Contents

1 Purpose

The purpose of this Standard Operating Procedure ("SOP") is to describe the overall roles, responsibilities, and authority, and the distribution of tasks during planning, start up, conduct and completion of 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 SOPs Legislation and Guidelines.

The responsibilities and tasks for clinical trials follow from:

- ICH GCP R2 (R3 from 23 July 2025)
- Helseforskningsloven with related legislation

2 Regulation 536/2014 (Clinical Trial Regulation, CTR) Scope

This SOP is applicable for clinical trials conducted in Helse Bergen HF and is complementary internal procedures regulating ICT, privacy and data protection and research projects.

3 Definitions

SOP Definitions

Abbreviation	Term
CI	Coordinating Investigator
CTR	Clinical Trial Regulation
CRO	Contract Research Organisation
CTIS	Clinical Trial Information System
CTU	Clinical Trial Unit
DPIA	Data Protection Impact Assessment
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
PI	Principal Investigator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction

4 Responsibilities

Sponsor has the overall responsibility for conducting clinical trials in accordance with applicable laws, regulations and guidelines. See section 4.1 for description of the sponsor's responsibilities.

At Haukeland University Hospital the Sponsor responsibility resides with Level 2 leader (clinic director/department director).

The sponsor may transfer any or all of the sponsor's trial-related duties and functions to a service provider 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 conducted on its behalf. Transfer of duties shall be specified in a written agreement.

The principal investigator (PI) at each study centre is responsible for the conduct of the clinical trial according to the protocol and applicable laws, regulations and guidelines.

Tasks can be delegated. Responsibilities and delegated tasks are summarised in the table in section 8.

5 Role, responsibility, authority, and distribution of tasks

The most important functions/roles in the conduct of clinical trials are: sponsor (the health institutions, research responsible), coordinating investigator (CI) / PI for single centre trials /, PIs, medical monitor, other trial staff, monitor, data manager and statistician. A brief description of the functions and associated roles, responsibilities and tasks is given below.

Coordinating investigator / principal investigator for single centre trials have the same responsibilities and is hence synonymous terms in this document. The term Coordinating investigator is therefore used for simplicity.

NorCRIN procedures, located at metodebok.no, are to be used for trials.

5.1 Sponsor

The health institution responsible for the trial overall and usually where the CI is employed, is the study sponsor. For trials in Norway in collaboration with universities, agreements defining the sponsor may apply. In clinical drug trials on behalf of the industry or for a non-commercial organisation in Norway or abroad, the company/organisation will generally be the sponsor.

Under the CTR, there may be more than one sponsor. The responsibilities of the co-sponsors should be described and agreed by contractual agreement.

Participating institutions in a multicentre trial are responsible for the research in the trial that is conducted in their own institution.

5.1.1 Responsibilities and tasks

Tasks can be delegated to a larger extent than described in this SOP, e.g. in international trials where tasks for practical reasons should be performed nationally. These delegations must be regulated in an agreement between the parties.

5.2 Coordinating Investigator

For clinical trials, a CI has the responsibility for the coordination of all investigators at different centres. In addition to ensuring that the investigators fulfil their responsibilities and tasks, the CI is responsible for performing sponsor tasks for the other countries in multinational studies as well as its own, see Table 1 section 8.

The CI may delegate sponsor task to principal investigators or CTUs/others in other countries through a written agreement. The responsibility for the tasks resides with the Sponsor.

5.2.1 Responsibilities and tasks

The CI's responsibilities and tasks are recorded in Table 1 section 8.

5.3 Data Manager

Sponsor will assign data management tasks to suitably qualified and experienced personnel, who will function as data managers throughout the trial. All staff who are involved in data management tasks (for example database management, data verification and validation) must have necessary qualifications.

5.4 Medical Monitor

Sponsor should have a person or a defined team with competence to assess the safety aspects for a clinical trial. This includes reviewing serious adverse events (SAEs), evaluating the risk/benefit ratio at all times, reporting suspected unexpected serious adverse reactions (SUSARs) to relevant authorities, writing an annual safety report, informing the investigators about SUSARs, or other safety issues and any change in the risk/benefit evaluation of the trial. This medical monitor can be the same person as the CI, although it is recommended to have a group of persons. In blinded trials, the medical monitor should be able to see unblinded data if necessary.

5.5 Principal Investigator

The principal investigator (PI) is the investigator leading the trial at the individual trial centre (hospital). Documentation of qualifications to lead and conduct the trial in own institution must be available, including documented ICH GCP knowledge.

5.5.1 Responsibilities and tasks

PI's responsibilities and tasks are recorded in Section 8. In single centre clinical trials, the PI will also have the responsibilities and tasks of the CI.

5.6 Trial Staff

The PI can delegate tasks to named trial staff. The delegation must be in writing. Trial staff will normally be other investigators and trial nurses/coordinators from the same institution that contribute to the conduct of the trial at site.

