TASC

Tayside Medical Sciences Centre

VitalBE

Site Initiation Visit

Investigator responsibilities

Investigator responsibilities

ICH GCP section 4 details the investigator responsibilities.

http://ichgcp.net/4-investigator

Investigator responsibilities

- Investigator and site staff qualifications
- Site agreements
- Adequate resources to conduct the study
- Medical care of trial subjects
- Compliance with the protocol
- Knowledge of the Investigational Medicinal Product including the Reference Safety Information
- Randomisation Procedures and Unblinding
- Informed consent of trial subjects
- Records and Reports
- Safety Reporting

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Monitoring

Purpose of Monitoring

- To verify that the rights and well-being of participants are protected
- To ensure that reported trial data is accurate, complete and verifiable from source data
- To ensure that the trial is compliant with the protocol, Good Clinical Practice (GCP), SOPs and regulatory requirements

Monitoring Schedule

The monitoring schedule is detailed in the monitoring plan located in the site file.

Visits are as follows:

- Site initiation
- FPFV
- 6-8 months following FPFV
- Further visits will be determined on the occurrence of factors including breaches, SAE reporting, high number of actions at previous visits, frequency of staff changes, high consent rate.
- Close out visit.

Monitoring visits

- Prior to a monitoring visit the monitor will email the site contact to arrange a visit date and request information to be provided ahead of the visit.
- During a visit the monitor will require access to:
  - patient notes, eCRF and source data
  - ISF/PSF
  - Screening logs and informed consent forms
  - Sample storage and temperature logs.
- Post visit the monitor will issue a monitoring visit report. This will document the visit and the actions to be completed.
- Actions are to be completed and returned via email to the monitor: tay.ctmonitor@nhs.scot

Audit and Inspection

- The study can be selected for inspection by the MHRA or audit by the Sponsor or at any time.

- This could occur either during the study or after the study is closed.

Monitor Questions

- Essential Documents
- Study Equipment
- Emergency Medication
- Lab Equipment
- Sample storage
- Source data

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Informed consent

Who can receive consent in VitalBE study?

- The Principal Investigator (PI), Research Nurse or delegate can receive consent at each site
- The person receiving consent should be suitably trained and qualified and have sufficient knowledge of the study
- The person receiving consent must be recorded on the delegation log

Important Things to Remember

- ☑ Use most recently approved version of Informed Consent Form and Patient Information Sheet on headed paper
- ☑ Ensure the participant is fully informed of the study
- ☑ Ensure the participant has received all the approved documentation and has had adequate time to read it (usually at least 24 hours)
- ☑ Ensure the participant has had the opportunity to ask questions
- ☑ Consent should be received before any trial specific procedures are carried out
- ☑ Ensure that the participant has initialled all boxes
- ☑ The consent form should be signed by the participant and by the person taking consent on the same day
- ☑ Any corrections should be scored through and initialled and dated
- ☑ A copy of the signed consent should be given to the participant, a copy filed in the patient notes, and the original filed in the Investigator Site file.