Ahus - Responsibility in quality and research projects

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1.0 Purpose

This document describes the responsibility for organizing and executing quality and research projects. Quality and research projects include:

• Health research, which must be approved by the Regional Committee for Medical and Health Research Ethics (REK)
• Other research, such as pure experimental studies (laboratory research), health services research, or quality studies where external institutions are involved
• Internal quality assurance, such as corporate governance and internal quality registers

In the following, the various project types are referred to collectively as projects. The procedure applies to everyone involved in or associated with such project activity at Ahus, regardless of employment, source of funding, and other collaborative relationships.

2.0 Scope

This procedure ensures ongoing collaboration with OsloMet and the University of Oslo (UiO) at all levels. The procedure is in line with the overall collaboration agreement between Ahus and UiO, as well as other relevant partners.
For clinical drug trials and trials of medical devices, roles, responsibilities, and tasks are specified in separate procedures; Roles and responsibilities in clinical trials of medicinal products (EQS ID 32437) and Roles and responsibilities in trials of medical devices (EQS ID 42846). These procedures supplement the current liability procedure.

3.0 Job description

A general principle is that research management at Ahus follows the hospital's ordinary management structure, but with delegated executive authority for some special functions:

- Executive Director to the Director of Research and Innovation
- division/clinic director to the head of research in the division/clinic

3.1 Liability

3.1.1. Chief Executive Officer (Level 1)

Research and data manager and has overall responsibility for quality and research projects at Ahus, and has delegated tasks related to this.
Research is part of the ordinary activities at Ahus. Similar to other activities, the chief executive has assigned management and management of research to managers at levels 2 and 3 in the organisation through delegation of responsibilities, tasks, and authority. The managers shall safeguard and exercise the health trust's research and data responsibilities and authority in the division/clinic/department they are assigned to lead, including subordinate units.

3.1.2. Director of Research and Innovation (Level 2)

Exercises authority as a research manager and shall ensure that research is planned, organised, conducted, and concluded in accordance with applicable regulations.
The Director of Research and Innovation has been empowered to:
a) administratively responsible for quality and research projects where Ahus is the institution responsible for research
b) carry out contract negotiations with external partners, including industry partners

c) sign contracts within the limits established by the power of attorney booklet.
d) decide on the transfer of a research biobank to/from another institution.
e) exercise overall data responsibility for quality and research projects
f) be the system owner for research biobanks and an electronic notification form to the data protection officer (eSkjema).
g) exercise internal control over research activities, including ensuring that governing documents are prepared, maintained, and published in the enterprise's electronic quality system, EQS.
h) exercise ongoing cooperation with UiO and OsloMet on behalf of Ahus in matters concerning research
i) represent the company's research in relevant forums internally, at the enterprise level, and externally
j) follow up suspected misconduct in quality and research projects and research non-conformities of high severity.

3.1.3. Divisional/Clinic Director (Level 2)

Ensure that all phases of the projects in the division/clinic are planned, organized, exercised, and concluded in accordance with applicable regulations, norms of research ethics, and internal routines. Assess the division's/clinic's project activity concerning professional relevance and the company's strategies. Ensure that good prioritisation is made between projects and focus areas. The Divisional/Clinic Director shall also ensure that internal resources are set aside for project activities and that the projects are carried out within the approved budget.
The Divisional/Clinic Director has the following duties:
a) facilitate, coordinate, and promote good and sound project activity, as well as promote scientific quality through advice and guidance to research groups and researchers
b) ensure follow-up of ongoing projects, including ensuring that internal control systems are implemented in underlying units
c) sign contracts within the limits established by the power of attorney booklet.
d) represent research in relevant forums internally, at enterprise level, and externally
e) prevent and follow up on nonconformities and suspected misconduct in quality and research projects
f) have regular contact with the Research and Innovation Division and with the relevant head of the clinic in Campus Ahus in matters concerning research.

The division/clinic director shall appoint a research manager, ref. functional description for research managers, who can be delegated the above tasks.