By delegation, the PI has the responsibility to ensure that the trial staff has sufficient competence to conduct the assigned tasks. Only defined tasks can be delegated, not the responsibility.

5.6.1 Responsibilities and tasks

Trial staff performs tasks after specific delegation from the principal investigator. These tasks must be specified in a delegation log.

Trial staff defined as health personnel by the helsepersonelloven has however an independent responsibility under § 4 on requirements for proper patient care.

5.7 Monitor

All clinical trials must have a monitor appointed, responsible for monitoring the trial. Monitor conducts his/her activities on behalf of the sponsor. Monitor cannot be the same person as any of the investigators or site trial staff.

The monitors should have a thorough knowledge of all relevant laws and legislations and sufficient scientific and/or clinical knowledge of the trials.

5.7.1 Responsibilities and tasks

Monitor shall conduct monitoring according to the current monitoring plan and in accordance with ICH GCP including conducting monitoring visits and reporting to the sponsor / principal investigator through monitoring reports / follow-up report.

5.8 Statistician

The sponsor will assign a trial statistician who shall ensure that the statistical parts in the protocol, including design, is properly described and fit for purpose, that the statistical activities and analyses are validated and have the required quality. The statistician should follow the procedure for statistics.

6 Noncompliance Management

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

7 Supporting SOPs

SOPs and templates

8 Table listing responsibilities and tasks for sponsor, coordinating investigator, and principal investigator

	Tasks	Sponsor (Institution)	Coordinating investigator (CI)	Principal investigator (PI)
R = Responsible D = Delegated task				
Overall responsibilities	Ensure GCP is followed	R	D	R
	Ensure that required insurance for the trial subjects is available	R	D	
	Ensure that valid insurance for all countries is present throughout the study. In Norway annual renewal of insurance is required.	R	D	
	For clinical trials regarded as advanced therapy (i.e somatic cell therapy, gene therapy or tissue therapy): ensure that	R	D	R

	Tasks	Sponsor (Institution)	Coordinating investigator (CI)	Principal investigator (PI)
	specific additional requirements are met according to SOP Clinical Trials of Advanced Therapy Medicinal Products			
	Ensure that the trial is conducted according to approved trial protocol	R	D	R
	Ensure oversight of any trial-related duties and functions conducted on behalf of the sponsor.	R	D	
	Facilitate monitoring, and if applicable, audits and inspections	R	D	R
Internal research approval and securing funding	Ensure internal approval of the trial according to Forsknings- og kvalitetsprosjekt: Oppstart, gjennomføring og avslutning		R	R
	Obtain relevant advice regarding personal data protection and information security (storage and transfer of data etc.) to ensure that a Data Protection Impact Assessment (DPIA) is conducted if required and that legal basis for handling personal data and health data is present according to Forsknings- og kvalitetsprosjekt: Melding i eProtokoll and Forsknings- og kvalitetsprosjekt: Personvernkonsekvensvurdering (DPIA)		R	R
	Ensure proper handling of human biologic material (information security and personal data protection) according and assign responsible person for research biobank according to Forsknings- og kvalitetsprosjekt: Ansvar, roller og oppgaver	R	D	D
	Ensure that the institution where the principal investigator is employed has systems and routines that safeguards that research data is handled and stored properly according to Forsknings- og kvalitetsprosjekter: Innsamling, bruk, tilgjengeliggjøring og oppbevaring av personopplysninger			R
	Register the trial at clinicaltrials.gov if applicable and at the institution's clinical trial directory (web site) according to Forsknings- og kvalitetsprosjekt: Registrering i internasjonale databaser, informasjon på internettsider og publisering av resultat	R	D	
Application to authorities	Obtain approval of the study from competent authorities and ethics committees through CTIS. Ensure all	R	D	

	Tasks	Sponsor (Institution)	Coordinating investigator (CI)	Principal investigator (PI)
	participating centres in all countries are recorded in application.			
	Ensure that study approval from relevant authorities is present for other participating countries, if not covered by CTIS (outside EEA)	R	D	
	Obtain approval of substantial modifications from competent authorities and ethics committees through CTIS.	R	D	
	Obtain approval of substantial amendments from the relevant authorities are present for other participating countries, if not covered by CTIS (outside EEA)	R	D	
Protocol, information sheet, consent form, IB / SmPC	Develop protocol, information sheet, consent form, Investigator's Brochure (IB) and/or pharmaceutical-chemical documentation if applicable, Case Report Form (CRF) / questionnaires and study specific guidelines.	R	D	
Contracts/ Agreements	Ensure that the trial is monitored	R	D	
	Enter into written agreements with cooperating institutions and service providers such as research support, monitoring, radiology, lab etc.	R	D	
Creating and maintaining study files	Establish Trial Master File (TMF) for the trial and Investigator's Site File (ISF) at each study centre	R	D	
	Keep TMF updated with relevant information	R	D	
	Keep ISF updated with relevant information			R
	Close and archive the clinical trial	R	D	R
	Ensure that electronic systems used for archiving is according toForsknings- og kvalitetsprosjekt: Oppstart, gjennomføring og avslutning	R	D	R
	Have oversight over where the clinical trial documentation is stored	R		R
Risk evaluation	Conduct risk assessment before trial start	R	D	
	Conduct risk assessment throughout the study	R	D	
Training and start-up	Train investigators and trial staff in the protocol and guidelines.	R	D	
	Develop written overview of tasks delegated to trial staff			R
	Supervise trial staff conducting delegated tasks or function and ensure they are qualified and properly trained			R

