Roles, Responsibilities & Informed Consent

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COURSE CONTENT:
Sponsor & Investigator Roles & Responsibilities, Informed Consent
Contents

• Sponsor and Investigator Roles

• Consent in clinical trials
All trials require:

• A **sponsor** who is responsible for:
  – The initiation of the study
  – The management of the study
  – *Sometimes* the financing of the study
  – In addition the sponsor must be satisfied that trial can be initiated and managed in accordance with GCP

• An **investigator**, who is an *authorised health professional*, responsible for:
  – Conduct of the study at the trial site
  – The study team at the study site
Sponsors Role and Responsibilities in non CTIMPs

• Confirming that everything is ready for the research to begin;
  • Study initiation
  • manage and funding of the study

• Satisfying itself the research protocol, research team and research environment have;
  • passed appropriate scientific quality assurance;
  • the study has ethical approval before it begins;

• Must ensure that arrangements are kept in place
  • for good practice in conducting the study,
  • for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions (SUSARs)
The Investigator: Essential Skills

- Qualified
  - Education
  - Experience & Training

- Knowledge
  - Understands science behind the trial
  - Knows the protocol

- Delegates
  - To appropriately trained and qualified staff
  - Maintains delegation log

- Complies
  - with GCP
  - Sponsor processes

- Supervises
  - Staff
  - Adherence to protocol
Investigator Responsibilities: Pre Trial

- Financing
- Assess study viability
- Sufficient numbers
- Time to do study?
- Staff Requirements
  - Are they qualified
  - Do they know protocol
• Medical Care

• Suitably qualified for trial related medical decisions
• Informs GP (where agreed)
• Assess and follow up adverse events
• For withdrawals must make effort to determine reason – whilst respecting participants rights
• Investigator and Protocol Compliance

• Conduct trial to agreed, signed protocol
• No deviations from protocol without sponsor and ethics approval
  – Exceptions allowed- ie to prevent immediate harm
  – Minor administrative amendments
• Protocol amendments
• Investigator and Ethics

• Pre initiation
  – Must have ethics approval, dated and study period defined
  – Written consent and Participant Info Sheets
  – Recruitment procedures
  – Copy of protocol
- Investigator: Records

- Records must be accurate, complete and legible

- Derived from source data

- Corrections, dated, initialled and explained

- Must be maintained before, during and after trial

- Archived appropriately
• Investigator: Reports

• Annual report to Ethics and Sponsor
• Premature termination
  – Whoever terminates early (sponsor or ethics) must give detailed written explanation to other
  – Must inform participants and instigate any appropriate therapy
• Final Reports
  – Summary of trials outcome
Investigator: Safety

• **Serious Adverse Events**
  – Death or life-threatening
  – >24hrs hospitalisation or prolonged stay
  – Persistent or significant disability
  – Congenital anomaly
  – Others discretionary

• **Reactions** – Thought to be causally linked

• **Unexpected SAR** – SUSAR

• Should be defined in the study protocol

• Decided by Chief Investigator
Safety Reporting in nonCTIMPs

• Any SAE occurring to a research participant should be reported to the SPONSOR & main ethics committee
  – Within 15 days to Main IEC
    • *No responsibility to inform all REC* in multi-site study

• Related- resulted from any of research procedures

• Unexpected- event not listed in protocol as expected

• Annual progress and safety report

• NB- any Urgent Safety Measures
  – CI responsibility to report to IEC *immediately*
Role of the Investigator: Key Learning Points

• Procedures are in place to ensure collection of high quality, accurate data

• Ensure data integrity

• Importance of safety reporting even in NCTIMP studies

• Maintenance of adequate and accurate records
How do we obtain Consent?

A guide to the process of informed consent
Things to consider....

• Who can take informed consent?

• When should it be taken?

• Is it appropriate?

• Are you well prepared?

• Documentation
Who can obtain informed consent?

- **Declaration of Helsinki**
  > ....the physician or another appropriately qualified individual must then seek the potential subjects freely-given informed consent........

- **ICH GCP**
  > 4.8.5 The investigator, or a person designated by the investigator should fully inform the subject......
  > 4.8.9 The consent form should be signed by the person who carried out the informed consent discussion

- **Adults with Incapacity**
  > Able to assess competency
The process of informed consent should include:

1. The discussion
2. Assessment
3. Reinforce the discussion
4. The consent form
The discussion

- Comfortable, relaxed, no interruptions
- The participant can bring a close friend or relative
- Repeat, explain and reinforce information
- Ask questions to ascertain level of understanding
- Let them ask questions
- Timing
The Assessment

• Is ongoing

• The way in which the information is conveyed is as important as the information itself

• It’s important to acknowledge diversity
Reinforce the discussion

- Commonly through the use of the patient information sheet
- Potential participants can take this away with them, show it to friends and family
- According to ICH GCP 4.8.10 there are 20 essential elements of the PIS......

The consent form

• Use NRES/TASC template form
• Ensure correct version & date
• Give potential participant time to read each statement and **initial** the boxes.
• Ensure that it is signed and dated by the potential participant and the person taking consent.
• Copies
From UoD_TCTU_SOP07 v1.0

N.B Remember to put version number and date at bottom of ICF.
### Trial Management

<table>
<thead>
<tr>
<th>SOP</th>
<th>Title</th>
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<tr>
<td>TASC_SOP02</td>
<td>Establishing and maintaining a Trial Master File (TMF) for the control of clinical trials of investigational medicinal products</td>
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<tr>
<td>TASC_SOP06</td>
<td>Establishing and maintaining an Investigator Site File (ISF) for clinical trials of investigational medicinal products</td>
</tr>
<tr>
<td>TASC_SOP07</td>
<td>Obtaining informed consent from competent adults in clinical trials of investigational medicinal products</td>
</tr>
<tr>
<td>TASC_SOP10</td>
<td>For establishing and maintaining a training record</td>
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</tbody>
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**SOPs & Policies**

- TASC_SOP02
- TASC_SOP06
- TASC_SOP07
- TASC_SOP10
Summary

• Sponsor Role is clearly defined
• Investigator has numerous responsibilities
  • pre to post study
• Knowledge of the study protocol is essential
• Informed consent and participant welfare at heart of clinical trials
• Data integrity crucial.