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Decision regarding research misconduct

Decision

The National Board for Assessment of Research Misconduct ("the Board") finds [redacted] and [redacted] guilty of research misconduct.

The Board finds [redacted] and [redacted] not guilty of research misconduct.

Background

On 10 June 2022, a case of alleged research misconduct was reported to the Board by [redacted] and [redacted].

The research concerns transplantations of synthetic tracheas and research concerning various porous plastic materials intended to be used for synthetic tracheas, especially how well stem cells attach to the various materials.

The report relates allegations of fabrication and/or falsification in the following:

- [redacted] (2012). Viability and proliferation of rat MSCs on adhesion protein-modified PET and PU scaffolds. *Biomaterials*, 33(32), 8094–8103. https://doi.org/10.1016/j.biomaterials.2012.07.060.

  The allegations relate to fabrication and/or falsification through incorrect description, in several places in the article, of the follow-up of the patient who had a synthetic trachea transplanted at Karolinska Hospital in June 2011. The authors whose names are underlined conducted their respective parts of the research at a Swedish entity responsible for research.

Respondents' statements with respect to the allegations

[redacted] statement

[redacted] contests the allegation that she is guilty of fabrication or falsification. During her work on the article, she was a doctoral student at the Department of Cell and Molecular Biology at Karolinska Institute, with [redacted] as supervisor. She says that she and [redacted] were asked to teach two medical students from [redacted]

[redacted] group, [redacted] (now, and below, [redacted]) and [redacted]. The medical students spent six weeks in their laboratory learning how to culture and analyse cells by means of various methods. [redacted] writes that she and [redacted] helped to plan the experiments for the article, but that execution, analysis and compilation were performed by the medical students themselves. She and [redacted] read and approved the article before it was submitted for publication in June 2012, but she states that they had no access to medical records or clinical studies regarding the patient in question.

[redacted] statement

[redacted] contests the allegation that he is guilty of fabrication or falsification. He states that he conducted work on the article during his time as a doctoral student at Karolinska Institute. He explains that he is not a medical doctor and was not involved in the care or follow-up of the patient in question. He states that he lacks the expertise to assess the patient records attached to the allegation report. Instead, his contribution to the article consisted in analysis of the rat cells used in the experiments.

[redacted] statement

[redacted] contests the allegation that he is guilty of fabrication or falsification. He explains that he did not take part in care of the patient concerned; had no access to notes in patient records; and lacked opportunities for discussing patients with treating physicians. He agrees that the description of the clinical outcome did not tally with reality, but thinks the alleged offences probably do not constitute research misconduct.

[redacted] statement

[redacted] contests the allegation that she is guilty of research misconduct. She explains that, not being a medical doctor, she is unable to assess the clinical data attached to the allegation report. However, the allegations appear to have a solid foundation, in her view. On 8 June 2012, she and [redacted] received a draft of the article from [redacted], the first author. They read the draft and submitted comments on the parts of the manuscript that they perceived as being within their sphere of expertise, which did not include the description of the patient concerned. In addition, [redacted] submitted the same account as [redacted] of the division of labour between herself and [redacted], on the one hand, and the students [redacted] and [redacted] on the other.

Other authors' statements

[redacted] and [redacted] were invited to express their views on the case, but chose not to do so.

Expert's assessment

The Board has obtained an expert's statement of opinion on the matter. This expert[1] has had the task of assessing whether the article concerned contains fabrication and/or falsification and whether, if so, this should be regarded as a serious breach of good research practice.

[1] Professor Peter Naredi, Institute of Clinical Sciences, University of Gothenburg.

The expert's assessment is that key information regarding the follow-up of the patient concerned has been omitted, and that this constitutes falsification. He considers that the article contains descriptions that are falsified and involve serious deviations from good research practice.

The expert explains that what the article describes is an experimental study, and that the results of the experiments are not what are being called into question. What is suspected of constituting fabrication and/or falsification are descriptions of the follow-up of a previous patient. These descriptions may be found in the introduction and discussion sections of the article. As an example of an incorrect description, the expert cites the following sentence from the article: "The transplantation was a success and resulted in no major complications at 12 month follow up, [...]." He reviews and analyses the information from the medical records that is attached to the report, and judges which events constitute "serious complications". He also describes his view of what may be considered a "success" in this context, and thinks this assertion becomes misleading when what it means is not defined in the article. Summing up, the expert witness considers that, for a scientifically correct description, the article should have included all relevant postoperative failures and complications. He thinks that key information has been omitted to give a false impression of the results of the previous operation, and that this constitutes falsification, which is a serious deviation from good research practice.

