Ahus - Roles and responsibilities in testing medical devices

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Approved by: Øystein Mæland Revision deadline: 27.03.2024 Revision: 1.0

1. Purpose

The purpose of this procedure (Standard Operating Procedure - SOP) is to outline the overarching roles, responsibilities, and task distribution for the planning, initiation, execution, and conclusion of trials involving medical equipment (without CE marking, or outside current CE marking).

The SOP aims to ensure compliance with national and international laws, regulations, and good clinical practice (NS EN ISO 14155:2020) for clinical trials of medical equipment. The relevant laws, regulations, and guidelines for GCP are detailed in MU-SOP.

2. Scope

The SOP applies to clinical trials of medical equipment at Akershus University Hospital HF (Ahus) and complements the document "Responsibilities in Quality and Research Projects", EQS ID 15673.

If the sponsor is external, such as a manufacturer of medical equipment, the sponsor's SOPs can be used, provided they align with national and international laws, regulations, and guidelines**.**

3. Responsibilities

The sponsor has the overarching responsibility to conduct trials of medical equipment in accordance with prevailing laws, regulations, and guidelines. The sponsor's responsibilities are outlined in section 4.1.1 of this SOP.

The principal investigator at each study centre is responsible for conducting trials of medical equipment in line with the current study protocol, laws, regulations, and guidelines.

Tasks can be delegated. Responsibilities and delegated tasks are summarised in section 8.1, table 1.

4. Role, Responsibility, Authority, and Task Distribution

The key roles in the execution of medical equipment trials are the sponsor, the national coordinating investigator, the principal investigator, study personnel, and monitor. A brief description of these roles, along with their responsibilities and tasks, is provided below.

Current NorCRIN procedures are used for the trials.

4.1 Sponsor

In investigator-initiated studies, the healthcare institution where the principal investigator (single-centre study) or national coordinating investigator (multi-centre study) is based will act as the sponsor.

In clinical trials of medical equipment in collaboration with colleges and universities, the healthcare institution will act as the sponsor.

For clinical trials of medical equipment commissioned by the industry or other non-profit organisations in Norway or abroad, the principal contractor will generally act as the sponsor.

Under the Health Research Act, collaborating institutions in a multi-centre study are responsible for the part of the project conducted in their institution. This means that where the Health Research Act allows for several research-responsible institutions in a multi-centre study, the Drug Trial Regulations stipulate that in such cases, there can only be one sponsor. This is also the case for medical equipment trials. Legally, the responsibility of the sponsor is assigned to the institution by the top executive. However, the sponsor will typically have one or more representatives in their own institution depending on the size of the operation. At Ahus, the sponsor will be represented by the Department Head. In cases where the department head is the national coordinating investigator or principal investigator, the responsibility will be represented at the next level in the management line. When signing overarching agreements/contracts, the Akershus University Hospital - Authorisations apply, see "Research Area".

4.1.1 Responsibilities and Tasks

The sponsor's responsibilities and tasks for the trial of medical equipment are derived from the Norwegian Standard NS-EN ISO 14155:2020, the regulation on medical equipment, and the Health Research Act sections 5 and 6 with regulations.

Tasks that the sponsor must ensure are followed up are listed in section 8.1, table 1.

Tasks can be delegated to a greater extent than described in this procedure, for example, in international clinical trials where the sponsor is not a Norwegian institution and tasks for practical reasons should be performed nationally. These delegations must be regulated in a written agreement between the parties.

4.2 National Coordinating Investigator

In a multi-centre study, there should be a national coordinating investigator with overarching responsibility for the trial at the relevant study centres in Norway. In such cases, the national coordinating investigator is the same as the project manager in accordance with the Health Research Act and is responsible for obtaining necessary approvals from REK, including any reporting.

The national coordinating investigator is the link between the sponsor and the Norwegian centres. The national coordinating investigator can also act as the principal investigator in their own institution and will then have the same responsibilities as described in section 4.3.

4.2.1 Responsibilities and Tasks

The responsibilities and tasks of the national coordinating investigator are described in section 8.1, table 1, and follow from the Norwegian Standard NS-EN ISO 14155:2020 and the Health Research Act section 5 as far as it applies to medical equipment trials.

4.3 Principal Investigator

The principal investigator is an investigator who leads the trial at the individual trial site (healthcare facility or other institution). As the principal investigator, it must be documented that they possess sufficient qualifications to lead and conduct the trial at their own healthcare facility/institution, including GCP knowledge.

