

Summary of LOWI opinion 2018-06

Keywords: duty to disclose commercial interests, conflict of interest, primary interest of academic practice, secondary interests of the scientist.

Relevant provisions: Principles 4 and 5 of the Netherlands Code of Conduct for Academic Practice.

Boards involved: Executive Boards of VU Amsterdam and VUmc

Petition

According to the Petitioners, the Interested Party failed to disclose fully his conflicts of interest in a number of publications, when providing scientific advice to an institution, and when submitting a research proposal.

Opinion of the Research Integrity Committee (RIC) and decision by the Boards

The primary interest of a scientist must be reliable academic practice. Given that valorisation of knowledge is seen as a goal to be pursued, the existence of secondary interests is not unusual. It is conceivable that a secondary interest causes bias. A conflict between the primary and secondary interests is referred to as a "conflict of interest". The requirement of extra vigilance if there is a chance of the outcome of a study being determined in advance in order to also serve secondary interests applies to the scientist himself, but also to the scientific forum. This requirement is supported by requiring that potential conflicts of interest be disclosed. It is also the case that not disclosing a conflict of interest is only culpable if a relevant secondary interest is concerned, i.e. that that interest can be served by the outcome of the study. Failure to disclose relevant secondary interests does not imply that the scientist has given priority to secondary interests. The duty to disclose is therefore also a derived obligation: failure to fulfil that obligation does not necessarily mean that the primary obligation has been violated. Failure to comply with the duty to disclose is a case of negligence. The extent to which this is culpable depends on the extent and nature of the secondary interest. The Boards adopted the opinion of the RIC.

The Petitioners' most relevant objections are as follows:

- Objection to the RIC's assessment framework, which wrongly made a subdivision into primary and secondary interests and amended the standards in favour of the Interested Party. This would allow scientists to have secondary interests, as long as the primary scientific interest was paramount. This is contrary to the Netherlands Code of Conduct for Academic Practice.
- The Netherlands Code of Conduct for Academic Practice stipulates that a scientist must always disclose other interests. The Interested Party did not disclose his commercial interests when drawing up a research proposal, and in a number of his publications the disclosure of his commercial interests was incomplete.
- The Interested Party did not demonstrate that he had obtained the consent of the participants to perform commercial tests.

The most relevant considerations in the LOWI's opinion:

- The LOWI can agree with the RIC's assessment framework, with its exposition of the primary importance of reliable academic practice and the potential existence of secondary interests

that could lead to bias. However, the LOWI cannot agree with how the RIC applied that assessment framework.

- When providing scientific advice to an institution, the Interested Party did not disclose two relevant secondary interests, thus violating the institution's rules. The institution and the Minister then imposed measures. In the opinion of the LOWI, this does not mean that the behaviour of the Interested Party could not be reviewed under the Netherlands Code of Conduct for Academic Practice, or that the Board had no responsibility in this regard. After all, the RIC's assessment framework applies not only to scientific publications but also to other forms of academic practice.
- Since 2010, it can be assumed within the context of scientific endeavour that conflicts of interest must be disclosed. Moreover, the Interested Party has since 2008 been the editor of a journal that has been applying rules for disclosing conflicts of interest since 2007. He may therefore be assumed to have been familiar with this duty to disclose since 2008. When providing scientific advice to the institution, the Interested Party – in violation of the Netherlands Code of Conduct for Academic Practice – failed to disclose his conflict of interest. It has not become apparent, however, that the Interested Party's views, which are shared by other research groups, were influenced by his commercial interests. The Petitioners have not demonstrated that that was the case.
- Submitting a scientific research proposal constitutes academic practice within the meaning of the Netherlands Code of Conduct for Academic Practice. Although it has been established in that context that there is no statutory obligation to disclose a conflict of interest, it is possible that there may be an obligation to do so pursuant to the Netherlands Code of Conduct for Academic Practice. The requirement of reliable academic practice also applies, after all, to other forms of academic practice than publications. When submitting the research proposal, the Interested Party, who had been aware of the duty to disclose since 2008, failed to disclose that he held shares in the company that provided the test for the study. This is contrary to the Netherlands Code of Conduct for Academic Practice. The LOWI considers that only reporting the test to be used in the research proposal is insufficient. However, it has not become apparent that the research proposal was influenced by his commercial interests. The Petitioners have not demonstrated the bias which they believed there had been.
- In the opinion of the LOWI, there is insufficient reason to re-examine the 12 publications challenged by the Petitioners. The Petitioners have not made a substantiated case as to why the RIC's findings regarding commercial interests are incorrect. The LOWI does, however, arrive at a different classification for not fully disclosing the commercial interests. In the opinion of the RIC, there is no question of culpable negligence if the researcher amends his course of action. Prior to the complaints procedure, the Interested Party had made the necessary corrections in two publications. As a result of those corrections it was clear that the Interested Party had previously disclosed his conflict of interest insufficiently and that, in the view of the RIC, he had, after all, disclosed the correct commercial interests. In the opinion of the LOWI the publications in question were, however, in the public domain for years with an incomplete statement of the conflict of interest, despite the Interested Party having been aware of the duty to disclose since 2008. He also did not correct the publications of his own accord but only after reports had appeared in the media. The LOWI is

