Guidelines for examining suspected deviations from good research practice

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1 Introduction

The Higher Education Act (1992:1434) provides that in the course of their operations, higher education institutions 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 in the activities of the entity responsible for research, the entity responsible for research must submit the case documents for examination 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 Higher Education Institution itself (Chapter 1 Section 17 Higher Education Ordinance [1993:100]).

The provisions 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.

Special rules

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 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 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*.

Cases of other deviations from good research practice are examined by KI's internal *Council for the Examination of Deviation from Good Scientific Practice*. Decisions on such cases are pronounced by the president.

4 Council for the Examination of Deviations from Good Research Practice

KI shall have a *Council for the Examination of Deviations from good research Practice* (the Council).

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 with the exception of 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.

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
- handle matters relating to the reporting obligation provided in Section 13 of the Act on responsibility for good research practice and the examination of research misconduct.

5 Opening a case

5.1 Written report

Any suspicion of scientific misconduct must immediately be reported in writing to the National Board for Assessment of Research Misconduct 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 for Assessment of Research Misconduct judges that a case does not qualify as scientific misconduct but as another deviation from good research practice, it is 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 account of the matter.

The departments and the university administration 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 must 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 statement is to be sent to the complainant and the respondent and should also be sent to the external expert (if engaged). The Council then submits its proposal for decision to the president.

The final decision on the case is taken by the president after presentation.

7 Final decision

The president decides on cases of other deviations from good research practice.

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 for Assessment of Research Misconduct or another higher education institution).

8 Further action

When the National Board has decided that the case is one of scientific misconduct or following his or her own decision on another deviation from good research practice, the president is to decide whether there are grounds for considering further action, disciplinary or otherwise.

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

It is the president's responsibility to ensure that financiers, authorities, scientific journal and other parties concerned are informed should a case be judged one of scientific misconduct or other deviations from good research practice.

It is the president's responsibility to ensure that a report is submitted to the National Board for Assessment of Research Misconduct on the action that KI has taken or intends to take as a result of a board decision on scientific misconduct, or if a board decision makes it clear that there has been a serious deviations from good research practice in the form of fabrication, falsification or plagiarism without established intentionality or gross negligence. Such a report is to be submitted by no later than six months from when the board's decision becomes legally binding.

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 12 months.

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 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 exists during an investigation.

- a) There is an immediate health hazard involved (human or animal).
- b) There is an immediate need to protect Federal funds or equipment.
- c) There is an immediate need to secure evidence.
- d) There is a reasonable indication of possible criminal violation.
- e) 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.
- f) It is probable that the alleged incident is going to be reported publicly.

10.3 Initial inquiry

An inquiry must be completed within 60 days of its initiation.

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

10.4 Full investigation

If a full investigation is to be conducted, the ORI is to be informed of the outcome of the inquiry, provided with a copy of the inquiry and be notified of the coming investigation within 30 days of completion of the inquiry.

An investigation should ordinarily be completed within 120 days of its initiation. If this is not possible, a written request for an extension must be submitted to the ORI.

If the Council finds that an investigation should be discontinued, it must notify the president promptly. The president then reports the discontinuation and the reason for it to the ORI.

10.5 Action taken

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

10.6 Documentation

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