



Guidelines for the handling of cases concerning potential violations of recognized norms of research ethics for the Commission on Research Integrity at the Department of Clinical Medicine at the Faculty of Medicine, the University of Oslo, Oslo university hospital HF and Akershus university hospital HF.

These guidelines have been established by the University of Oslo, Oslo university hospital HF and Akershus university hospital HF pursuant to the Research Ethics Act (Law 28 April 2017 no. 23 on the Organization of Research Ethics § 6 third section.

1. Purpose

The University hospitals; Oslo university hospital (OUS) and Akershus university hospital (Ahus), will together with the Department of Clinical Medicine, UiO (Klinmed) facilitate for good and responsible practice so that questions of research ethics will be discussed and clarified together with colleagues in the research environment or in the administrative line, in accordance with the Research Ethics Act. The ombudsman for science may provide guidance in questions on research ethics.

Notifications on possible violations on recognized norms of research ethics should undergo justifiable and safe processing. The handling of cases should follow general principles in administrative law, regarding impartiality, contradiction and the right of access for each party. Violations of recognized norms of research ethics may only be concluded after a written statement has been provided by the Commission on Research Ethics.

2. Scope

These guidelines apply to the handling of cases of possible violations of recognized norms on research ethics involving persons who have or have had an affiliation with OUS, Ahus or Klinmed.

The Commission on Research Integrity shall upon request also handle cases from other Health Trusts within Helse Sør-Øst.

3. Definitions

Recognized norms on research ethics:

General and specific guidelines of good scientific practice as these at any time are described by current national and international guidelines and conventions. Of special importance in this connection are the general and specific guidelines prepared by the National Committees for Research Ethics

Violations on recognized norms on research ethics:

Violations on general and specific guidelines of good scientific practice, especially important in this connection are general and specific guidelines prepared by the National committees on research ethics.



Scientific misconduct:

Forgery, fabrication, plagiarism and other severe violations on recognized norms on research ethics committed intentionally or with gross negligence in the planning, execution or reporting of research, ref. the Research Ethics Act § 8, second section

The National Commission for the Investigation of Misconduct in research (Granskingsutvalget - GRU):

Is the appeal body in cases where the institutions have concluded that scientific misconduct has occurred and may also initiate an investigation by its own authority. The statements of the Commission of investigation are final and may not be appealed.

4. Responsibility

The Chief Executive Officers at the OUS and Ahus and Rector *has the superior responsibility for and the management of research activities within their institutions and shall make sure that:*

- The research at the OUS, Ahus and Klinmed is being conducted in accordance with recognized norms of Research Ethics
- System errors which may lead to violations of recognized norms of research ethics be prevented and corrected if they occur. This involves among other things making sure that:
 - necessary training in recognized norms of research ethics are given to candidates and employees
 - everyone conducting or participating in the research, are familiar with recognized norms of Research Ethics
- Cases of possible violations of recognized norms on research ethics are handled in a justifiable way
- A Commission on Research Integrity should be established, having the relevant competence to evaluate possible violations of research ethics at OUS, Ahus and Klinmed
- guidelines are established for the notification and handling of cases of possible violations of Norms of research ethics at OUS, Ahus and Klinmed. In the handling of such cases a statement should be obtained from the Commission on Research Integrity which should decide
 - a) whether the researcher has committed scientific misconduct or not
 - b) whether there are system errors at the institution and
 - c) whether the scientific work should be corrected or withdrawn.
- OUS, Ahus and UiO notify cases of possible serious violations of recognized norms on research ethics to the GRU.