of the opinion that it is not sufficient to note that the Interested Party did disclose the correct commercial interests after all. Moreover, the Board also has its own responsibility as regards research integrity.

- The Petitioners' objections regarding the drawing up of the Directive and the usefulness and necessity of the addition to the Directive are a matter of scientific debate. Moreover, the Interested Party explained that it was not he but a colleague who was involved in drawing up the Directive.
- The use of samples obtained by the Interested Party through previous scientific research is considered by the RIC to constitute "further use" for scientific research within the meaning of the Code of Conduct. This does not require separate consent from the participants in the study. In exceptional circumstances, a "no objection system" is sufficient. In the LOWI's opinion, a "no objection system" is sufficient, but then that consent must have been recorded. That is not clear from the documents, and it became apparent at the hearing that the statements of consent are not (or no longer) available. This is not in accordance with the Code of Conduct.
- In the opinion of the LOWI, the way in which the Petitioners' request for samples was dealt with does not constitute a violation of research integrity. According to the Interested Party, the number of samples was limited. The LOWI does not consider it incorrect to then weigh up the various interests. Moreover, the criteria formulated are not unreasonable.
- The Petitioners provided extensive substantive comments on the Interested Party's study. The LOWI agrees with the RIC that there is a difference in scientific understanding here. The information provided to the participants about the study was not misleading.
- The LOWI finds more parts of the complaint to be well-founded than does the RIC. Individually, these would lead to a classification of culpable negligence. Taken together, the detected cases of negligence must be considered cumulatively as a violation of research integrity.

LOWI ruling and opinion:

The LOWI considers the Petition to be well-founded and recommends that the Board adopt its final decision in accordance with the considerations of the LOWI.

Final decision by the Boards:

- The Executive Boards follow the LOWI's opinion that the Interested Party disclosed his commercial interests incompletely as regards the six publications specified in the opinion. In the view of the Boards, this qualifies as a slight violation of research integrity.
- The Boards follow the opinion of the LOWI that there was no question of a violation of research integrity in the decision-making with regard to the issuing of samples to the Petitioners.
- The Boards have taken note of the LOWI's opinion regarding disclosure of the Interested Party's secondary interests to the institution. As regards that point, this institution and the Minister, as the competent authorities, have imposed measures themselves. The Boards do not assume the responsibility of the institution or of the Minister and respect their respective decisions.

- Unlike the LOWI, the Boards do not consider that the fact that the statements of consent for the further use of material for scientific research are no longer available, constitutes a violation of the Code of Proper Use. The information provided to the study participants at the time and the consent forms met the requirements. In the view of the LOWI, the “enhanced no objection system” applied by the VUmc at the time is sufficient for a case such as the one at issue here. There is no reason to assume that the forms concerned were not filled in by the participants. The fact that they are no longer available is only because the retention period has expired. The regulations on further use are still under active development and are the subject of nationwide discussion and possible decision-making. It is not up to the Boards to take decisions on the basis of this case that pre-empt this nationwide decision-making.