3.1.4. Head of Department (Level 3)

Responsible for all projects in the department, and approves the start-up of new projects in eSkjema. The responsibility also entails facilitating proper planning, organisation, implementation, and completion of projects. The head of the department has personnel responsibility for research personnel in his department. The head of department corresponds to the division/clinic director for questions within research, or to the head of research in the division/clinic.
The head of the department shall:
a) safeguard the personnel responsibility for research personnel in their department, including attending to performance appraisals, follow-up of sick leave, personnel matters, conflict management, etc.
b) approve projects in eSkjema before start-up and change notifications
c) approve completed Data Protection Impact Assessments (DPIAs) that are filed in Public 360

d) sign contracts within the limits established by the power of attorney booklet.
e) ensure that employees familiarise themselves with laws, norms of research ethics, and internal routines
f) assess the feasibility of the projects, including adequate resources, patient base, infrastructure, and support staff
g) keep an overview of research activity in their unit, and carry out systematic reviews, among other things to ensure that ongoing projects have the necessary approval(s) and basis for processing in accordance with data protection legislation
h) ensure that the project manager has entered into/enters into necessary agreements, such as (data processing agreement, collaboration agreement, agreement on transfer of data (DTA) or material (MTA), internal agreements, etc.)
i) Prevent, report, and follow up on nonconformities and suspected misconduct in quality and research projects
j) exercise ongoing cooperation with a designated KLINMED employee in the department that includes, at a minimum;
o to ensure that the department's KLINMED employees are active partners in the department's planning and prioritization work about research;
o to assess the scientific quality and relevance of projects in light of adopted strategies.

3.1.5. Project Manager

Ahus is responsible for research:

In projects where Ahus is responsible for research, quality and research projects must have a named project manager who is responsible for the day-to-day operation of the project. A project manager must be employed at Campus Ahus or have an employment relationship at Ahus of at least a 20% position. If the project manager is only employed at Campus Ahus, he or she must have an "unpaid employment" relationship at Ahus, i.e. he or she is affiliated with a division/clinic/department in a 0% position according to the reporting line for research. The same applies to OsloMet.

In research projects, the project manager must also have the necessary research qualifications and experience to be able to fulfill the project manager's duties pursuant to legislation, this will as a general rule be a relevant doctoral degree.
Professor emeritus can conduct research at Ahus in accordance with the rules at the relevant educational institution, but cannot be a project manager at Ahus if he or she does not have an employment relationship at Ahus in a minimum 20% position.

The external institution is responsible for the research:

In projects where an external institution is responsible for research, and Ahus is a partner or contractor, you must in any case have a local project manager at Ahus who is either employed at Ahus or Campus Ahus in a minimum 20% position.
For multicentre studies, where the formal project manager responsibility is assigned to another institution, there must be a named employee at Ahus with responsibility for the part of the project carried out at the enterprise. In such cases, the tasks mentioned below apply as far as appropriate.

Project manager's responsibilities:

The Project Manager must ensure that the project:
a) planned, implemented, and concluded in accordance with applicable regulations, norms of research ethics, and internal routines.
b) are approved in the management line at Ahus and have sufficient resources for the implementation of the project

c) has been reported to the data protection officer in eForm, and that change and final notification is sent via eSkjema during the project
d) is approved by relevant authorities such as REK, the Norwegian Medicines Agency, the Norwegian Directorate of Health and the Data Protection Officer. Relevant approvals and the opinion of the Data Protection Officer must be available before the start of the project.
e) destroy biological material and delete data by REK decisions
f) have an overview of project staff and ensure that they have valid support for Ahus to participate in research.
g) engages in dialogue with external sources of funding, including quality assurance of agreements and follow-up reporting.
h) enter into necessary agreements such as (data processing agreement, cooperation agreement, agreement on transfer of data (DTA) or material (MTA), internal agreements, etc.)
i) ensure that all project staff have sufficient competence to carry out assigned tasks in the project, and familiarize themselves with relevant courses at Ahus, such as Good Clinical Practice, Package pathways for research, etc., and that tasks are solved within current regulations and guidelines for research at Ahus and externally.
j) prevents, reports, and follows up on nonconformities and suspected misconduct in quality and research projects
k) prevents conflicts and takes action.

