PREPARING WRITTEN INFORMATION AND INFORMED CONSENT FORMS

1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for preparing written information and consent forms for subjects volunteering to participate in clinical drug trials.

This SOP ensures compliance with ICH Guideline for Good Clinical Practice (ICH GCP) and national and international laws and regulations, specified in the SOP Legislation and guidelines.

For obtaining informed consent, see SOP Obtaining Informed Consent

2 SCOPE

This SOP is valid for all clinical drug trials sponsored by hospitals that have implemented the NorCRIN SOPs.

3 RESPONSIBILITIES

The sponsor has overall responsibility for ensuring that written information and consent forms are prepared in compliance with this SOP.

The sponsor's responsibilities shall be described in the quality system of the sponsor institution. Tasks are delegated according to SOP Roles and Responsibilities in clinical trials implemented in the institution.

The sponsor may transfer any or all of the sponsor's trial-related duties and functions to a third party vendor such as a Contract Research Organisation (CRO), but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf. Transfer of duties shall be specified in a written agreement.

The coordinating investigator shall ensure that patient information, consent forms and other written information given to subjects have been approved by the ethics committee before use.

4 PROCEDURES

4.1 Preparing written information

The Informed Consent Document, information sheet and consent form, is required for the application to the ethics committee and must be approved by the ethics committee before any subjects are enrolled into the trial.

Informed Consent Document shall be developed in accordance with the requirement of the ethics committee. If the ethics committee provides template(s) for the Informed Consent Document, it is recommended to use them to ensure compliance.

Other written information provided to subjects in a clinical trial usually requiring EC approval includes:

- Advertising text / recruitment materials (including what is posted on sites such as the hospital website if not taken from the Informed Consent Document)
- Questionnaires/ PROM
- Any other written information that is provided to trial subjects

In trials with patient reported outcome measures (PROM), the subjects should be informed whether the information recorded on the PROMs are checked on an ongoing basis or not. If not, the subjects should be informed about other means to share concerns with the investigator.

For paediatric trials, consent must be obtained from parents/guardians. Both parents/guardians must sign. In addition, a separate information sheet suitable for children 12 – 16 years must be prepared. Minors aged 16 and above must assent in addition to the parents/guardians consent. The Regional Committees for Medical and Health Research Ethics (REK) have provided templates.

In emergency situations when the trial subject is not able to give consent, this must be clearly stated in the protocol and application to the ethics committee. Any deviation from the requirement of written informed consent prior to trial start must be explicitly approved by the ethics committee. The subject or the subject's legally designated representative should be informed about the trial as soon as possible and consent to continue should be requested. If such delayed consent is not obtained, data from the subject cannot be used unless the EC has approved it explicitly (usually on a case by case basis).

For more information about trials involving subjects who are incapacitated, minor, pregnant or breastfeeding women or emergency situations, see EU Regulation articles 31-35.

Some hospitals/institutions have their own informed consent templates with their logo that can be used.

The following general requirements are applicable to all information sheets and consent forms:

- All pages will have a header with short title and date, version number.
- The contents of the information sheet shall be in accordance with ICH GCP 4.8.
- The content will be adapted for the specific trial and intended subjects, especially if this includes vulnerable subjects who have a reduced ability to provide consent.
- The information sheet shall be written in a short, clear and understandable way without the use of unnecessary technical or medical terminology
- The information sheet and consent form is not a legally binding contract for the participants and should not be designed as such

In cluster trials, the Member States may accept that informed consent is obtained by simplified means, see article 30 of the EU Regulation.

Information sheets and consent forms for other countries will be prepared in compliance with the applicable national legislation.

Traveling costs in connection with study visits are covered in the same way as ordinary treatment, see Pasientreiseforskriften

It is recommended that the template for Informed Consent Form Version Tracking Log is used to keep a record of versions of the informed consent form.

4.2 Revision of written information

The information sheet and any other written information for the subjects will be revised whenever important new information becomes available, that may be relevant for the subject's willingness to consent.

The coordinating investigator will submit the revised informed consent document to the ethics committee for approval prior to use.

5 DOCUMENTATION

Approved versions of subject information sheet, consent form and correspondence with ethics committees, will be filed in the investigator's site file and the sponsor's trial master file.

6 NON-COMPLIANCE MANAGEMENT

Non-compliance should be handled according to the procedures for handling non-compliance of the individual institution. Protocol deviations should be reported according to the trial protocol or the Protocol Deviation Handling plan.

7 REFERENCES

7.1 External references

- Helseforskningsloven
- ICH GCP, section 1.28., 1.37., 1.61., 2.9., 3.1.6., 3.1.7., 4.4.1. and 4.8.
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, articles 29 to 35

7.2 Internal references

- SOP Legislation and guidelines
- SOP Obtaining Informed Consent
- Informed Consent Form Version Tracking Log

8 ATTACHMENTS

None

9 DEFINITIONS

SOP Definitions.

Abbreviation	Term
CRO	Contract Research Organisation
EC	Ethics Committee
GCP	Good Clinical Practice
ICD	Informed consent document
ICH	International Conference on Harmonisation
PROM	Patient reported outcome measures
REK	The Regional Committees for Medical and Health Research Ethics
SOP	Standard Operating Procedure

10 CHANGES SINCE LAST VERSION

CT SOP version no 1.0

Main changes from LM SOP no. 2.06. Adapted to the wording of the clinical trial regulation no 536/2014.