

Case Research Integrity

2023

Financial conflict of interest in publications - wellfounded

EUR

1 Subject

Complainant reports a possible violation of research integrity involving a non-reporting of possible conflicts on interest in scientific publications.

1.1 Background and notification

1.2 Procedure

On [date], the secretary of the RIC received a report from the Complainant about a possible violation of research integrity. The report was made following the fact that the Executive Board had taken note of a news publication reporting a possible financial conflict of interest (hereinafter: FCOI). The Executive Board subsequently established an ad hoc FCOI committee to investigate this. As a result of this investigation, two documents were drawn up, in which it was indeed established that FCOI was an issue for the Defendant in several areas. This was sufficient reason for the Complainant to assume that this possible FCOI also played a role in the Defendant's scientific publications.

The RIC worked in accordance with the [institute's] Research Integrity Reporting Regulations of January 2023. The applicable code of conduct for the research period examined was the Dutch Code of Conduct for Research Integrity 2018. The Defendant was informed of the complaint on [date]. The RIC held consultations on [date]. As a result, additional questions were asked to the Defendant. He responded in writing on [date]. The RIC met on [date]. An interview with the Defendant was held on [date]. The draft report was submitted to the Complainant and Defendant on [date] to check for factual inaccuracies.

2 Position of the parties

2.1 The Complainants's position, in summary

The Complainant reports that the Defendant is a [specialist] within the [department], involved in [area of research]. These [activities] are performed using [products] by [companies]. According to the Complainant, manufacturers of these [products] often have close ties with [specialists] because they serve as their eyes and ears, contributing to the development and improvement of [products]. These manufacturers also gain access to their market through these relationships, as explained by the Complainant.

The Complainant further explains that manufacturers frequently provide financial support to [institute] for research purposes. Such contracts are always reviewed by legal experts at [institute]. Additionally, individual professionals often have agreements for activities like advisory work and presentations, which are typically compensated on a personal basis. The Complainant notes that there are rules governing such

personal agreements, covering aspects like payment, taxation, scope, transparency, and scientific integrity.

Unfortunately, it has recently come to light that there hasn't always been full transparency in these matters, states the Complainant. As a result, investigations have been initiated, including [...] inquiries into the Defendant's activities. Therefore, the Executive Board of [institute] has initiated an investigation. At the time of the complaint, it is evident that payments have been made to the Defendant's personal company for services provided to various companies. Two of these companies are [name] and [name]. The amounts involved are not negligible, according to the Complainant, on the order of [amount] per company per year, totaling approximately [amount] over the last [number of] years.

Upon reviewing the list of scientific publications authored by the Defendant, it appears to the Complainant that there have been publications related to research conducted using [products] from the mentioned companies with which the Defendant also had personal contracts. In some cases, it seems that there was no disclosure of this "potential conflict of interest," which could naturally be associated with the personal payments, in the articles, reports the Complainant. Furthermore, to the best of their knowledge, there are no issues related to fabrication or plagiarism. However, the Complainant would like an answer to the question of whether, in the past [number of] years, there have been articles published with the Defendant as a (co-) author where disclosure should have been made regarding the personal payments he received.

2.2 Defendant's position, summarized

The Defendant no longer resides in [location] and has left [institute] due to recent issues. However, he still maintains a hospitality agreement with [institute] that allows him to continue his research activities.

He is uncertain about the regular procedure because the request for the investigation came from his own department. He finds the reasons for filing the complaint weak. There has been an investigation in which no evidence of conflicts of interest was found, but it was determined that he should have disclosed his secondary activities to the university, resulting in an official warning, he explains. Subsequently, he mentions that the Complainant compared his COI forms with the publications of the companies, and the Complainant told him that this was better and safer to do due to [...] attention. He also notes that he believes this should apply to the entire department, not just him. The RIC explains that they do not have the authority to extend the complaint to other individuals. The Defendant wants the RIC to be aware that he has sufficient knowledge and evidence to file complaints against many other people.

