

Guidelines for examining suspected deviations from good research practice

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NOTE: This is a translation of the Swedish version (Riktlinjer för prövning av misstänkta avvikelser från god forskningssed). In the event of any discrepancy between the versions, the Swedish version constitutes the official decision, and the Swedish wording will prevail.



**Karolinska
Institutet**



Guidelines for examining suspected deviations from good research practice

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Revision with respect to:

The council's mandate to be responsible for feedback is removed. The council is tasked with assisting the Committee for Ethics and Good Research Practice. KI does not investigate deviations that occurred outside of KI's operations. Clarifications of the notified right to speak and of measures following cases in the national board. Adjustments regarding misconduct in research supported by the US Public Health Service. Linguistic and editorial changes.

1. Introduction

The Higher Education Act (1992:1434) provides that in the course of their operations, higher education institutions (HEI) shall uphold academic credibility and good research practice, and that the operations of higher education institutions shall be arranged to ensure that high standards are attained in courses and study programmes and in research. All deviations from good research practice must therefore be prevented and suspicions of such be handled in a way that does not undermine the confidence of the general public in research.

It is the researcher's responsibility to observe good research practice in his/her research. As research principal, Karolinska Institutet (KI) has overall responsibility for ensuring that its research is conducted in accordance with good research practice.

Further, the Act on responsibility for good research practice and the examination of research misconduct (2019:504) provides that if there is a suspicion of research misconduct the case should be examined by a national board. According to the Higher Education Ordinance, other suspected deviations from good research practice than the above are to be examined by the HEI itself (Chapter 1 Section 17 Higher Education Ordinance [1993:100]). The HEI must have guidelines for its examination of suspected deviations from good research practice.

KI thus has an obligation to investigate suspected deviations from good research practice that have occurred within KI's operations.

These guidelines pertain to everyone engaged in research activities at KI and those who handle cases of suspected scientific misconduct or other deviations from good research practice at KI.

In the event of suspected scientific misconduct in research financed by the Public Health Services (PHS) additional rules apply (see section 10).

Research conducted without an ethical or other type of permit is covered by separate rules and is therefore dealt with elsewhere.

These principles do not apply to research in the field of defence and security policy, which is regulated separately in the ordinance concerning exemptions from investigation of misconduct in defence and security policy research (2019:1176).

2. Definitions

Scientific misconduct is, according to 2 § of the act on responsibility for good research practice and examination of misconduct in research, defined as a serious deviation from good research practice in the form of fabrication, falsification or plagiarism committed intentionally or through gross negligence in the planning, execution or reporting of research.

Other deviations from good research practice includes such deviations that do not constitute misconduct but that damage or threaten to damage the integrity of the research processes, research or a researcher by act of intention or gross negligence in the planning, execution or reporting of research.

The examination of the latter shall be based on relevant national and international rules and principles in force at the time that the research in question was conducted or reported, such as the Swedish Scientific Council's report Good Research Practice, the European Code of Conduct for Research Integrity from ALLEA, the international publication standards set by the Vancouver Convention, and the COPE (Committee on Publication Ethics) ethical guidelines for peer reviewers.

3. Examination of suspected scientific misconduct and other deviations from good research practice

Cases of suspected scientific misconduct are examined under a separate system by the *National Board for Assessment of Research Misconduct* (the national board).

Cases of other deviations from good research practice are examined by KI's internal *Council for the Examination of Deviation from Good Scientific*

Practice (the council). Decisions on such cases are pronounced by the president.

Examination of misconduct in research or other deviations from good research practice may not be based on circumstances that are older than ten years when the case was initiated, unless there are special reasons for an examination.

4. KI's Council for the Examination of Deviations from Good Research Practice

The council comprises a chairperson who is or has been a legally trained judge, three faculty representatives with sufficient scientific competence and integrity, the chief legal officer and a student representative. All members, except for the student representative, are appointed by the president for a three-year term. The student representative is appointed for a term not exceeding one year. The appointment can be renewed for up to three years at a time for the members and up to one year at a time for the student representative.

If a member leaves KI, for whatever reason, or takes a central or departmental managerial position, the president appoints a replacement. All appointments are to be made with respect to principles of equality and equal opportunities. The president also appoints from their number a vice-chairperson.

The faculty and student representatives must also have deputies, appointed in the same manner and for the same period of time as the ordinary representatives.

The council is assisted by a legal expert appointed by the chief legal officer. The legal expert is the responsible case administrator.

Anyone who has a conflict of interest may not participate in the handling or examination of a case.

The council shall

- decide if a case qualifies as suspected scientific misconduct and, if so, pass it to the national board for examination

- investigate other suspected deviations from good research practice than scientific misconduct
- assist KI's committee for ethics and good research practice, for example in the committee's task of following up the council's statements and the president's decisions.

5. Opening a case

5.1 Written report

Any suspicion of scientific misconduct must immediately be reported in writing to the national board or the president.

Any suspicion of other deviations from good scientific conduct must immediately be reported in writing to the president.

The president refers the complaint to the council.

5.2 Handovers from the national board

If the national board judges that a case does not qualify as scientific misconduct but as another deviation from good research practice, it is, according to 11 § of the act on responsibility for good research practice and examination of misconduct in research, required to notify KI of such and hand the matter over to the KI president, who refers it in turn to the council for further investigation.

5.3 Own-initiative inquiry

If attention is drawn to suspected scientific misconduct or other deviations from good research practice by a means other than written report or a handover from the national board, KI is required to open an own-initiative inquiry at the discretion of the president.

The president refers the case to the council.

6. Investigation

6.1 Initial review

The council carries out an initial review of a report or an own-initiative inquiry to gather the information needed to determine whether or not the

case is to be passed to the national board, given further examination by the council or handled in another way.

