Collecting Written Informed Consent

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ICH – Efficacy Guidelines

International ethical and scientific quality standard, for the design, conduct, safety and reporting of studies that involve human subjects

- The rights of and well-being of the study participants are protected.
- The reported study data are accurate, complete, and verifiable from source documents.
- The conduct of the study is in compliance with the currently approved protocol/amendments and with the applicable regulatory requirements.

Key Principles of ICH GCP

- ✓ Staff are qualified, educated, experienced and trained
- ✓ Freely given informed consent is obtained
- ✓ Data accuracy
- ✓ Confidentiality of records
- ✓ Quality systems are implemented

Key Principles of Written Informed Consent

- ✓ Invitation to participate – are they eligible?
- ✓ Good overview of the study – what is involved?
  - ✓ Research, purpose, procedures, duration
- ✓ Risks and discomfort
- ✓ Benefits, alternative procedures (treatments)
- ✓ Participation is voluntary – how to withdraw?
- ✓ Access of data and confidentiality
- ✓ Contact information
- ✓ Questions

Informed Consent of Trial Subjects

- Comply with regulatory requirements.
- Provide subjects with any revisions/changes.
- Subjects should not be coerced into participating.
- Consent (oral and written) should be described in lay language and be non-technical.

Informed Consent of Trial Subjects

- Subjects should be informed of all pertinent aspects of the study.
- Subjects should be given ample time to consider and question the details of the study before consent is obtained.
- Prior to participating the consent should be personally signed and dated by the subject and the person conducting the consent.

Informed Consent of Trial Subjects

- If the subject or representative is unable to read an impartial witness should be present during the entire consent process.
- After the subject or representative has orally consented to the subjects participation and has/can sign the consent, the witness must also sign and date the consent.
- By signing the consent, the witness attests that the information is understood by the subject/representative and consent was given freely.

Informed Consent of Trial Subjects

- Prior to participation, a signed copy should be provided to the subject/representative. This includes the consent form any other written information.

- In studies where only a legal representative can consent (e.g. minors or patients with severe dementia), the subject should be informed to the extent compatible to their understanding. If capable the subject should sign and date the consent – see 4.8.14

Points to Remember

Informed consent is essential to maintain respect towards a study participant and ensure autonomy

The Informed Consent Form (ICF) is not synonymous with a meaningful informed consent dialogue between the researcher and participant

References

- International Council for Harmonisation (ICH)

http://www.ich.org/home.html

- Integrated Addendum to ICH E6 (R1): Guidelines for Good Clinical Practice E6(R2) – section 4.8