The Defendant states that he is aware of the definition of research integrity, has taken courses, and in this case, the committee investigates financial conflict of interest. However, he acknowledges that there can be other conflicts when collaborating with a company or an individual, such as reviewing a paper, and so on. Researchers are obligated to disclose all these conflicts in papers, he says, but nowadays, everyone primarily focuses on the financial aspect. He suggests that researchers may need to refuse to review papers if they have stocks or personal relationships, making it a broad topic. He believes that if you have to disclose everything, it becomes a long list.

The Defendant mentions that there is a difference in reporting responsibility among authors, with the first and last authors having the most responsibility. He emphasizes that there is a vast variety of forms on journal websites, where some ask for the disclosure of "potential" conflicts of interest, while others only ask for direct conflicts of interest. He states that he always tries to do it honestly and to the best of his knowledge, but he does it with respect to the subject of the research.

The RIC then inquires whether there is a conflict of interest when conducting research with [products] from a particular company while simultaneously engaging in private advisory work for that same company. The defendant responds, "not necessarily," but he is aware of the current public opinion on this matter. He believes that educational activities for companies do not affect his research, even if one of the companies is involved. He, for instance, has published negative results in such cases.

The RIC subsequently asks about payments to his company and whether he considered disclosing them in publications. The Defendant replies that the situation remains the same. Having your own consultancy company does not change his position regarding his research. He did not consider it would impact his research, which is why he did not disclose it in publications. He emphasizes that the RIC should consider the timeline in relation to the contracts because not all the work described in the articles falls within the period during which he (or his company) received money from the companies under investigation.

Furthermore, he mentions that in some journals, the main authors fill out everything, and he was not asked about his potential conflicts of interest by those authors. Therefore, he believes that this undoubtedly led to errors. He says that he did disclose his conflict of interest for one paper, but it was not included in the publication by the first author. He now believes that it doesn't matter how you receive the money; it is a potential conflict of interest. The RIC asks the Defendant to clarify: is it a conflict of interest when it affects you, when it could affect you, or something else? The Defendant says it is not about his (personal) opinion (which can be influenced); it is a relatively objective matter. In some cases, it is about a potential conflict, he says, for example, if you are a consultant for company A and you write about the competing company B.

The Defendant states that it is the nature of his work to use various [products] from different companies, but ultimately, it is still the author's assessment of whether they believe it influences the research. That is how he listed his conflicts of interest at the time. He admits that he may have made mistakes; he may not have been paranoid enough at the time. Now, he has updated his conflict of interest by linking it to ORCID, meaning that anyone can look up all his potential conflicts of interest because they are listed there.

The RIC asks if he discussed the completion of COI forms with co-authors. The Defendant says there has been little discussion about it. It is not teamwork, he says; it is the individual responsibility of co-authors, and that's how it should be. According to the defendant, there was no guidance from the department on how to do this. They all have their own responsibility. He believes that now, unimportant matters are reported out of fear. He finds it important to avoid hypocrisy. What is worse: being transparent about many things but acting without integrity or being limited transparent but acting with integrity.

The RIC wants to know how the defendant thinks the reporting should work since it is everyone's responsibility, but everyone will do it differently based on their own morals. The Defendant says that clear guidelines will help, and there have been clear (departmental) guidelines since [date], so he expects fewer problems from now on.

The RIC asks about the guidelines in the Dutch Code of Conduct, which have been in place since 2018. The defendant says he was aware of them, but even if you apply them to the best of your knowledge, the COI forms from different journals leave room for different interpretations. He now thinks that it would have been better to report everything because it had not harmed him. In hindsight, he says, it may look bad, but he still does not believe he filled them out incorrectly.

3 Considerations and conclusions

3.1 Regulations

The RIC investigates reports of (possible) violations of research integrity on the basis of the Complaints Procedure of [institute], which have been declared applicable to this case. In this case, the Committee advises the [institute's] Executive Board. The complaint relates to events and publications after October 2018, as a result of which a violation of research integrity must be defined as acting or omission in violation of the standards as specified in the Netherlands Code of Conduct for Research Integrity 2018.