4.3.1 Responsibilities and Tasks

The responsibilities and tasks of the principal investigator are described in section 8.1, table 1, and follow from the Norwegian Standard NS-EN ISO 14155:2020 and the Health Research Act section 5 as far as it applies to medical equipment trials.

In single-centre studies, the tasks of the principal investigator will also include the tasks of the national coordinating investigator (see section 4.2 or section 8.1, table 1).

4.4 Study Personnel

The principal investigator can delegate tasks to named study personnel and/or collaborators. Such delegation must be in writing. Study personnel will typically be other investigators and study staff from the same institution contributing to the project.

The principal investigator, when delegating, has a specific responsibility to ensure that study personnel have sufficient competence to carry out the assigned tasks. Only specifically defined tasks can be delegated, not the responsibility itself.

4.4.1 Responsibilities and Tasks

Study personnel perform tasks as delegated by the principal investigator. These tasks should be specified in a delegation log or equivalent document.

Study personnel defined as healthcare professionals under the Healthcare Personnel Act have independent responsibility under section 4 on requirements for proper patient treatment.

4.5 Monitor

Every trial of medical equipment must appoint a person (monitor) responsible for monitoring the study. The monitor carries out their activities on behalf of the sponsor. The monitor can either be internal or external but cannot be the same person as any of the investigators or study personnel.

The monitor is expected, among other things, to have in-depth knowledge of all relevant laws and regulations for the trial and sufficient scientific and/or clinical knowledge about the studies.

4.5.1 Responsibilities and Tasks

The monitor shall carry out monitoring according to the current monitoring plan/agreement for the individual trial and in accordance with GCP, including conducting monitoring visits and reporting to the sponsor/principal investigator through monitoring reports, see SOP monitoring.

For multi-centre studies, some additional tasks will be performed by a lead monitor. In single-centre studies, the monitor will have the role of the lead monitor.

4.5.2 Lead monitor

The lead monitor is the monitor located at the sponsor/national coordinating investigator's centre, unless otherwise agreed in an agreement between the monitors and their supervisors.

The lead monitor is responsible for keeping track of the monitors for the various study centres.

4.5.3 Responsibilities and Tasks

The responsibilities and tasks of the lead monitor are:

- To assist the study group in conducting risk assessments if requested
- To assist the study group in preparing a monitoring plan for all centres based on the risk assessment if requested
- To create a cost estimate for all centres and send it to the other monitors for consultation
- To send the final version of the risk assessment, monitoring plan, collaboration agreement, and cost estimate to the other monitors
- To provide training in the monitoring plan
- To initiate telephone meetings and other meetings with the other monitors as needed
- To continuously share information with the national coordinating investigator

5. Handling Deviations

Deviations from this SOP are handled according to the procedures for deviation handling of each healthcare institution/individual institution. Deviations identified during the monitoring of a clinical trial must be handled according to SOP Protocol deviation handling.

6. Background Information

6.1 External Background Documents

- Medical Equipment Act LOV-1995-01-12-6
- Medical Equipment Regulation FOR-2005-12-15-1690
- Clinical Examination of Medical Equipment for Human Use – Good Clinical Practice (NS-EN ISO 14155:2020)
- Health Research Act – especially §§ 5 og 6
- Healthcare Personnel Act – especially § 4

- Regulation on Organisation of Medical and Health Research 2009-07-01-955 – especially §§ 3, 4, 5 og 6
- General Data Protection Regulation, EUs personvernforordning
- Act on the Processing of Personal Data

6.2 NorCRIN Background Documents

- SOP MU Use of medical device in clinical investigation

6.3 Internal Background Documents

EQS ID	Dokument
32438	Clinical drug trials (reference document, NorCRIN)
15673	Responsibilities in quality and research projects
33743	Storage, archiving, and deletion of health and personal information
34153	Treatment, closure, and follow-up of research-related adverse events/deviations
34152	Workflow – handling of research-related adverse events/deviations
8238	Authorisations at Akershus University Hospital
32429	Archiving of documents for quality and research projects in Public 360
32435	Remote storage of questionnaires/research data (Skytta)

7. Definitions

NorCRIN- definitions

8. Appendix

8.1

Table 1: Description of responsibilities and tasks of sponsor, national coordinating investigator and principal investigator.

