AHUS - Research ethics and research integrity in medical and healthcare research projects

1.0 Purpose

The procedure shall help to ensure good research practice and ensure good handling of any breaches and system errors.

Akershus University Hospital HF (hereafter Ahus) is responsible for ensuring that all research in which the company participates is carried out in a responsible and trust-building manner and that it is planned, carried out and concluded in line with statutory requirements and recognized research ethics norms. The guideline describes research ethical norms and research integrity that must form the basis of all research at the hospital. Research ethics includes laws, rules and norms that must ensure that research is carried out in a responsible manner with regard to patients, employees and society's interests. The term research integrity is often used to mean that the research must be carried out in a way that inspires trust and credibility, and that underpins the credibility of the results and trust in the research environment and the institution. Research integrity can be summarized as reliability, honesty, respect and responsibility in research.

The procedure is a supplement to EQS ID 41067 Ahus - Processing of cases of possible violations of recognized research ethics norms and EQS ID 15673 Ahus - Responsibility in quality and research projects. It must be made known to everyone involved in research, form the basis for training and be followed in the planning, implementation and completion of research.

2.0 Scope

Where does the procedure apply	All units that carry out research at Akershus University Hospital HF.
Who touches the procedure	Researchers and research staff, managers with responsibility in research (level 3, 2 and 1), research leaders, research group leaders and other research support personnel.

The procedure applies to research work carried out at the hospital, and work carried out at other institutions where employees in their capacity at Ahus have participated in the implementation of research projects.

3.0 Job description

3.1 Liability

The managing director is the research and data officer with overall responsibility for quality and research projects at Ahus, and has delegated tasks related to this, see detailed description EQS id 15673 Ahus - Responsibility in quality and research projects.

The following functions have executive responsibilities related to safeguarding this procedure:

Director of Research and Innovation (Level 2):	• Has responsibility for the implementation of the procedure • Shall draw up overall measures to ensure safeguarding of research integrity at Ahus
Division/clinic director (Level 2):	• Has responsibility for ensuring that this the procedure is made known and complied with within one's own area of responsibility at divisional level.
Head of Department (Level 3):	• Has responsibility for ensuring that this the procedure is made known and complied with within one's own area of responsibility at departmental level.
Research leaders:	• Has responsibility for continuously keeping up to date. The research leader will be a central point of contact in the dialogue/information flow between the health institution's research management and the divisions/clinics.
Department for Research Support, The Research and Innovation Division (FID):	• Responsibility for ensuring that the approved procedure is updated at all times. • Assist with guidance

3.2 Action

Researchers have a statutory duty to "act with care to ensure that research takes place in accordance with recognized research ethical norms", cf. Act on the organization of research ethics (Research Ethics Act) Section 4. It is also a statutory duty for the institution to ensure that the research takes place in accordance with recognized research ethics norms and that the necessary training is provided in this regard, cf. § 5 of the Act. Also particularly important is § 5 of the Health Research Act. Accountability: "Medical and health-related research must be organized and carried out responsibly. The research must be based on respect for the research participants' human rights and human dignity.

Consideration of the welfare and integrity of the participants must come before the interests of science and society. Medical and health-related research must take care of ethical, medical, health-related, scientific and privacy matters."

The guideline is based on European standards, including guideline for research integrity "All European Academies, ALLEA" All European Academies (ALLEA)-
European guidelines for research integrity and Standard for research integrity for the University of Oslo Standard for research integrity - For employees - University of Oslo (uio.no).

3.3 Terms and definitions

Research ethics

Research ethics includes a number of norms, values and institutional arrangements that help to regulate research activities. Research ethics norms also have points of contact with legal rules: this applies, for example, to norms for co-authorship which have points of contact with the rules on joint works in Act 15 June 2018 no. 40 on

copyright to intellectual property etc. (the Copyright Act) Section 8 and the norms for good reference practice that have points of contact with the right of citation and the naming obligation in the Copyright Act.

Within medicine and the health sciences, the subject-specific research ethics norms appear essentially from the Declaration of Helsinki, Oviedo Convention and by the Health Research Act. Furthermore, a number of subject-specific norms for medicine and health sciences have been given by the National Research Ethics Committee for Medicine and Health Sciences (NEM) and in addition about the institutions' responsibilities from the national research ethics committees: Guide on the institutions' responsibilities for research ethics | Research ethics (2023). Ahus has established a quality system for medical and healthcare research to facilitate compliance with the norms that apply to medical research (see section "Related documents"). For research in medicine and health, it is of the greatest importance to apply the subject-specific norms in research. Research ethics also includes external norms. These must protect research participants through consent, privacy, risk assessments etc., as well as ensure the research's contribution to societal benefit and welfare.

Research integrity

The Research Ethics Act is primarily an act on the organization of research ethics work. The Research Ethics Act, however, contains several norms that apply to research integrity. Integrity in research is a central and fundamental objective for Ahus. Research integrity can be summarized as reliability, honesty, respect and responsibility in research. It is fundamental for all research to show honesty in planning, carrying out and publishing research. Pursuing probity in research requires more than avoiding scientific misconduct. It involves actively promoting transparency, accountability and justice in all parts of research activities, defining criteria for good research practice, and responding adequately to threats to or breaches of research integrity.

Scientific misconduct means "falsification, fabrication, plagiarism and other serious breaches of recognized research ethics norms committed intentionally or grossly negligently in the planning, execution or reporting of research", cf. Research Ethics Act section 8 second paragraph.