A violation of the standards of conduct does not by definition lead to a violation of research integrity. Careless conduct may occur without resulting in a violation of research integrity. Not every unintentional mistake or carelessness can be regarded as a violation of research integrity. The Code of Conduct therefore provides guidelines for assessing whether 'weighing' or the qualification 'violation' is appropriate. Weighting criteria include:

- a. the extent of the non-compliance;
- b. the level to which non-compliance was intentional and whether it was a form of gross negligence or was the result of carelessness or ignorance;
- c. the possible consequences for the validity of the research in question and for the prevailing scientific knowledge and scholarship;
- d. the potential effects on the trust in scientific and scholarly research and between researchers;
- e. the potential impact on individuals, society and the environment;
- f. the potential benefits for the researcher or other interested parties;
- g. whether the matter concerns a scientific or scholarly publication, as opposed to a popularizing article, teaching materials or an advisory report;
- h. opinions within the discipline(s) concerning the severity of the non-compliance;
- i. the researcher's position and experience;
- j. the extent of any prior violations committed by the researcher;
- k. whether the institution itself has failed in its duties of care;
- l. how much time elapsed before action was taken against the non-compliance within or outside the institution.

3.2 Standards and norms

In the Dutch Code of Conduct for Research Integrity 2018, the following norm is mentioned concerning this complaint that could be relevant:

- Norm 44: Be open and complete about the role of external stakeholders, commissioners, funders, potential conflicts of interest, and relevant secondary activities.

Based on the qualification model from Chapter 5 of the Code of Conduct, this norm falls into the category where the outcome of the assessment mentioned in 3.1 will determine whether the qualification 'violation of research integrity' is appropriate, or a less severe qualification, such as 'questionable behavior.'

3.3 Investigation into complaint

3.3.1 Possible conflicts of interest

In scientific publications, authors are expected not only to disclose actual conflicts of interest but also to be transparent about potential conflicts of interest. The Code of Conduct also takes into account potential conflicts. Reporting potential conflicts of interest is important because it helps ensure the integrity and credibility of research. It enables readers, editors, and reviewers to assess for themselves whether potential conflicts of interest could influence the results and conclusions of the research, even if the authors themselves believe it is not the case or when they are unsure. This assessment does not need to be done by the author. The goal is to provide complete transparency and minimize the chance of bias or influence.

In this light, the RIC believes that the use of [product] from a specific company not only obligates the disclosure of any ties to that company but also ties to potential competing companies. Some journals also inquire about this: "Does any author have a financial relationship with an entity that may closely compete with the [products] covered by this study?" In some cases, there is also a request for potential conflicts of interest involving family members of the authors.

In previous investigations by the ad hoc FCOI committee, it was found that between [year] and [year], the Defendant received payments from [company] and [company], either in his own name or to his own company. Therefore, the RIC limited its investigation to the failure to report potential conflicts of interest related to these [...] companies in scientific publications. The starting point for this investigation was the list of 58 publications provided by the Complainant from [year] to [year].

The RIC observed that in 2 of the 58 publications, the Defendant was not listed as an author. Among the remaining 56 publications, 34 mentioned one or more companies, and 11 indicated the use of [products] from one of the companies under investigation (or both). No company was mentioned in the remaining publications.

As a first step, the RIC conducted a sample examination by reviewing five of the provided publications from [year] in which equipment from one or both companies was used, to check for the disclosure of potential conflicts of interest.

In articles (1) and (2), the article itself states that the study received financial support from [company]. This satisfies norm 44 for these two articles regarding transparency about external funding. However, the RIC does not rule out that disclosure of financial support by companies may have been necessary for other articles not included in the sample. Therefore, it cannot be definitively determined whether the Defendant consistently complied with norm 44 in all articles during the period covered by the complaint regarding the reporting of financial support from companies.

None of the authors indicated a COI in articles (1) and (2), although the ongoing consultancy work for [company] by the Defendant should have been disclosed at that time. In articles (3), (4) and (5), the ongoing financial relationship with [company] was not disclosed by the Defendant.

The RIC considers that the absence of these relationships in the COI statements in the publications may be due to the fact that the Defendant was not the corresponding author for the publications and may not have been asked about his potential COI statements by the corresponding author. However, the Defendant does not cite this as a reason. In five of the 11 studies in which [products] from [company]

and/or [company] was used, the Defendant himself is the corresponding author. In only one of these five, the Defendant indicates receiving a grant from the company.