Respondents' statements with respect to expert assessment

[redacted] statement

[redacted] contests the allegation that she is guilty of fabrication or falsification. The article describes work she conducted as part of her degree project on the medical training programme [redacted] and [redacted] were her supervisors, and she performed the experiments described in the article in cooperation with [redacted]. The article is partly based on text from her degree project. She was not involved in the surgical procedure whose follow-up the allegations concern. Nor, at the time when the article was published, did she know of the complications suffered by the patient; instead, she relied on information from the supervisor, [redacted].

Other authors' statements

[redacted] and [redacted] were given the opportunity to express their views regarding the expert statement, but chose not to do so.

Legal regulation

Under the Act (2019:504) on responsibility for good research practice and the examination of research misconduct ("the Act"), the Board is tasked to investigate issues of research misconduct.

Section 2 of the Act defines research misconduct as a serious breach of good research practice in the form of fabrication, falsification or plagiarism, committed

with intent or through gross negligence, in the planning, conduct or reporting of research.

The Board's assessment takes place in stages, pursuant to the above provision.

Grounds for decision

Research covered

Section 3 of the Act covers research conducted by higher education institutions that have the Swedish state as the entity responsible for their research, and that are subject to the Swedish Higher Education Act (1992:1434), other government agencies, municipalities and regions and certain other specified activities.

[redacted] and [redacted] made their contributions to the research (on which allegations were reported) at Karolinska Institute, an entity responsible for research that is subject to Section 3 and, accordingly, to investigation by the Board.

[redacted] and [redacted] conducted their part of the research at a foreign research entity. As such, they are not subject to Section 3 and not investigated by the Board.

Researchers

Under Section 4 of the Act, researchers are responsible for complying with good research practice in their work.

People who count as researchers are those who are attending or have completed research education and are participating in research. Other individuals taking part in research activities, such as students at basic (first-cycle, bachelor's) or advanced (second-cycle, master's) level and technical and administrative staff, should not count as researchers.

[redacted] had not started her postgraduate studies when the article was published. The Board's assessment is that she is therefore not to be considered to have been a researcher and should not be subject to investigation by the Board.

The Board's assessment is that [redacted] and [redacted] were researchers when the article was published and are therefore subject to investigation by the Board.

Planning, conduct or reporting of research

As defined in Section 2 of the Act, breaches of good research practice that may constitute research misconduct must have been committed during the planning, conduct or reporting of research. This means that the term "misconduct" refers to breaches throughout the research process.[2] "Reporting" refers both to publication and to other types of disclosure.[3]

The Board considers that the case relates to reporting of research because the allegations concern wording in an article published in a scientific journal.

Fabrication, falsification or plagiarism

The Board's remit is to investigate three forms of research misconduct: fabrication, falsification and plagiarism. These terms are not defined by law, but the preparatory work for the Act refers to the fact that they are described in codes (codices) and guidelines on research ethics, such as *The European Code of Conduct for Research Integrity*.[4,5]

Fabrication means that the researcher invents results and documents them as if they were genuine.

Falsification refers to manipulation of research material, equipment or processes or unjustified alteration, omission or suppression of data or results.

The article describes experiments regarding various plastic materials and their suitability as materials for constructing synthetic tracheas. The text refers to a previous operation in which a patient received a synthetic trachea. The operation is described as successful and said not, at the follow-up, to have entailed any serious complications. According to the allegations reported, these assertions do not correspond to what actually happened and are therefore suspected of constituting falsification and/or fabrication.

[redacted] and [redacted] state that, in their assessment, what the article states concerning the patient's state of health after the operation is not correct. The other authors who have issued statements have not commented on this matter, or state that they lack the expertise to judge whether the description is incorrect.

[2] Swedish Government Bill 2018/19:58, p. 100.
[3] Swedish Government Bill 2018/19:58, p. 49.
[4] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 3.1.
[5] Swedish Government Bill 2018/19:58, pp. 45, 100.

The expert's assessment is that key information has been omitted regarding the previous operation so as to give a false impression of the results of the operation, and that this constitutes forgery.

Based on the patient records attached to the allegation report, the Board considers that the description of the operation as successful and the statement that it did not lead to serious complications within six months are incorrect. Making up information in this way and documenting it as if it were true constitutes fabrication. In addition, the Board considers that the omission of the complications documented at the time when the article was published constitutes falsification.

Serious breach of good research practice

Only serious breaches of good research practice can constitute research misconduct.

