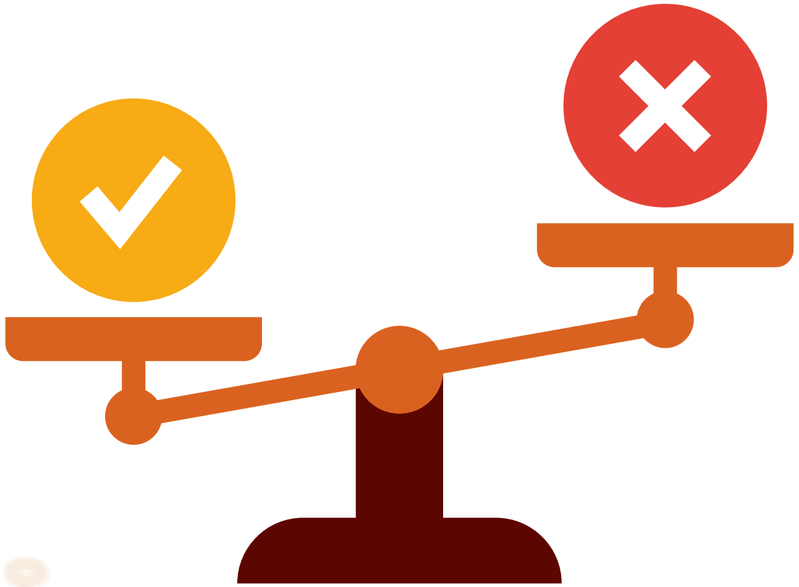
- Clinical trials should be conducted in accordance with ethical principles
- These have their origin in the Declaration of Helsinki
- All research trials must have an ethical review and must be approved before starting the study



2. Trial risk vs. benefit

- Balance of risks/inconveniences versus benefits for the resident and society should be weighed

- The anticipated benefits must justify the risks



3. Trial Participants

Rights, safety and well-being of participants are the most important consideration

4. Information on the Intervention

Should provide sufficient and clear information so that the residents can make an informed choice about whether to take part and continue

5. Good Quality Trials

The clinical trials should be scientifically sound and described clearly in the protocol

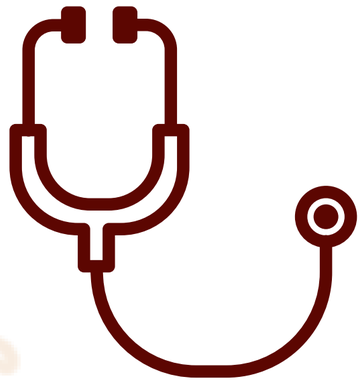
6. Compliance with the protocol

A trial should follow the protocol which has been approved by an NHS ethics committee and the Medicines and Healthcare products and Regulatory Agency

7. Medical Treatment

Standard care should be provided for all residents throughout the trial

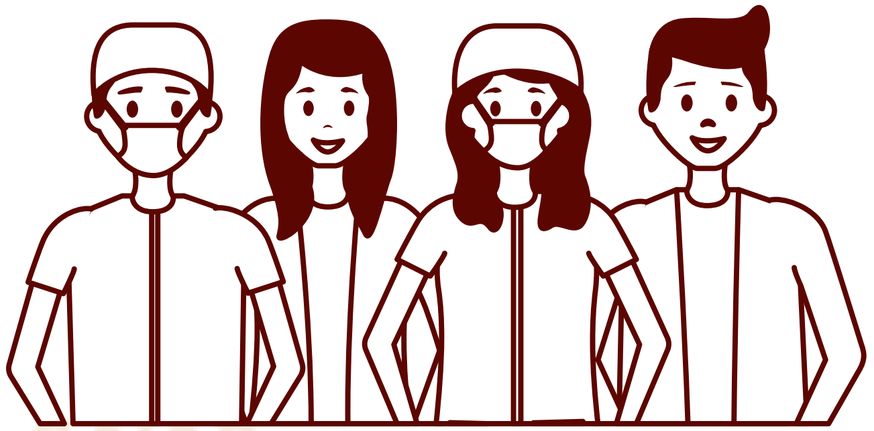
The medical care given to, and medical decisions made on behalf of, participants should always be the responsibility of a qualified physician