If after such a review the council chairperson finds, in consultation with the faculty representative, that the matter qualifies as suspected scientific misconduct, he or she must report it immediately to the president, who promptly decides whether it is to be referred to the national board.

6.2 Investigation

The council investigation is to be concluded with the least possible delay and with respect for the complainant, the respondent and everyone else concerned.

In the process of its investigation, the council is to provide the respondent with an opportunity to give his or her verbal or written account of the matter. The respondent has the right to access all material added to the case.

The departments and the professional services are to assist the council in its work to whatever extent the council so wishes. It is the responsibility of the departmental heads and the university director to ensure this happens.

The council may engage an external expert unaffiliated with KI. The expert's statement should be made in writing.

When the investigation is deemed concluded, the council is to write a statement explaining its proposal for a decision on the case. The respondent must be given the opportunity to comment on the statement. The statement should also be sent to the external expert (if engaged) for information. The council then submits its proposal for decision to the president.

7. Final decision

The president decides after a completed investigation whether the circumstances are such that other deviations from good research practice were present or not. The president makes a decision after the presentation.

The president decides whether a case is to be closed and cancelled if

- the allegations are clearly unfounded
- the complaint is so incomplete that it cannot be used as the basis of an investigation
- the matter has already been investigated, and no new information has been forthcoming to affect the previous decision
- the matter should be examined by KI in another way
- the matter has already been examined by an external body (e.g. the national board or another HEI)
- the case concerns research that did not take place within the framework of KI's operations.

8. Actions directed at the individual

The head of the department concerned is responsible for the department offering the employee the necessary support during the investigation at the national board or in the council. The head of department is also responsible for following the case during the investigation and for contacting the labour law function at the HR department as soon as possible if there is reason to investigate whether any labour law measures need to be taken. Disciplinary measures in the form of salary deductions or warnings as well as separation from employment through termination due to personal reasons or dismissal are decided by KI's personnel disciplinary committee.

If a researcher is freed from suspicions of misconduct or another deviation from good research practice, appropriate steps must be taken to remedy any possible damage caused by the allegations and their handling.

9. Reporting

The council secretariat shall inform the department concerned if the president decides that there has been a deviation from good research practice and if the national board has decided that there has been misconduct in research, or if it is apparent from the board's decision that there has been a serious deviation from good research practice in the form of fabrication, falsification or plagiarism without intent or gross negligence having been established. The department shall

- as soon as possible after the national board's decision, inform the relevant research funders, authorities, scientific journals and other interested parties about the decision, and inform them that the decision may be appealed
- report taken and planned actions as a result of the president's or the national board's decisions to the council's secretariat.

If several departments are affected by the decision, they may decide among themselves which department will send out information and report actions.

The president is responsible for reporting back to the national board, within six months of the national board's decision becoming legally binding on the measures that have been taken or intend to be taken in response to the decision.

The president is required to submit anonymised details to the national board by 30 March every year on deviations from good research practice that have been examined by KI over the past calendar year.

10. Separate rules for suspected scientific misconduct concerning research financed by the USA's Public Health Service (PHS)

10.1 Introduction

In the event of suspected scientific misconduct concerning research financed by the Public Health Service (PHS) communicated through one of its bodies, particularly the National Institutes of Health (NIH), the following shall apply according to the policies on Research Misconduct – Final Rule 42 Code of Federal Regulations (CFR), Part 93.

The Office of Research Integrity (ORI) is a body of the USA's Department of Health and Human Services (DHHS) charged with overseeing and directing research integrity activities.

A case according to the procedure below shall only be opened for scientific misconduct that occurs within six years of the date on which the DHHS or the president of KI receives an allegation of scientific misconduct.

10.2 Notice to ORI

ORI must be notified immediately if and when any of the following conditions exist during an investigation:

- There is an immediate health hazard involved (human or animal).
- There is an immediate need to protect Federal funds or equipment.
- There is a need to discontinue research activities.
- There is an immediate need to secure evidence.
- There is reasonable suspicion of criminal acts or violations of other legislation.
- There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations.

The Compliance & Data Office (CDO), at the Research Support & External Relations Office, is responsible for ensuring that notification is made.

10.3 Initial inquiry

The council shall, after submission from the president, complete a preparatory investigation within 90 days of the case being initiated.

If the council finds that an inquiry should be discontinued, it must notify the president promptly. CDO then reports the discontinuation and the reason for it to ORI.

10.4 Handover to the national board

If, after the preliminary investigation, the council finds that the matter should be referred to the national board, this shall be reported promptly to the president. ORI shall be informed of this within 30 days. ORI shall at the same time receive the documentation from the preliminary investigation.

The national board shall be informed in connection with the submission that the matter is covered by the above-mentioned American regulations.

10.5 Full investigation

If the matter is not referred to the national committee but the council finds that a full investigation into other suspected deviations from good research practice should be conducted, ORI shall, within 30 days, be informed of the

findings of the preliminary investigation, receive a copy of the investigation and be notified that a full investigation will be conducted.

A full investigation should be completed within 180 days of the date the investigation was initiated. If this is not possible, an application for a deferral should be made to ORI. The complainant shall be given access to the investigation report and other supporting documents and shall be given the opportunity to submit comments on the material within 30 days.

If the council finds that a full investigation should be discontinued, this must be reported to the president as soon as possible. CDO must report this to ORI, explaining the reason for the discontinuation.

10.6 Action taken after decision

ORI must be promptly informed about the investigation, KI's final decision and the action KI intends to take.

10.7 Documentation

All documentation must be kept for at least seven years to be made available to the ORI or authorised PHS personnel.

