

Short GCP course

For doctors who screen, include and obtain consent in acute drug trials

Clinical Research Unit
Department of Intensive Care, Rigshospitalet

PROGRAMME

- 01** GCP and roles
- 02** Consent in acute trials
- 03** Consent: content and documentation
- 04** Protocol compliance
- 05** Safety recording

GCP and roles

Good Clinical Practice (GCP) is the international standard for clinical trials. Its purpose is to protect the rights, safety and wellbeing of trial participants and to ensure that the data are reliable.

01

SPONSOR

The party with overall responsibility for the trial.
Responsible for the trial as a whole and for reporting to the authorities.

02

INVESTIGATOR

The person responsible for the trial at the department. Ensures that the protocol is followed and that the consent process is correct.

03

DOCTOR AT THE DEPARTMENT

Screens, includes and informs.
Obtains consent and assesses safety events together with the investigator.

04

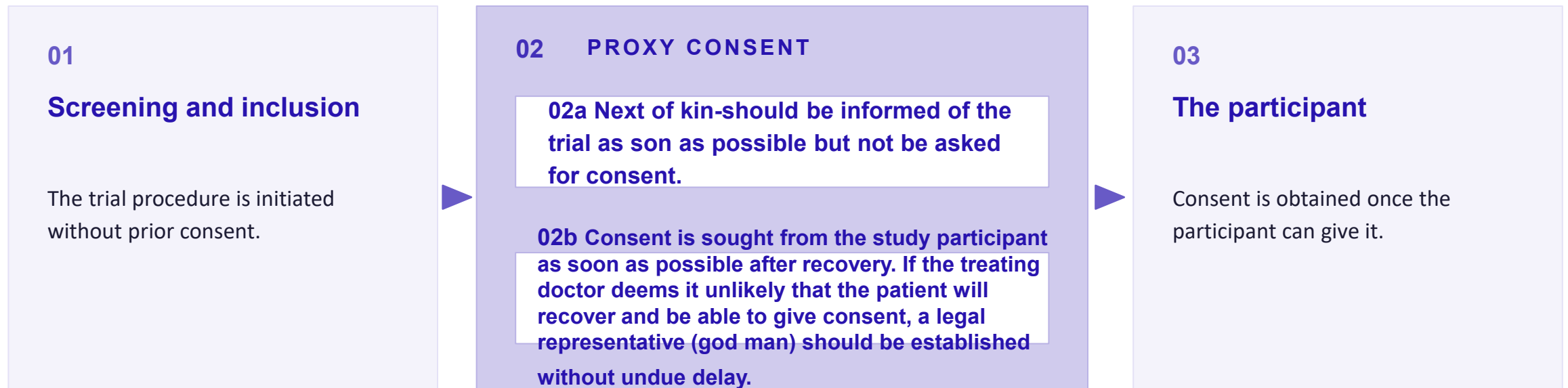
OTHER PROJECT STAFF

Assists with screening, inclusion and consent, enters data and keeps the site file and other documentation up to date.

Delegation: you may only screen, include or enter data once you are on the trial's delegation log and have been trained in the protocol.

Consent in acute trials

Consent ensures that participation is informed and voluntary. In acute drug trials, trial procedures are initiated before consent can be obtained.



Investigator is responsible for ensuring that the process is conducted continuously and correctly. Consent may always be withdrawn by the consenting party, without explanation.

Consent: content and documentation

01 THE INFORMATION

All materials have already been prepared specifically for the trial. Use them, and refer to them, when you orally inform participants.

- Purpose, procedures, risks and expected benefits of participation
- Given both orally and in writing, in a language the consenting party understands
- Inform of the opportunity to ask questions, to have time for consideration, and to bring a support person

Withdrawal: consent to participation may always be withdrawn by the consenting party, without explanation and without consequences for further treatment.

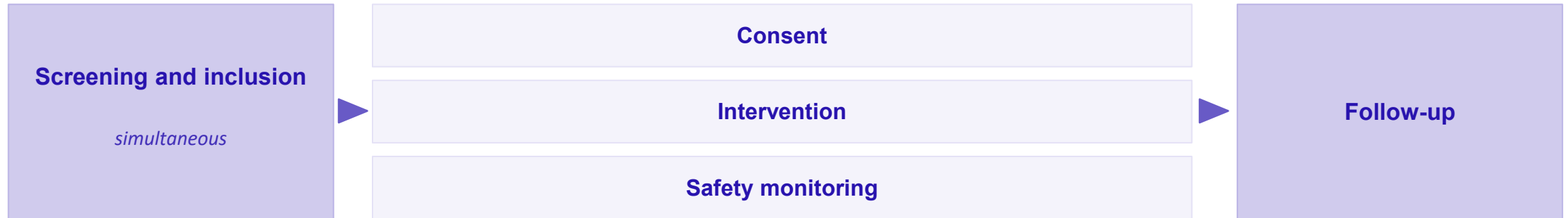
02 THE DOCUMENTATION

- The consent form is signed and dated by the participant or legal representative by the informing doctor
- The participant must receive a copy
- The original is uploaded to the electronic case report form (eCRF) and filed in the site file
- Consent is recorded in the patient's medical record

Always ask further: may data continue to be collected? This is a separate question. If in doubt, ask the investigator.

Protocol compliance

The protocol must be adhered to in all aspects of the trial.



The trial participant's course. Consent, intervention and safety monitoring run in parallel from inclusion onwards.

THE GENERAL RULE

The protocol is followed as written. If you are in doubt about a criterion, a dose or timing, clarify with the investigator before acting.

EXCEPTIONS

The protocol may be deviated from if this is done to prevent a risk to the trial participant.

Deviations are documented in the eCRF by project staff.

Safety recording

Three concepts you need to be able to distinguish in a low-risk trial.

Serious adverse reaction

SAR

The relevant serious adverse reactions are often predefined in the protocol, but not always. Typically recorded by the staff entering data from the medical record.

Serious adverse event

SAE

Does not need to be reported routinely in low-risk trials. Any treating doctor may ask the investigator to report one.

SUSAR

suspected unexpected serious adverse reaction



All 3 met constitutes a possible SUSAR.

Contact the investigator. Reporting to sponsor must occur within 24 h

24 hours

The investigator and sponsor then assess together whether it is a SUSAR.

Fatal or life-threatening SUSAR: sponsor reports to all trial sites and to the authorities within 1 week.

The signature on the written material is documentation of completion of this GCP course.