The Directors of Division at the university hospitals OUS and Ahus, and the Dean at the Faculty of Medicine at UiO *shall as representatives of the Chief Executive Officers and Rector, respectively, at its own institutions:*

- facilitate that the research is conducted in accordance with recognized norms of research ethics
- make sure that necessary training in recognized norms of research ethics is given to candidates and employees in their own unit
- make sure that everyone conducting or taking part in the research are familiar with recognized norms of research ethics
- report on possible violations of recognized norms of research ethics to the Commission for research ethics if a case has affiliations to their own unit and make sure



- the case is submitted to the commission for research Ethics with a description of the contents of the case as well as the documents of the case for further processing

The Chief Executive Officers in the university hospitals and the university director shall

- report to the GRU when a case concerning a possible violation on recognized norms of research ethics has been processed to completion at the OUS, Ahus and Klinmed

The ombudsman for research is employed by the Faculty of Medicine, in understanding with OUS, Ahus and the university director, following an internal announcement. The ombudsman for research has as his task to

- provide guidance and advice to scientific employees finding themselves in a situation which is considered to be problematic with regard to research ethics.
- provide independent, impartial information and treat any inquiries and cases in confidence.

The Commission for Research Integrity is a professionally independent organ established by the Rector and Chief Executive Officers in the university hospitals as a commission for the investigation of research misconduct at OUS, Ahus and Klinmed, in order to

- provide statements in cases pertaining to research ethics in line with these guidelines for the handling of cases on possible violations on recognized norms of research ethics.
- provide statements in cases which are affiliated with all units at OUS, Ahus and Klinmed
- be an advisory organ for work pertaining to research ethics at OUS, Ahus and Klinmed

The Commission for Research Ethics cannot be instructed

UiO's Director of Internal Audit at the Internal Auditing Unit - EIR reports to the board of the university

- has the responsibility for keeping an overview of audits by external supervisory authorities.
- is responsible for conducting internal audits

5. Processing of cases

5.1 Introductory processing of cases

5.1.1 Submission

Notification of possible violations on recognized norms on research ethic are submitted in writing on a separate form to the Commission on Research Ethics.

The Commission on Research Integrity may in its meetings address any case on its own authority. The secretariat will obtain the necessary documents. Otherwise, the processing of the cases is done as in other cases.

5.1.2 Reception

On reception a case is created in UiO's system for case processing. Case processing is exempt from publicity from the moment of receipt of a notification until a statement in the case is available

The secretariat for the Commission on Research Integrity will provide the notifier with a message that the notification has been received.



The Commission on Research Integrity will then perform an introductory evaluation of the notification to establish any further processing of the case.

5.1.3 Rejection

The case is rejected in a meeting

- if it is obviously unjustified, ie. it does deal with questions of possible violations on recognized norms on research ethics
- if the notification on possible violation on recognized norms of research ethics lacks a factual basis
- if the notification has been submitted to the wrong institution

5.1.4 The competence of the chair of the Commission

The chair of the Commission may reject a case before it is presented for handling in the Commission if it is considered to lie outside the factual and institutional area of activities of the commission.

In cases dealing with several institutions, the chair of the commission following a discussion with the corresponding Commissions of Research Ethics at these institutions, make a decision as to which commission should handle the case.

5.1.5 Impartiality

The members of the Commission on Research Integrity will evaluate their own impartiality within each case.

The same goes for any deputy members who may have been summoned.

5. 1. 6. The distinction between cases pertaining to research ethics and whistleblowing-/cases pertaining to human resources

In the cases where the Commission on Research Integrity is informed of a whistleblowing case/a human resource case which has been established, the commission should not receive information on matters associated with such cases. The background for this is that the own evaluations of the members associated with a notification of possible violations of recognized norms of research ethics should not be influenced by the whistleblower case. Cases pertaining to research ethics should be kept separate from Human Resource and whistleblower cases.

5. 1. 7. Experts

The Commission on Research Integrity will evaluate the need for external expertise and possible need for an ad hoc-commission established with members from the Research Ethics Committee at the UiO and the Commission for Research Ethics, respectively, in order to handle the case.

