

## Summary of LOWI opinion 2017-14

Keywords: retrospective study, prospective study, Medical Ethics Review Committee, Medical Research Involving Human Subjects Act [WMO]

Relevant provisions: Elaborations 1.1 and 1.2 of the Netherlands Code of Conduct for Academic Practice, Article 1(2) of the Medical Research Involving Human Subjects Act [*Wet medisch-wetenschappelijk onderzoek met mensen*].

### *Petition*

The Petition concerns a scientific publication by a number of authors about a study carried out abroad by one of the authors. According to the Petitioner, a medical ethics committee should have approved the study.

### *Opinion of the Research Integrity Committee (RIC) and decision by the Board*

Pursuant to the Medical Research Involving Human Subjects Act [*Wet medisch-wetenschappelijk onderzoek met mensen, WMO*], medical research may only be carried out if the research protocol has been approved by a Medical Ethics Review Committee (METC). No prior approval is required for retrospective research. Based on the informed consent forms and access to the treatment log, the RIC concludes that the study is retrospective in nature. During the study, the author/researcher had no ties with a Dutch research institute, so that the WMO was not applicable. The RIC has not been able to establish that the treatments abroad or in the Netherlands can be regarded as unusual or experimental. The RIC recommended that the Board rule the complaint unfounded. The Board resolved to adopt the RIC's conclusions.

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

The decision is based on the *a posteriori* reasoning that the study was retrospective. The publication contains elements that are appropriate to a prospective study. Highly detailed information is provided about the material and method. That is not possible in the case of a retrospective study, which is not based on prior research planning.

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

- Whether the WMO applies depends on the nature of the study. The study displays features of both retrospective and prospective research. Information from the treatment log with the records of the treatments and the informed consent forms do not provide a definite answer to this question. This makes the authors' detailed explanation highly relevant. However, that explanation varies, and there is a major difference between the picture – of a prospective study – outlined by the authors in the publication and the explanation to the RIC that it was a retrospective study. The LOWI therefore concludes that the nature of the study can no longer be determined with absolute certainty.
- If the study is to be considered prospective, then the WMO applies and the author/researcher should have taken account of the provisions of the WMO regulations (a treatment protocol approved by a Medical Ethics Review Committee (METC), prior informed consent). Because of the principle of honesty and scrupulousness (Elaboration 1.2 of the Netherlands Code of Conduct for Academic Practice), the authors should not have used the

patient data for a scientific publication. In the opinion of the LOWI, ignoring that principle is so serious that it must be classified as a violation of research integrity.

- If the study must be considered as retrospective, then the authors misrepresented the facts in the publication. In the opinion of the LOWI, misrepresenting the nature and value of a study is a violation of the principle of honesty and scrupulousness, and in particular of Elaboration 1.1 of the Netherlands Code of Conduct for Academic Practice. Given the way it is expressed in the publication and in the informed consent forms, the LOWI finds that this course of action must be classified as a violation of research integrity.

#### LOWI ruling and opinion:

The study displays features of both a retrospective study and a prospective study; in the view of the LOWI, there is much that indicates a prospective study.

Now that the authors' detailed explanation that it is a retrospective study is decisive, it is well conceivable that the Board will maintain its initial opinion that this was a retrospective study. If that is the case, the LOWI advises the Board to adopt the considerations of the LOWI and to categorise the authors' course of action according to those considerations.

The LOWI also advises the Board to request the authors to arrange for a rectification. In the title and the text of the publication, the study is presented as a prospective study, whereas it was considered to in fact be a retrospective study. The LOWI considers this to be misleading and the publication should be rectified.

#### Final decision by the Board:

The Board maintains its finding that the study is retrospective. The considerations of the RIC, the arguments of the authors, the time lag between the actual actions and the later scientific analysis of the patient data, and the dating of the informed consent forms well after the treatment data were decisive in this respect. The Board also notes that the title of the publication was rectified at the initiative of the authors.