8. Trial Staff

Each staff member working on the trial should be qualified by education, training and experience to perform their role in the trial

This slide set delivers some of this training



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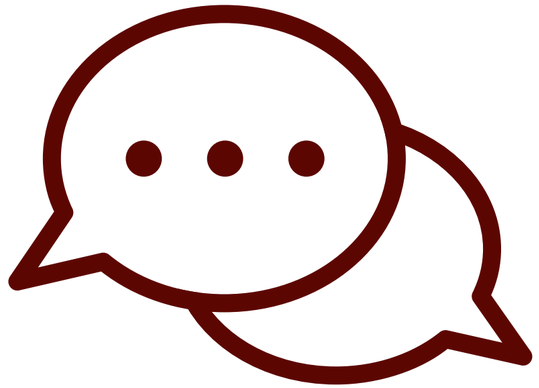
9. Informed Consent

Freely given informed consent should be obtained from every resident prior to trial participation

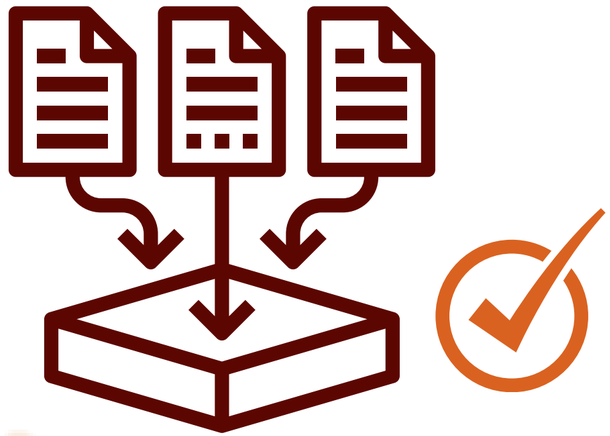
If a resident lacks capacity, a personal legal representative only, who may be a close friend or family member, shall be consulted



10. Clinical Trial Data

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

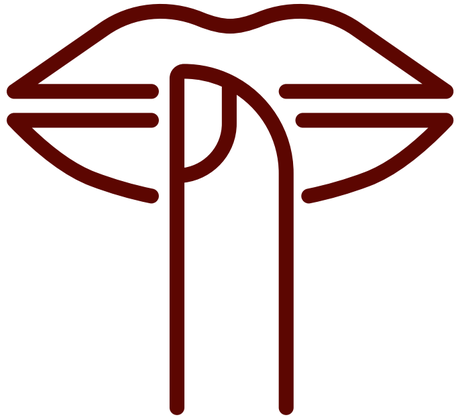
Information should be collected systematically and reliably recorded and verified



11. Confidentiality

Information should be collected in confidence

Records should be protected respecting the privacy of the resident, in the same way that health/care records would be



12. Good Manufacturing Process

The intervention should be manufactured, handled and stored in accordance with good manufacturing practice (GMP)

Each care home needs to ensure the trial products are handled in accordance with the trial protocol

13. Quality assurance

Quality systems should be implemented to assure the quality of every aspect of the trial

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GCP and Safety

It is important if any of the residents who are taking part in the trial become unwell, that the care home staff inform the PROTECT-CH trial team as soon as they become aware

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It is important if any of the residents who are taking part in the trial become unwell, that the care home staff inform the PROTECT-CH trial team as soon as they become aware

It doesn’t matter if your care home are not taking the trial medication. It is important that the trial team can compare any potential side effects the medication group have to the group who are not taking the trial medication. This is part of assessing the risk/benefit of the medication

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Thank you for watching!

You have now completed the

Trial Specific GCP

Training Module

NEXT

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Please remember to complete your self certification form to confirm you have undertaken this training.

This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=1&ModuleVersion=1

Or you can access it via mobile here:

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Please get in touch with us if you have any questions:

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thank YOU