



ADVISORY OPINION

Case: CWI 20 – 02

Regarding the investigation commissioned by the Executive Board on 14 February 2021 concerning [REDACTED] (the Person Concerned).

The Academic Integrity Committee of Leiden University and the Leiden University Medical Center appointed to deal with this procedure comprised:

- Prof. F. R. Rosendaal, LUMC (chair)
- Dr M.Y.H.G. Erkens, Leiden University
- Prof. J. G. van der Bom, LUMC
- Prof. J.J. Goeman, LUMC
- Prof. P.G.M. van der Heijden, Utrecht University

of whom the last three were appointed as ad hoc members by the Executive Board,

- W.J. de Wit, LL.M., secretary.

For practical issues, the Committee is assisted from the Faculty of Social and Behavioural Sciences by Ms C.J. Donner.

The course of the procedure

Following the judgement of the Executive Board (11 November 2019, procedure CWI 2019-01), concerning breaches of scientific integrity by [REDACTED], at that time employed by the Faculty of Social Sciences, the Executive Board tasked the Academic Integrity Committee with a follow-up assignment with effect from 14 February 2020. The assignment, pursuant to article 5.2. of the Complaints Procedure on Academic Integrity of Leiden University and the Leiden University Medical Center, is formulated as follows:

Enquiry into possible breaches of academic integrity in:

- all academic articles written by the Person Concerned; and
- the research proposals submitted by her to [REDACTED] (whether or not the proposals have been honoured) during the period in which she was affiliated with Leiden University or related to this period.

The Committee informed the Person Concerned of the investigation and the composition of the Committee on 1 April 2020.

General findings

It proved impossible to find a corresponding CEP protocol for a large proportion of the articles. This was due to:

- the use of so-called *umbrella protocols*, where one CEP protocol formed the basis for various studies and articles;
- uncertainty whether a protocol was submitted;
- a lack of any visible relationship between the time, authors, title of the article and the title of the CEP protocol.

For a large number of publications, no corresponding thesis or internship report was found, presumably in part because students were not involved in the data collection for all the research activities. For the articles where discrepancies were discovered on the basis of a comparison of the article with an available CEP protocol, thesis or internship report, or this was considered necessary for some other reason, data files were sought, and where these were available, they were used for further evaluation.

An initial finding is that for a substantial number of articles data points, in the sense of all data from a number of test subjects, were omitted from the publication without justification, or without even being reported. In some cases this related to the data of only a small number of test subjects, but often it related to a larger number. Moreover, in a number of cases, the Committee came to the conclusion that the data were treated selectively, which means that the conclusion drawn in the article differed from the conclusion that would have been justified on the grounds of all the data.

The Committee questioned whether it would have been acceptable in the field of Psychology to omit data, in particular where the data related to 'outliers', in other words measurements that differ largely from the average. This is not the case, and the prevailing norm is specifically that any omissions of data or subjects must always be justified. In addition, deviations were regularly found between the CEP protocol, data files and the publication with regard to the research design; this means that the design as described in the CEP protocol either was not followed, or the research was carried out in line with the protocol, but nonetheless only certain measurements and results were reported in the article.

Method

The Faculty of Social and Behavioural Sciences (FSW) drew up from various sources a list of Leiden publications by [REDACTED] and arrived at 174 unique publications. Of these 174 articles, in the first instance 53 articles were identified for investigation. For these articles, available information in the form of protocols for the Ethics Committee (CEP), theses, internship reports and comments from FSW was sought. The articles were then assessed. As new information became available, this was made available to the Committee.

The Committee jointly determined the working method. Two Committee members (Van der Bom and Goeman) then individually studied and assessed the available information in a first round. During

meetings of the full Committee, the findings were discussed in order to arrive at a shared judgement. The aim was to reach a judgement of 'Green' (based on the available information, no indications of malpractice were found) or 'Red' if evidence of malpractice was found (such as changes in the research design, subsequently adding a control group, omitting data points without justification). After an initial screening, files of raw datasets were requested from the co-authors. This led to a final assessment in the categories mentioned. The articles qualified as 'Red' were classified into those where withdrawal of the article was indicated, and those where it was considered necessary to consult with the editorial staff of the journal in which the article was published, in order to decide on withdrawal or a corrigendum. The first category comprises articles where the Committee concluded that the malpractices were such that it was either evident that the conclusions of the article were incorrect, or that this was likely, and the second category comprises malpractices that could weaken the conclusions and where the reader should at least be informed of this.