In principle, fabrication and falsification are always serious breaches of good research practice.

In the expert's assessment, these instances of falsification constitute serious breaches of good research practice.

The premise of the Board's assessment is that fabrication and falsification are, in principle, always serious breaches of good research practice. No reason to deviate from this premise has emerged in the case. Accordingly, the Board's conclusion is that the breaches constitute serious breaches of good research practice.

Intent or gross negligence

Since 1 January 2020, researchers' responsibility to comply with good research practice in their work has been subject to statutory regulation under Section 4. The potential or required extent of such responsibility must be examined and assessed in each individual case.

Under Section 2 of the Act, for research misconduct to be found, the serious breach of good research practice must have been committed with intent or through gross negligence.

"Intent" means that the researcher understood what (s)he was doing, while "negligence" means that the researcher, in any case, should have understood this.

"Gross negligence" requires the conduct to stand out as particularly serious or reprehensible. According to the preparatory work, oversights, carelessness or misunderstandings should not, as a rule, be regarded as gross negligence.[6]

[6] Swedish Government Bill 2018/19:58, pp. 50–51, 100.

According to international guidelines,[7,8] every partners in a collaboration must take responsibility for the integrity of the research. The guidelines also state that all authors are fully responsible for the content of the publication unless otherwise stated. Swedish law is based on this international regulation.

The article does not specify any division of responsibility for different sections in the text.

The complainants assert that [redacted] was continuously informed of the patient's condition and, when the article was written and published, knew of the complications that had arisen.

[redacted] and [redacted] have issued statements and explained that, at the time the article was published, they were unaware of the complications ensuing from the operation.

The Board lacks knowledge of what the other authors knew about the complications that had occurred or the condition of the patient concerned when the article was published, since they chose not to express their views on the case.

The expert witness draws the conclusion that [redacted], at least, knew of the complications that had arisen and refers, for example, to information in the allegation report regarding two bronchoscopies performed on the patient in November 2011, the second of which [redacted] attended.

[redacted] was the project manager and surgeon in charge for the transplantation of a synthetic trachea that is described in the article in question. The Board's assessment is therefore that it is highly unlikely that [redacted] was unaware of the serious complications affecting the patient at the time the article was published. This is also supported by information found in the patient's medical record, including the fact that [redacted] attended a bronchoscopy performed in February 2012. [redacted] is the corresponding author of the article, and this position entails a special responsibility. There were strong incentives for [redacted] to present the follow-up of the first transplant of a synthetic trachea as successful and having no serious complications, since both his clinical work and his research were based on this type of transplantation. The Board can draw no other conclusion than that he described the operation as successful for his co-authors and, in the article, deliberately omitted information about the complications experienced by the patient. [redacted] is therefore considered to have acted with intent, and is thus guilty of research misconduct.

Besides [redacted], three authors are subject to investigation by the Board: [redacted] and [redacted], who are also authors of an article,

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[7] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, 2023, Chapter 2.6.

[8] *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.* Updated May 2022, International Committee of Medical Journal Editors. https://www.icmje.org/recommendations.

now withdrawn, in which the operation in question is described.[9] This means that they had more opportunities to ask questions about the patient's condition and have the expertise to assess whether the operation could be seen as successful. The Board believes that each of them acted, if not with intent, at least with gross negligence when they approved the existing wording referring to the earlier operation. [redacted] and [redacted] are thus guilty of misconduct in research.

The Board's assessment is that the other authors, [redacted] and [redacted], had a more limited insight into, and the knowledge to assess, the patient's condition. The main focus of the article is not on the operation in question, but the outcome of the operation is mentioned as an example in the introduction and at the end of the article. These co-authors state that they relied on [redacted] data. The Board considers that it was negligent, but not grossly negligent, of them to rely on his account of the operation and follow-up of the patient. [redacted] and [redacted] are thus not guilty of misconduct in research.

Summary of the decision

Summing up, the Board finds [redacted] and [redacted] guilty of research misconduct. The Board finds [redacted] and [redacted] not guilty of research misconduct.

The Board has made a decision on this matter, following a presentation by Sofia Bergström, caseworker.

Catarina Barketorp
Chair

Sofia Bergström
Caseworker

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[9] [redacted] (2011). Tracheobronchial transplantation with a stem-cell-seeded bioartificial nanocomposite: a proof-of-concept study. *The Lancet* (London, U), 378(9808), 1997–2004. https://doi.org/10.1016/S0140-6736(11)61715-7 (Retraction published in *The Lancet*. 2018 Jul 7;392(10141):11.)