	Tasks	Sponsor (Institution)	Coordinating investigator (CI)	Principal investigator (PI)
	Conduct necessary training of all new investigators and trial staff in the protocol and trial specific guidelines	R	D	
Data management	Create Data Management Plan	R	D	
	Follow the Data Management Plan	R	D	
Statistics	Create Statistical Analysis Plan	R	D	
	Follow the Statistical Analysis Plan	R	D	
Handling of investigational medicinal product	Ensure drug supplies if applicable	R	D	
	Ensure that trial drug including comparator, auxiliary medicinal products, medical devices used for administration and procedures specifically required by the protocol is not borne by the subject.	R	D	
	Ensure sufficient drug supplies throughout the study	R	D	
Notifications and reports	Ensure information to ethics committees and competent authority through CTIS about first subject recruited, end of trial nationally, end of entire trial, temporary halt, non-substantial modifications to the protocol etc.	R	D	
	Report serious breaches to authorities.	R	D	
	Assess Serious Adverse Events (SAE) and report Suspected Unexpected Serious Adverse Reaction (SUSAR) to the authorities through Eudravigilance and on an ongoing basis assess the trial's risk benefit ratio. Submit annual report. Inform all PIs about suspected adverse reactions that are serious or unexpected.	R	D	
	Update registries such as clinicaltrials.gov if applicable and the institution's clinical trial directory when inclusion of study subjects is stopped.	R	D	
	Report deviations according to sponsor's requirement for reporting of protocol deviations and according to the institution's internal procedures		R	R
	Submit end of study notification to ethics committees and competent authorities	R	D	

9 Referanser

Interne referanser

1.3.1.1-01	Forsknings- og kvalitetsprosjekt: Kontroll ved ansvarlig leder
1.3.1.2-01	Forsknings- og kvalitetsprosjekt: Begreper og definisjoner
1.3.1.2-02	Forsknings- og kvalitetsprosjekt: Ansvar, roller og oppgaver
1.3.1.2-04	Forsknings- og kvalitetsprosjekt: Melding i eProtokoll

1.3.1.3-01	Forsknings- og kvalitetsprosjekt: Oppstart, gjennomføring og avslutning
1.3.1.3-03	Forsknings- og kvalitetsprosjekt: Registrering i internasjonale databaser, informasjon på internettsider og publisering av resultat
1.3.1.3-06	Forsknings- og kvalitetsprosjekt: Ansvar og roller ved klinisk utprøving av medisinsk utstyr (engelsk tekst)
1.3.1.10-02	Forsknings- og kvalitetsprosjekt: Personvernkonsekvensvurdering (DPIA)
1.3.1.10-03	Forsknings- og kvalitetsprosjekter: Innsamling, bruk, tilgjengeliggjøring og oppbevaring av personopplysninger
1.3.1.12-02	G101 Forsknings- og kvalitetsprosjekter: Planlegging, gjennomføring og avslutning
1.3.1.12-03	Forsknings- og kvalitetsprosjekter: Avslutning av prosjekt
1.3.1.12-04	Forsknings- og kvalitetsprosjekter: Informasjon og samtykke
1.3.1.12-06	Forsknings- og kvalitetsprosjekter: Oppfylling av de registrerte sine rettigheter

Eksterne referanser

1.12.2 Forskrift om klinisk utprøving av legemidler til mennesker
1.17.5.3 Personopplysningsloven - kapittel GDPR
1.17.5 Personopplysningsloven - Lov om behandling av personopplysninger (GDPR)
1.9.7 Forskrift om organisering av medisinsk og helsefaglig forskning (se Memo)
1.17.6 Personopplysningsforskriften - Forskrift om behandling av personopplysninger
1.9.1 Helsepersonelloven - Lov om helsepersonell m.v.
1.9.6 Helseforskningsloven - Lov om medisinsk og helsefaglig forskning

Regulation 536/2014 on Clinical Trials (R3)
ICH: E 6 (R2): Guideline for good clinical practice - Step 5ICH E6 (R3) Guideline on good clinical practice (GCP)_Step 5

10 Endringer siden forrige versjon

Korrigert referanse.
Forlenget gyldighet til 10.07.2027