Ahus - Processing of cases of possible breach of recognized research ethics norms

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The deadline for revision of this document has passed, but the document is still valid.

1.0 Purpose

The procedure shall contribute to

- Clarify compliance with the duty to notify in the event of suspicion of scientific misconduct related to research projects at Ahus.
- facilitate a uniform case flow and discussion of cases with questions about scientific misconduct.

Research at Ahus must be carried out in accordance with recognized research ethics norms. Ethics must be integrated in all stages of the research process, through attitudes, actions, decisions and interaction. Ethics must also be reflected in routines, systems and organisation.

2.0 Scope

Where applies the procedure :	All units that conduct research at Akershus University Hospital HF.
Whose touching the procedure :	Research support staff, project staff, project managers, department heads, research managers, division/clinic directors, and the CEO must know this procedure.

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.

The procedure distinguishes between less serious breaches of recognized scientific norms which are assumed to be dealt with in the line in the clinic/division (cases that fall under ordinary non-conformance management, possibly personnel conflicts etc.), and cases which deal with more serious breaches ("scientific misconduct") which can, where the conditions are fulfilled, the joint integrity committee for research is notified.

Scientific misconduct refers to falsification, fabrication, plagiarism and other serious breaches of recognized research ethics norms committed intentionally or through gross negligence in the planning, execution or reporting of research (Research Ethics Act § 8).

The procedure is primarily limited to questions of misconduct in research. Matters that fall under the category of adverse events/deviations must be reported in EQS, under the reporting category research, see EQS id 34153 *Treatment, closure and follow-up of research-related adverse events/deviations*

If a notification deals with conditions other than violations of research ethics norms and is not a deviation that must be reported in EQS - these conditions must be processed in line with the routine for notification of objectionable conditions (EQS id: 7574) and guidelines for the handling of notification cases (EQS id : 33134).

3.0 Job description

3.1 Liability

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

Liability in research projects with suspected scientific misconduct:

Research and innovation director (Level 2):	• Prepare general measures for the prevention and treatment of scientific misconduct in research. • Receive information and participate in follow-up of suspected misconduct in research projects anchored at Ahus, or in projects where Ahus is affected.
Division / clinic director (Level 2):	• Prevent and follow up suspicions of misconduct in research projects based in or associated with their division. • Lead the investigative work in cases reported in the relevant division/clinic.
Head of Department (Level 3):	• Prevent and follow up suspicions of misconduct in research projects based in or associated with their department. • Assist level 2 manager in investigation work in reported cases.
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 • Be represented by a contact person for probity matters from Ahus who is reported to the joint probity committee.

3.2 Duty to notify

All employees who, as part of their work at Ahus, become aware of possible breaches of recognized research ethical norms, have a responsibility to report them. To ensure proper treatment, the person reporting should do so in writing. Notifications can either notify in accordance with already created notification routine see "Notification system" at Ahusveven (see also EQS id 7574), or notify directly to manager level 3 or division/clinic director, with a description of:

- What the suspicion is about
- Who is the suspect
- In what context is there a suspicion of a breach, including the time/period
- If the breach relates to results that have been published and/or are about to be published.

The employee can request an oral meeting with the manager (level 3, possibly level 2) to explain the suspicion. In that case, the leader must keep minutes of the meeting. Otherwise, point 3.3 below applies regarding competence and conflicts of interest.

The current line manager who receives the notification/message must create a case number in public 360 with ad hoc access. The case archive (postmottak@ahus.no) must then be contacted, so that access is only created for people with official needs. All documents related to the case must be archived on this case number with the title " *Assessment of research ethics norms* ". Case title will be visible in public 360, but only personnel responsible for follow-up will have access to associated documents. The director of research and innovation, as well as representatives from the department for research support, will have access/inspection to all matters marked " *Assessment of research ethics norms* ".

The director of research and innovation must be informed as soon as possible about the work that is being initiated.

The Department for Research Support, the Research and Innovation Division, can, upon request, provide advice and guidance in connection with notification of possible breaches.

The research ombudsman, shared by Oslo University Hospital, the Department of Clinical Medicine, UiO and Akershus University Hospital, can also assist with independent advice and guidance, in case of any suspicion. See mandate under section 5.0 appendix.

Cases that are assessed for suspected violations of the Research Ethics Act must also be assessed for reporting to the Norwegian Health Authority and/or the Norwegian Data Protection Authority, if the suspicion includes a possible violation of the Norwegian Health Research Act and/or the Personal Data Act.

3.3 Follow-up responsibility in line and competence

A manager (level 3) who receives a notification of a possible breach of recognized research ethics norms is obliged to pass it on to a superior manager (level 2) if the relevant person so requires. Manager (level) 3 assists the division/clinic director in connection with the investigation of the case. The line manager is always obliged to keep the division/clinic's research manager informed.

If the case is initially considered to be less serious, or in the category of unwanted event/deviation, the manager (level 3) must process the case in line with the procedure "Responsibility in quality and research projects"

In cases that cannot be handled in subordinate units due to impartiality or other significant conflicts of interest, the employee can report the case directly to the division/clinic director (level 2) or research manager. In cases where there are competence or other conflicts of interest that prevent a proper follow-up in line, the responsibility for follow-up and case management can be transferred to the director of research and innovation, or alternatively a division director/clinic manager in another division/clinic. In such cases, the department for research support will assist with clarification as to which clinic/division/research manager can take the case further.