Furthermore, the RIC selected three other publications from 2022 in which the Defendant indicated that the two companies were not involved. In all three articles, the Defendant claims to have no COI. In article (6) and (7), the respective companies are indeed not mentioned. However, two other companies are mentioned, and one of the other authors acknowledges being a consultant and receiving speaker fees from those companies. In article (8), the RIC believes that one of the other authors also incorrectly fails to disclose this.

As a final check, the RIC examined a publication from [year] (the final version was published in [year]) (9) that was not on the list provided by the Complainant. [Company] is mentioned in this publication, but again, there is no mention of the financial relationship between the company and the Defendant.

Sponsorship by the [...] company of which the Defendant was the sole shareholder and/or employee should also have been disclosed in the COI statement.

Therefore, the RIC concludes that norm 44 was not adhered to by the Defendant.

3.3.2 Awareness within the work environment

While the RIC, in this case, is limited to providing advice regarding a potential violation of norm 44 in the Code of Conduct concerning publications, it does note that the reporting of conflicts of interest outside of this Code is covered by various other regulations, including the Collective Labor Agreement for [...], the [...] Act, the [...] Code of Conduct, the guidelines on [...], and the transparency register for [...]. A [...] specialist engaged in [...] research and working in a field where many [products] are used should be familiar with this legislation and regulations.

The RIC does believe, based in part on the interview with the Defendant, that the department in question may have paid insufficient attention to promoting and monitoring compliance with the rules regarding secondary activities and conflicts of interest in recent years. The then head of the department did not seem to be sufficiently aware of secondary activities, and it appears that these were not systematically inquired about. Even the reported activities were not documented in writing. There was (and still is) no discussion within the department among colleagues about potential conflicts of interest and how to transparently address them.

3.4 Weighing of non-compliance with standards

Whether the qualification 'violation' is applicable to the non-compliance with the standards depends on an evaluation of the Defendant's actions based on, among other factors, those mentioned in section 3.1. According to the RIC, this evaluation leads to the conclusion that there is a violation by the Defendant, based on the following criteria:

In favor of the Defendant, the following circumstances speak:

- There are no prior instances of the researcher's shortcomings in the field of scientific integrity known to the RIC.
- The implementation and monitoring of regulations regarding secondary activities and potential conflicts of interest within the department where the Defendant worked may have been insufficient in the period from [year] to [year].

Against the Defendant, the following circumstances speak:

- The extent of non-compliance is substantial and includes multiple publications.
 - Failure to disclose conflicts of interest may have an impact on trust in science and among scientists.
- The Defendant's position and experience (an experienced researcher with a large number of publications to his name).

3.5 Conclusions and advice

In light of the above, the RIC concludes that there is insufficient adherence to the standards and principles as formulated in the Code of Conduct by the Defendant. The RIC advises the Executive Board to declare the complaint well-founded and to classify the actions of the Defendant as a 'violation of scientific integrity.'

Since the Defendant is no longer employed by [institute], further employment-related measures towards the Defendant are not possible. The RIC advises the Executive Board to ask the department to reconsider whether a hospitality agreement with the Defendant is desirable, or if additional conditions are necessary.

The RIC also advises the Executive Board to request the involved department to correct the COI statements in the articles via the journals, and not limit the verification solely to the Defendant's statements.

Finally, the RIC advises the Executive Board to ask the department to clearly document and communicate the rules regarding the reporting of secondary activities and potential conflicts of interest within the department in writing, and to ensure that employees also communicate with each other about these matters, as is customary in an open and transparent work environment.

4 Initial opinion of the Executive Board

The Executive Board has decided to follow the Committee's advice on October 17, 2023, and has therefore come to the conclusion that the allegations are well-founded. The Executive Board supports and endorsed the recommendations of the Committee to the Department.

5 National Board for Research Integrity (LOWI)

No request was received by the LOWI.

6 Definitive opinion of the Executive Board

The initial opinion of the Executive Board became the definitive opinion on November 28, 2023.