3.4 Institutional responsibility for training, as well as handling system errors

Ahus has clear statutory frameworks for its overall operations, including research activities. *Research* at Ahus is regulated in special legislation for health research. The Health Research Act is particularly central. In the Act on the specialist health service, research is mentioned in section 3-8: *Tasks of hospitals.*

Ahus also has an institutional responsibility to facilitate good research ethics and - integrity, cf. Research Ethics Act §5, subsection 2:

> Research institutions must ensure that the research at the institution takes place in accordance with recognized research ethical norms. The institution is responsible for:
>
> a. necessary training of employees in recognized research ethical norms and
> b. that everyone who carries out or participates in the research is familiar with recognized research ethics norms.

At Ahus, research is organized in research groups with a clear professional and scientific management. All researchers must be associated with a research group. This is important for both professional, ethical, social and culture-building reasons. Emphasis is placed on making group leaders and line management aware of this responsibility, see EQS ID 33943 House - Mandate for research groups and EQS ID 33993 Ahus - Job description for research manager in division/clinic

3.4 Principles of research integrity

Ahus lays down the following principles for research integrity and fair conduct in research (to a large extent corresponds to the Standard for research integrity at UiO)

Within Ahus's framework, resources and management powers, the researcher has the right to choose the topic and method for his research, but this must be anchored in the line management in line with EQS ID 15673 Ahus - Responsibility in quality and research projects, and in line with the Health Research Act. The researcher and Ahus must protect the freedom and independence of research. The researcher is responsible for assessing acceptable risk and proportionality. All research must follow good referral practice. Training in this is a necessary prerequisite to avoid all forms of plagiarism.

- Researchers must assess and disclose conflicts of interest.
- The Vancouver criteria set minimum standards for academic eligibility co-authorship for all subject areas, ref EQS ID 15913 Ahus - Quality assurance of scientific publications emanating from Akershus University Hospital HF
- Researchers have a duty (cf. the Declaration of Helsinki) to publish their results and must ensure that such publication takes place, even negative results. This also applies to industrial collaboration and terms for this are regulated in the collaboration agreements entered into with the industry. Cooperation with industry must be based on an agreement that ensures that the hospital and employees are able to fulfill their statutory duties, including that commercial and academic interests are safeguarded in a responsible manner in accordance with the law, internal guidelines and recognized research ethics norms. Collaborative projects with industry must be organized in such a way that neither research participants, patients nor society can call into question the independence, integrity or professional judgments of the company or the employees.
- The relevant research basis must be made available in accordance with good practice in the relevant field, but provided that procedures for handling special categories of health data (sensitive data) are followed.
- It is a goal that all Norwegian scientific articles financed by public funds should be openly accessible by 2024, and the Ministry of Education has set "National goals and guidelines for open access to scientific articles". For researchers, the guidelines imply that they "must examine the possibilities of publishing their articles in open journals and choose open journals where it is professionally sound" and that the articles must be deposited in the scientific archive no later than the time of publication. It is also necessary to ensure that data sharing in connection with publication takes into account the necessary requirements for privacy.

- Managers, research leaders, research group leaders and supervisors must do their best to create and establish a culture of research integrity and compliance. Research results should be presented to the research group both before and after publication.
- All research must be assessed according to scientific quality, not just according to quantitative measures, cf. The San Fransisco Declaration on Research Assessment - DORA declaration
- In the case of research that involves collaboration across disciplines, institutions or countries, collaboration agreements should be entered into which also regulate issues of research integrity.
- Researchers treat the participants with respect and care, in accordance with legal and ethical provisions, be they humans, animals, culture, nature or the environment (ref. ALLEA, 2.4)

- Data must be stored, managed and shared responsibly, in line with the FAIR principles, cf. Guide for using the FAIR principles for health data sources - ehelse (ref. ALLEA 2.5)

4.0 Deviation/Dissent

Employees who become aware of possible breaches of recognized research ethical norms have a responsibility to report this, see also EQS ID 41067 Ahus - Handling of cases about possible breaches of recognized research ethical norms and EQS ID 15673 Ahus - Responsibility in quality and research projects

5.0 Related Documents

Ahus - Processing of cases of possible breach of recognized research ethics norms.
Ahus - Responsibility in quality and research projects
House - Mandate for research groups

Ahus - Job description for research manager in division/clinic
Ahus - Quality assurance of scientific publications emanating from Akershus University Hospital HF
Ahus - Responsibility in quality and research projects
Standard for research integrity at UiO

6.0 Basic information

6.1 Laws regulating health research

- Act of 20 June 2008 no. 44 on medical and healthcare research (Health Research Act)
- Regulations on the organization of medical and healthcare research (the health research regulations)
- Act 2017-02-10 no 23: Act on the treatment of ethics and honesty in research (research ethics act)
- Act of 5 December 2003 no. 100 on the human medical use of biotechnology etc. (Biotechnology Act)
- Act 2014-06-20 no 43: Act on health registers and processing of health information (Health Register Act)
- Act 2018-06-15-38: Act on the processing of personal data (Personal Data Act) with associated regulations
- Act 1999-07-02 no. 64: Act on healthcare personnel etc. (the healthcare personnel act)
- Act 1999-07-02 no. 63: Patient Rights Act (Patient Rights Act)
- Act 1992-12-04 no 132: Act on pharmaceuticals etc. (Pharmaceuticals Act)
- Regulation of 24 September 2003 no. 1202 on clinical trials of medicinal products for human beings

Set of norms included in the guidelines for research integrity:

- All European Academies (ALLEA) - European guidelines for research integrity.
- The national research ethics committees (NEM): Guidelines
- The national research ethics committees (FEK): Guidance on the institutions' responsibilities for research ethics | Research ethics
- The Declaration of Helsinki
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations
- OpenAccess - National goals and guidelines for open access to scientific articles
- The Oviedo Convention
- The Vancouver recommendations
- World Conference on Research Integrity