Good Clinical Practice - E-Learning (GCP)

November 2018

- international, ethical and scientific quality standard for clinical trials.

Process of research

1. Idea, design and planning
2. Application and approval
3. Study set-up
4. Study conduct, recruitment, data collection
5. Analysis and results

→ enables NHS to improve current and future health of patients

Research is essential to deliver better care, so can have evidence and improve treatment and service.

Principles of GCP - safeguard and protect research subjects by reducing risks
- Medicines for Human Use (Clinical Trials) Regulations (2004)

Clinical trials should be conducted in according to with the principles of 'Declaration of Helsinki' (1964)

1996 - International Conference of Harmonisation guideline (ICH GCP)
→ important international standard
→ supports adherence to Medicines for Human Use (Clinical Trials) Regulations

DoH and ICH GCP - support the conduct of high quality, credible clinical research

UK Policy Framework for Health and Social Care Research (2017)

- requires that all research conducted in NHS is done to same high standard

Standards, policies and Laws

- Medicines for Human Use (Clinical Trials Regulation) — for vulnerable participants.
- Overarching Laws
  - Data Protection Act (1998)
  - Freedom of Info Act (2000)
  - Equality Act (2010)
- Local policies and SOPs
- Study specific requirements
  - Protocol
  - supporting doc.
  - study specific training
- ICH GCP — ICH Guideline for GCP (1996)
  - Declaration of Helsinki
- UK Policy Framework
- Clinical Research in the NHS

Study Set and Responsibilities

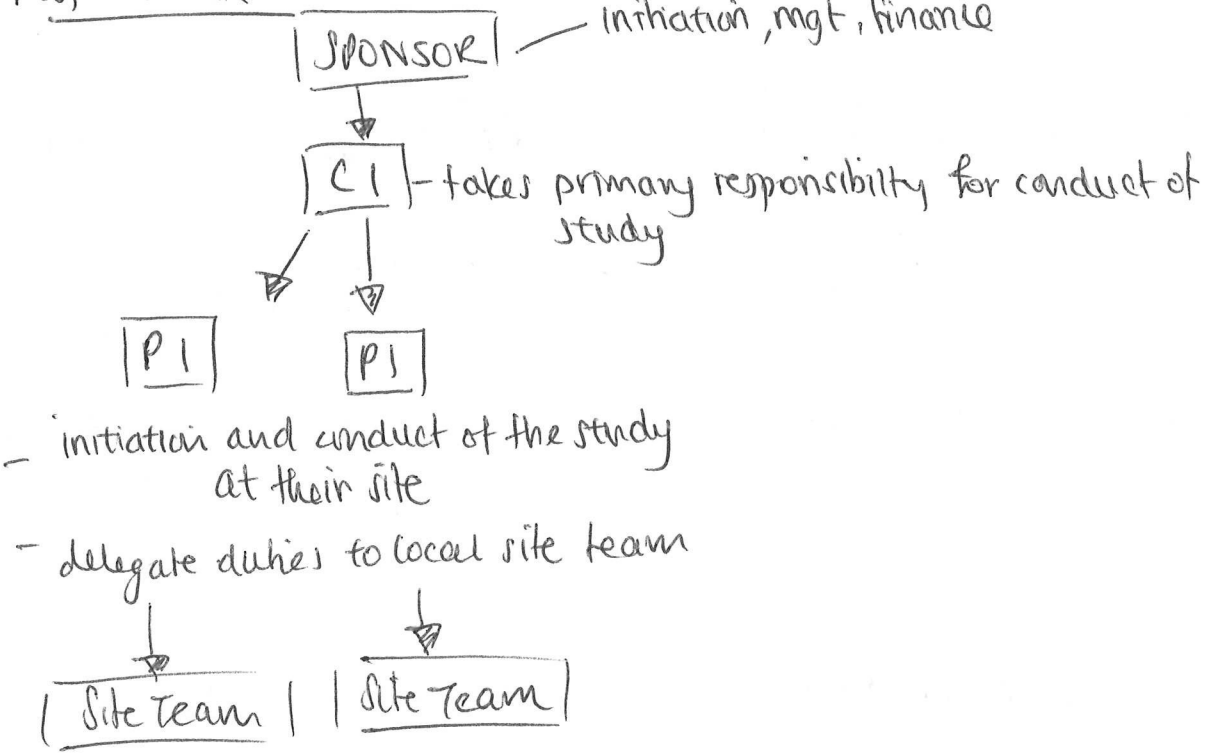
Delegation of duties log – identifies whom the PI has delegated study specific tasks.

- Must have signatures and dated to be clear who was responsible for what activity

Must have CV and log training record in LogBook

- ensure that individuals are competent

Responsibilities



Informed Consent

→ voluntary process which a subject confirms their willingness to participate in a trial

Data Collection and Documentation

Sponsor - appoints Monitor — verify conduct of study
- check source data
- source verification data

data collection tool/ collect anonymised data

Data are copied Source data → CRF (Case Report Form)

1° source of where data stored — original record of clinical findings

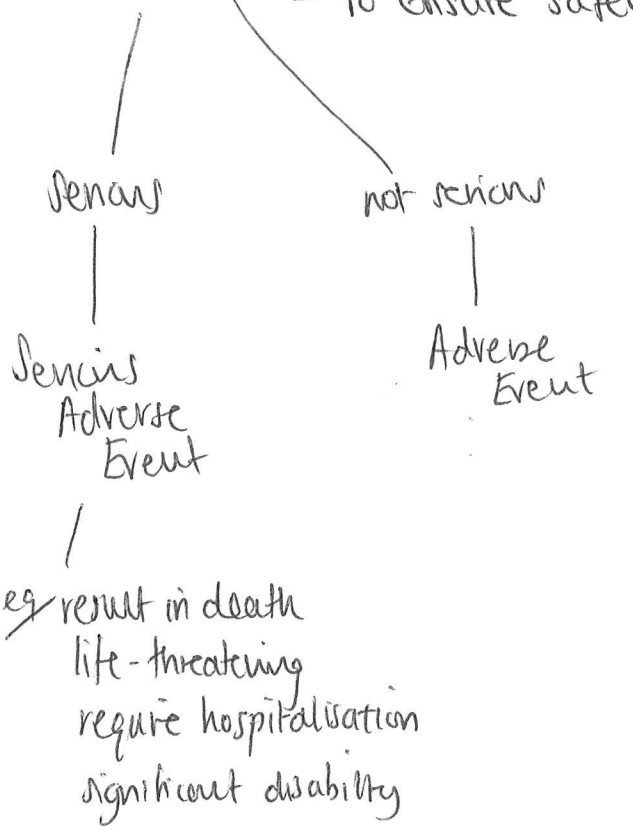
Serious breaches = likely to effect to a significant change degree
eg systematic failure / routinely failing

Recording source data ← study-related health issues

- general health
- allergies to Contrast
- Study data required in protocol
- clinical observation

Safety Reporting

- Adverse Event - any untoward occurence that happens during study
  - to ensure safety of participants



- process which researchers gather info about adverse events