A manager who processes a report according to this procedure does not have the opportunity to delegate this task to the research representative, but can be assisted where all parties concerned agree to this.

3.4 Case processing at the institution

Heads of department (level 3) who receive a report are responsible for bringing the case forward to the division/clinic director for further follow-up and treatment of the case. The basis for this case management is:

- Ensure that the case is adequately disclosed
- Ensure that affected parties are given the opportunity to express themselves
- Ensure that the matter is dealt with at a level where there are no conflicts of interest or other conflicts of interest
- Ensure that the confidentiality of the parties is safeguarded in a reassuring manner
- Ensure that the case is assessed with regard to the reporting obligation to the Norwegian Health Authority and/or the Norwegian Data Protection Authority

The following procedure applies to treatment:

1. Investigation (mapping, assessment and follow-up). It is recommended to design a timeline for all correspondence in the project.
2. Dismissal (the concern is unfounded or it is found after the investigation that there are no grounds for pursuing the case as a result of a lack of documentation or that the case deals with matters other than questions of misconduct in research). Dismissal with reasons must be in writing, and documented in p360 on created case no . See section 3.2.
3. Placement of follow-up responsibility in the line, at a lower management level if appropriate. Division director/clinic manager (level 2) delegates any tasks to a lower management level.

Anyone who has registered a case, and who himself has a role in the project in question, must receive feedback within a reasonable time about the plan for handling the case. Where the information in the case requires discretion according to the privacy regulations, this must be taken into account when giving feedback. If the notifier does not have a role in the project or is involved in the form of holding a managerial responsibility, no further information about the proceedings will be disclosed.

Managers at all levels also have a duty of care for the employees involved in this type of case, both the person who conveys a concern and the one concerned. Professional assistance can be obtained from the occupational health service, which in turn can provide different types of support personnel as needed.

As part of processing the case, the manager can request independent advice from the research representative.

3.5 Statements

The manager, who according to this procedure has dealt with a report of suspicion of objectionable circumstances in research, must prepare a written statement on the matter. The statement can be drawn up by the level 3 manager, but must always be approved and signed by the division/clinic director (level 2). The document is stored in P360 on the created case number. The statement must contain at least:

- Whether it can be proven that the researcher has behaved in a reprehensible manner
- If there are system errors that line management believes must be followed up
- Whether there are grounds for withdrawing an already published work as a result of the conditions that have been uncovered

If, during the proceedings, information emerges that gives grounds for assuming that there may be gross violations of recognized scientific norms ("scientific misconduct"), the case must be referred to a joint integrity committee. The divisional/clinical director and/or research manager can also ask the department for research support, FID, for assistance in assessing

whether a case should/should be submitted to the Ethics Committee. If it is decided to report the case, the report must be sent from the department for research support, FID, on behalf of the institution responsible for research, see form to the integrity committee

3.6 Processing of cases in the integrity committee for research

An Integrity Committee has been established for research in collaboration with the Department of Clinical Medicine at the Faculty of Medicine, University of Oslo, Oslo University Hospital HF and Akershus University Hospital HF.

The integrity committee's tasks are set out in its own mandate and case management rules, see section 5.0 appendix. As a starting point, the committee will only deal with cases where there is suspicion of "scientific misconduct" according to Section 8 of the Research Ethics Act.

The head of the Integrity Committee for Research has, in accordance with the rules of procedure, the opportunity to reject cases that the person in question believes do not fall within the committee's mandate.

3.7 Preparation for submission to the integrity committee

Cases for consideration by the integrity committee must be presented in writing in a separate form and must follow the committee's case management rules. For more information on case preparation and requirements for documentation, as well as the notification form for cases to the fairness committee, see the separate websites in the link under section 5.0.

Matters that are reported to the joint integrity committee must also be considered for parallel reporting to the relevant supervisory authority, including the Norwegian Health Authority and/or the Norwegian Data Protection Authority.

3.8 Assessment of consequences

The result of the treatment may require measures aimed at individuals (sanctions/facilitation, knowledge raising) or at the organization (changes/improvements/compliance) that affect routines, systems and/or organisation.

Line management is responsible for choosing measures/further follow-up, see EQS id 15673 *Responsibility for quality and research projects*

The manager must assess follow-up/reporting to other institutions/collaborating partners where applicable. The manager must also assess the need for dialogue with relevant journals/editors and collaboration partners

4.0 Related Documents

Ahus - Responsibility in quality and research projects

Ahus - Treatment, closure and follow-up of research-related adverse events/deviations

Ahus - Workflow - handling of research-related unwanted incidents/deviations

Ahus - Overarching procedure for the treatment and follow-up of unwanted incidents/deviations

Ahus - Treatment, closure and follow-up of patient-related adverse events/deviations

Ahus - Overview of obligations to report unwanted incidents/deviations

Ahus - Joint integrity committee for research for the Department of Clinical Medicine and the university hospitals

Ahus - Mandate for Research Representative

6.0 Basic information

6.1 Basic documents

Act on the organization of research ethics work (Research Ethics Act)

Research ethics guidelines

6.2 Definitions

Scientific misconduct: Scientific misconduct refers to falsification, fabrication, plagiarism and other serious breaches of recognized research ethics norms committed intentionally or through gross negligence in the planning, execution or reporting of research (Research Ethics Act § 8).