3.1.6. Responsible person for research biobank

Each research biobank must have a responsible person with a medical or biological education of a higher degree under the Health Research Act. The person in question must have an employment relationship of at least 20% position at Ahus.
The person in charge has day-to-day operational responsibility for the research biobank and must ensure that the collection, registration, storage, processing, and destruction of material is carried out in an ethically justifiable manner by relevant regulations and internal guidelines. The project manager is responsible for this but can delegate day-to-day operations and control to other employees without exempting the project manager from overall responsibility.

3.1.7. Project employee

Project members have an independent responsibility to familiarise themselves with relevant regulations governing research, including relevant internal governing bodies' Documents. In addition, attend relevant courses at the enterprise, e.g. Package courses for research, Good Clinical Practice, etc. External project employees, who are to be given access to information systems at Ahus, are subject to the health trust's guidelines.

3.1.8. Special responsibility for doctoral projects

Employees with supervisory responsibility for Ph.D. candidates who are employed at Ahus are responsible for familiarising themselves with and following up on their supervisory responsibility by the Ph.D. Regulations. relevant institution.
The supervisor employed at Ahus is also responsible for keeping the head of department and head of research in the division/clinic informed of the status of funding of research fellowships and any nonconformities and conflict cases as part of the implementation of a Ph.D. project. If a doctoral project is externally funded, the supervisor is responsible for maintaining a dialogue with an external funding source, including secure agreements and following up reporting.
For research fellows employed at Ahus, the responsibility routine and responsibility as a project employee apply. In addition, the research fellow is responsible for familiarising himself with and following the opp's obligations under the PhD- regulations at the institution in question.

If the supervisor (main supervisor and co-supervisor) is also the project manager, see the responsibilities described in section 3.1.5.

3.1.9. Research support

The Research and Innovation Division (FID) consists of two departments, including the Department of Research Support and the Department of Health Services Research (HØKH). The division shall provide guidance and advice to researchers and managers at Ahus, and help to ensure that research activities comply with the health trust's guidelines and other regulations. In addition, research support services have been established in several divisions.

3.2 Action

Approval of quality and research projects

Projects registered in the eForm must be approved by the head of department, level 3. If the head of the department is involved in the project, the project must be approved by the division/clinic director, level 2, or head of research in the division/clinic if delegated responsibility. Applications and agreements are signed by the current authorisation structure.

4.0 Related documents

For each procedure, there are supervisors under the related documents tab in the EQS.

- Functional description for the research manager in division/clinic EQS ID 33993
- Organization of data protection work, EQS ID 28397
- eForm: http://eskjema.ad.ahus.no/
- Archiving of documents for quality and research projects in Public 360, EQS ID 32429
- Roles and responsibilities in clinical trials, EQS ID 32437
- Roles and responsibilities in testing medical devices, EQS ID 42846
- Processing, closing, and follow-up of research-related unwanted incidents/non-conformities, EQS ID 34153
- Workflow - handling of research-related unwanted incidents/non-conformities, EQS ID 34152
- Routines for remote storage of questionnaires/research data in paper format
- Disclosure of data to external institutions
- Checklist for quality and research projects
- Ahus - Responsibility and personnel administration in research - «Who does what», EQS ID40822

5.0 Basic documents

- The Health Research Act
- The Research Ethics Act
- The Biotechnology Act
- The Health Data Filing System Act
- The Personal Data Act, including the EU General Data Protection Regulation
- Regulations relating to medical quality registers
- Personal Data Regulations
- The Health Personnel Act
- The Patients' and Users' Rights Act
- The Patient Records Act
- Medical Devices Act
- The Medicines Act
- Product Liability Act
- Regulations relating to clinical trials of medicinal products for human use
- Regulations relating to experiments with animals

• Regulations on the use and maintenance of electromedical equipment
• Convention for the Protection of Human Rights and Human Dignity in the Application of Biology and Medicine: Convention on Human Rights and Biomedicine
• The Declaration of Helsinki
• Guideline for good clinical practice, ICH-GCP
• Regulations for the degree of philosophiae doctor (Ph.D.) at the University of Oslo