

GCP course material (one page) for staff who screen, obtain consent and follow the protocol in acute, low-risk drug trials. There is an accompanying PowerPoint presentation, which can be viewed and listened to via www.incept.dk (under 'Resources' => 'Courses').

Informed consent

1. **Purpose:** Consent ensures that participation in the trial is informed and voluntary.
2. **Screening and inclusion:** In acute drug trials, trial procedures are initiated without prior consent. Next of kin-should be informed of the trial as soon as possible but not be asked for consent. Consent is sought from the study participant as soon as possible after recovery. If this is unlikely to take place, a legal representative (god man) should be established without undue delay.
3. **Content:** The purpose, procedures, risks and expected benefits of trial participation. Information is provided both orally and in writing, in a language the consenting party understands. Participants must be informed of the opportunity to ask questions, to have time for consideration, and to be accompanied by a support person.
4. **Documentation:** Consent must be in writing, dated and signed by the participant (or proxy) and the informing doctor. The participant must receive a copy. The original must be uploaded to the eCRF and filed in the site file. The consent must be recorded in the participant's medical record.
5. **Withdrawal:** Consent can always be withdrawn by the consenting party without explanation.
6. **Responsibility:** The investigator (the person responsible for the trial at the department) ensures that the process is conducted continuously and correctly.

Compliance with the protocol

1. The trial protocol must be adhered to, including screening, inclusion, consent, delivery of the intervention, recording of safety data and follow-up.
2. In general, deviations from the protocol are only permitted where this is done to prevent a risk to the trial participant.

Safety reporting

1. The known serious adverse reactions to the trial medicinal products are typically recorded by the staff entering data from the trial participant's medical record.
2. There is no requirement to report all serious adverse events in low-risk trials, but any doctor treating the patient may ask the investigator to report a serious adverse event.
3. Serious adverse events that are suspected to be related to the trial drug (*suspected*) and *unexpected* constitute a possible SUSAR (*suspected, unexpected, serious adverse reaction*), which must be reported to the sponsor (the person with overall responsibility for the trial) within 24 hours. The investigator assesses, together with the sponsor, whether the event is a SUSAR. If it is assessed to be a SUSAR, and it was fatal or life-threatening, the sponsor reports it to all trial sites and to the authorities within one week.

Name: _____

Date: _____ Signature: _____