5.2 Preparation of a case and decisions on further processing

The Commission on Research Integrity will send a formal response to the inquiry to the notifier with an invitation to a conversation. The Commission on Research Integrity will send a written advance notice to the notified that the commission has received a notification of a possible violation of recognized norms for Research Ethics, and that the case will be admitted for processing. The letter should contain the notification and an invitation to a conversation with the commission.



The notifier and the notified will themselves decide whether to meet for a conversation.

The notifier and the notified have the right to bring supporting persons to the meeting.

If the contents of the case so indicate, the Commission on Research Integrity may decide that the entire commission will not take part in the meeting.

5.3 Processing in the Commission on Research Integrity

The conversations will be conducted with the notifier and the notified and minutes of the meeting will be prepared.

The parties will have an opportunity to comment on the written draft of the minutes concerning their own conversation. A deadline for this is normally fixed at two weeks.

The comments will thereafter be evaluated by the Commission on Research Integrity before final minutes are prepared and which are sent collectively to both the notifier and the notified.

If the notifier or the notified does not wish to attend a conversation, the processing of the case is conducted in writing as far as they are concerned.

The Commission on Research Integrity will evaluate the total collected information in the case and will prepare its statement.

The Commission on Research Integrity will make a decision on whether a violation has occurred of one or several recognized norms of Research Ethics which should be adhered to at the University of Oslo and to evaluate the degree of severity. This includes the serious violations fabrication, forgery and plagiarism. It will also be decided whether the violation has been done intentionally (on purpose) or grossly negligent (marked deviation from justifiable behaviour).

The statement should always take into account:

- a) whether the researcher has behaved scientifically dishonest or not
- b) whether system errors are present at the institution
- c) whether the scientific work should be corrected or withdrawn

Drafts of a statement from the Commission will be prepared and sent to the notifier and the notified with a possibility to make a statement.

The Commission will prepare the final written statement.

5.4 Statement from the Commission on Research Ethics

The final statement is sent to the notifier and the notified with a copy to Rector, Chief Executive Officer of the university hospitals, the leader of the clinic (OUS)/departmental director (Ahus) of the university hospital and the dean of the Faculty of Medicine at the UiO.

The final statement from the Commission on Research Integrity will be published in an anonymized form.



5.5 Right of appeal

If the Commission on Research Integrity finds that scientific misconduct has occurred, the researcher shall be informed that the decision may be appealed to the GRU. Only the researcher receiving the statement that this person has committed misconduct has the right of appeal to the GRU. The deadline for appeal is three weeks from receipt of the statement. This should be stated in the statement from the Commission on Research Ethics.

A notifier, who is not successful in the allegation that scientific misconduct has been committed, does not have the right of appeal. There is also no right of appeal against statements that violations of recognized norms on research ethics have occurred, that are not covered by the concept of “scientific misconduct”, or the further follow-up of these cases.

6. Completion of internal and external follow-up.

When the final statements is available from the Commission on Research Ethics, the case may be followed up in the way that appears most appropriate for the contents of the case.

Where no violations on recognized norms on research ethics have occurred:

If the case has entail unlawful harm to the reputation of a researcher, the leader(s) of the Institution shall make sure the harm is limited.

Where violations on recognized norms on research ethics have occurred:

The Directors of Division at the university hospitals OUS and Ahus, and the dean of the Faculty of Medicine at the UiO may request that the researcher submit an “Errata” to the journal or withdraw the article or initiate another suitable reaction. If the researcher does not follow up on this, The Directors of Division in the university hospitals OUS and Ahus, and Dean of the Faculty of Medicine must themselves make sure that this is completed.

System error

If the statement from the Commission on Research Integrity points to substantial system errors in the case, this will be presented to the Directors at OUS or Ahus and Rector for follow-up.

Notification to the GRU

The Chief executive officers at OUS and Ahus and the Director of the University will submit a report on the institution’s handling of the case to the GRU.

Follow up by Human Resources

Potential follow-up by the Department of Human Resources will be initiated and completed by the management in the usual manner.