Responsibility of the Chief Investigator

Sponsor Oversight delegated to the CCTU includes review of regulatory and REC approval submissions, GCP monitoring on trial conduct, amendments and reporting review. Any CCTU support or activities regarding Sponsor Oversight in CTIMPs must be clearly defined and negotiated by the Chief Investigator. Additional support must be specified and included in grand applications with sufficient funding attached.

The Chief Investigator is responsible for ensuring all research studies and clinical trials supported by the CCTU follow CCTU SOPs, forms and templates.

ICH Good Clinical Practice guidelines include the following as responsibilities of the Chief Investigator:

1. **Adequate resources** in terms of funds, staff and necessary infrastructure
2. **Medical care** of trial subjects
3. **Qualifications of trial staff** (GCP, delegation of trial-related duties)
4. **On-going communication with REC/MHRA** throughout trial (amendments, annual reports etc)
5. **Ensure full compliance with protocol** and document deviations and submit amendments to REC
6. **Investigational Medicinal Product** (if applicable) accountability at site/s (can be assigned to appropriate pharmacist)
7. **Randomization procedures and unblinding** following applicable randomization and blinding/unblinding procedures
8. **Informed consent** following GCP guidelines
9. **Records and reports** – Trial Master File, Site Files, CRF and source documentation, maintenance of trial documentation, financial agreements and archiving
10. **Progress reports** – Development Safety Update Report (DSUR) to MHRA and Annual Progress Report to REC and Sponsor
11. **SAE reports** to sponsor
12. **Premature Termination or Suspension of Trial** ensuring trial subjects, institution sponsor and REC are promptly informed if trial ends prematurely or is suspended
13. **Final report** provided to institution, REC, regulatory authorities and Sponsor