Task	Sponsor (institution)	National coordinating investigator (main investigator for single-center studies)	Main investigator
A = Accountability D = Delegated Task			
PLANNING PHASE			
Ensure adequate anchoring of the trial in own healthcare institution by registration via eForm (data protection officer)		A	A
For medical equipment containing sensitive personal		A	A

data, ensure assessment and opinion from information security/data protection			
Collect relevant information about storage and processing of personal data and ensure that a Data Protection Impact Assessment (DPIA) is conducted if necessary, and that the legal basis for handling personal and health data is present		A	A
Ensure proper treatment of human biological material in accordance with EQS IDs 41208, 41209 and 41210, and appoint the responsible person for the biobank	A	D	D
Ensure that the institution where the principal investigator is employed has systems and routines that ensure that research data is processed and stored in accordance with internal routines, EQS ID 33743, 32429 and 32435			A
Obtain approval of the study and any changes from REC before start-up. Ensure that all study centres are registered as institutions responsible for research		A	
Obtain approval of the study and any changes from SLV and other relevant authorities, before starting the study	A	D	
Enroll the study on clinicaltrials.gov and helsenorge.no/ahus.no, EQS ID 34316	A	D	
Ensure that necessary approvals are obtained from relevant authorities in all participating countries	A	D	
Ensuring GCP is followed	A	D	A
Design of the Clinical Investigational Plan (CIP),	A	D	

information letter, declaration of consent, Investigator's Brochure (IB), Case Report Form (CRF)/questionnaire, as well as study-specific guidelines			
Create a plan for data management (data management plan)	A	D	
Provide supply of the medical equipment when needed	A	D	
Ensure that the necessary insurance is taken out via the Norwegian Pharmaceutical Liability Association for Drug Studies and confirmation from NPE/other insurance for testing of medical devices	A	D	
Ensure that the study is monitored	A	D	
Establish a written agreement with collaborating institutions and others	A	D	
Create internal agreements with collaborating divisions/departments	A	D	
Conduct a risk assessment in accordance with ISO 14971	A	D	
Provide necessary training for all investigators and study personnel in accordance with protocol/CIP and guidelines for the individual trial	A	D	
Create a Trial Master File (TMF) for the trial and Investigator's Site File (ISF) for each study centre (health trust)	A	D	
IMPLEMENTATION PHASE			
Ensure that the trial is conducted in accordance with approved CIP	A	D	
Seek approval from REC in the event of significant changes to the protocol		A	

Seek approval from SLV and other relevant authorities in the event of significant changes to the Protocol	A	D	
Ensure that approval of significant changes is available from the relevant authorities in all participating countries	A	D	
Provide valid insurance for all countries throughout the execution of the trial	A	D	
Report adverse medical incidents (SAE) and equipment deficiencies/faults to the Norwegian Medicines Agency (SLV) within the deadlines, and make a continuous assessment of the benefit and risk ratio for the trial	A	D	
Update clinicaltrials.gov and helsenorge.no/ahus.no when the recruitment period is over, EQS ID 34316	A	D	
Ensuring GCP is followed	A	D	A
Ensure that the medical device is available throughout the trial period	A	D	
Prepare a written overview of delegation of tasks to study staff			A
Follow your data management plan	A	D	A
Ensure that monitoring of the trial is carried out and followed up	A	D	A
Facilitate monitoring, possibly audit and inspection	A	D	A
Supervise persons or parties to whom the principal investigator has delegated study-related tasks or functions, and ensure that these are qualified for the tasks and functions delegated to them			A
Provide an overview of any trial-related task and function	A	D	

performed on behalf of the sponsor			
Ensure written agreements are made with all new collaborating parties/institutions	A	D	
Carry out risk assessment throughout the trial period	A	D	
Provide necessary training for all new investigators and study staff according to CIP/protocol and study-specific guidelines	A	D	
Keep TMF up to date with relevant information	A	D	
Keep ISF up to date with relevant information			A
Report nonconformities in accordance with Sponsor's requirements/guidelines for reporting protocol deviations and in accordance with the institution's internal procedures, EQS ID 34152 and 34153			
CLOSING PHASE			
Discontinue and Archive the Medical Device Clinical Trial, EQS IDs 32429 and 32435	A	D	A
Send final report to REK and SLV	A	D	A
Ensure that the electronic system used for archiving complies with internal guidelines, EQS ID 32429	A	D	A
Have an overview of where the trial documentation is stored	A	D	A