

## Summary of LOWI opinion 2018-20

Keywords: right of complaint, burden of proof, separate hearings, financed research, conflict of interest, relevant secondary interests

Relevant provisions: article 7.6 of the LOWI Regulations (old); article 4, subparagraph d, under 9 of the Regulation for Scientific Integrity at Maastricht University

Board involved: Executive Board, Maastricht University

### *Petition*

The Petitioner states that a researcher, after the onset of a previously implemented improvement process, has violated the scientific integrity again.

### *Opinion of the RIC & decision by the Board*

The RIC considers that part of the complaint is due to conflicting personalities of the researchers and the failing institutional academic culture within the research department. In addition, some of the elements of the Petitioner's complaint are not substantiated with written evidence. The RIC has advised the Board to rule the complaint unfounded. The Board decides in compliance with this advice and considers taking further steps with regard to the worrisome institutional academic culture within the research department.

### *The Petitioner's most relevant objections are as follows:*

- Next to general, procedural complaints, the Petitioner states that the researcher has not or wrongly reviewed the results of the research on one of the patients. By doing so, the safety of the patient has been put at risk.
- The independence and objectivity of the research are in dispute due to the main goal of the research: satisfaction of participants about a specific product. The manufacturer had a commercial interest in a high score of satisfaction.
- The researcher has not mentioned his conflicts of interest (coi).
- The researcher has pressured other researchers in order to avoid a negative opinion of the METC.
- The Petitioner states that the researcher has allowed the manufacturer to affect the results. Moreover, a reviewer has concluded that there is an acceptable conflict of interest.
- The Petitioner has substantiated three cases of duplicated publications by the researcher and one case of plagiarism with evidence.

### *Below are the most relevant considerations in the LOWI's opinion:*

- The right of complaint is not meant to resolve conflicts. A few of the complaint items are clearly not related to the principles of research integrity. The LOWI agrees with the RIC that the Petitioner has not substantiated the complaint items with objective evidence.
- Due to the existing relationship of authority, there is no need to hear the parties separately. The principle of adversarial requires that parties are aware of what has been brought forward during the hearing and that they can react on each other's positions. That this has not happened in this case, is unjustifiable. The reactions of the Petitioner

on the reports of the hearing, which have been brought into the procedure by the Board, are considered by the LOWI.

- Patient care does not fall within the scope of research integrity. The remaining points did not need to be mentioned by the researcher as 'adverse event', because they were not part of the trial. The patient was not included in the trial, because there had been no indication for an intervention. Moreover, the surgery was cancelled. There is no reason to conclude that the safety of the patient was at stake. The LOWI agrees with the Board that the researcher did not have to mention the exclusion of this participant in the publication, because there have been no signs that this has affected the results of the research.
- The Petitioner did not substantiate the complaint item that the Interested Party has put the interest of the manufacturer first or that he has pressured other researchers. The claim that the interest of the research or financial interest was preferred over the interest of the patient has not been underpinned with evidence either. A research that aims to investigate the possible advantages of a specific product is legitimate and, by itself, does not violate the research integrity.
- The Petitioner has not substantiated that the academic practice of the Interested Party is questionable. First, starting the debate about the aims of the research and its methods before the definitive research protocol is determined is not a violation of the principles of research integrity. Furthermore, research that is valuable for the manufacturer does not necessarily violate the principles of research integrity and the commercial interests do not prevent the research from being executed. What is more important, is clarity about the fact that the manufacturer is financing the research. It is not uncommon that the financier finances that contract of the researcher. Taken together, there is insufficient reason to conclude that the objectivity of the research is at stake. The LOWI agrees with the RIC that it is more relevant that the research is conducted according to a protocol that has been approved by the METC and the Board of Directors.
- With regard to not mentioning the conflicts of interests, the LOWI considers that not disclosing a conflict of interest is only culpable if a relevant secondary interest is concerned, i.e. that that interest of the researcher can be served by the outcome of the study (LOWI opinion 2018-06). The Petitioner has not demonstrated in which specific publications and which specific secondary interests should have been disclosed.
- According to the LOWI, the accusation that the researcher has ordered the Petitioner to commit fraud as well as that he has put pressure on other researchers to avoid a negative opinion of the METC has not been substantiated. Neither has plagiarism under pressure by a PhD student.
- The publication of results from 'industry driven clinical trials' is, by itself, not in violation with the principles of research integrity, as long as one is transparent. One dismissive opinion of a reviewer is insufficient to conclude that the research integrity has been violated.

#### LOWI ruling and opinion:

The LOWI rules the complaint unfounded and advises the Board to adopt its proposed decision unamended as its final decision.

#### Final decision by the Board:

The Board complies with the LOWI advice and rules the Petitioner's complaint partly admissible but not founded.