Articles assessed as Red

Of the 53 articles, the following articles have been assessed as 'Red', for one or more of the following reasons:

- A. Discrepancy between the number of test persons in the raw data and the number reported without this being justified (the number of test subjects omitted varied from 1 to 22);
- B. A control group was added later;
- C. The research design was changed after the CEP protocol or after the data was collected, and measurements were omitted from the article.

For the following seven articles, the manipulations were of such a serious nature that the advice is to request the relevant journals to withdraw these articles.

1. [REDACTED]
[REDACTED] (internal numbering: 89)

Twenty-one test subjects were removed who as a group did not show any positive association, and there is a large discrepancy between the number of test persons described in the article and the number of individuals actually tested (40 vs 61).

2. [REDACTED]
[REDACTED] (internal numbering: 97)

The research design reported is substantially different from that in the protocol, a control group has been added and important data and test subjects were omitted.

3. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 98)

The research design was a cross-over design, while the research was reported as a parallel-arm study. Seven test subjects have also been omitted.

4. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 120)

Sixteen test subjects were omitted.

5. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 121)

Sixteen test persons were omitted, who are described in one of the files as the “best 30 subjects”. Moreover, the original cross-over design was not followed.

6. [REDACTED]
[REDACTED]
(internal numbering: 145)

Twelve test subjects were omitted from the published article.

7. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 154)

Data from two groups studied, with a different result than assumed, were omitted from the publication. At least 49 subjects were omitted.

In the case of the following eight articles, it was not evident to the Committee that the manipulations had influenced the results and conclusions of the article. The manipulations are nonetheless such that the journal editors should be advised so that they can decide either how the readers should be informed or to retract the articles.

1. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 131)

A number of test subjects were omitted, and a control group was added post hoc.

2. [REDACTED]
[REDACTED] (internal numbering: 144)

Six test subjects were removed from the analysis.

3. [REDACTED]
[REDACTED] (internal numbering: 147)

At least 12 test subjects were omitted.

4. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 162)

Six test subjects were omitted.

5. [REDACTED]
[REDACTED]
(internal numbering: 139)

Two test subjects were omitted.

6. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 129)

Three test subjects were omitted in the published article.

7. [REDACTED]
[REDACTED] (internal numbering: 146)

There are discrepancies between the number of test subjects in data files and the article.

8. [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 130)

There has been a deviation from the original design, a crossover study, where the comparison between the groups was published, and thus half of the measurements were omitted. The data files do not allow the number of subjects omitted to be traced, and more genetic variations were measured than reported.

Articles assessed as Green

Of the 53 articles, the following articles have been assessed as Green since no indications were found for discrepancies on the basis of the available data.

- 1 [REDACTED]
[REDACTED] (internal numbering: 156).
- 2 [REDACTED]
[REDACTED]
(internal numbering: 111)
- 3 [REDACTED]
[REDACTED] (internal numbering: 113)
- 4 [REDACTED]
[REDACTED] (internal numbering: 159)
- 5 [REDACTED]
[REDACTED] (internal numbering: 134)
- 6 [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 132)
- 7 [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 136)
- 8 [REDACTED]
[REDACTED] (internal numbering: 155)
- 9 [REDACTED]
[REDACTED]
(internal numbering: 163)

- 10 [REDACTED]
[REDACTED]
(internal numbering: 166)
- 11 [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 172)
- 12 [REDACTED]
[REDACTED] (internal numbering:
99)
- 13 [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 177)
- 14 [REDACTED]
[REDACTED]
[REDACTED] (internal numbering: 108)

Finally, 27 articles were not examined for the following reasons:

- Publication year in or before 2015
- No additional information was found
- Datasets were not available or studies were not done abroad by persons other than the Person Concerned
- There was no direct indication for study based on information from FSW

II. Grant applications submitted to [REDACTED]

Method

The Committee received the subsidy applications from the Faculty of Social and Behavioural Sciences and from [REDACTED]. Since three grant applications submitted in the course of the earlier investigation into infringement of scientific integrity by [REDACTED] had shown that results of research that had not been carried out were presented as preliminary results, this was a particular concern. This was examined by looking for results of obviously extensive research for which no results could be found in the published literature. The two previously investigated [REDACTED] applications are mentioned below (as nrs. 2 and 3) but were not investigated again.

The relevant grant applications are mentioned below:

1. [REDACTED]
2. [REDACTED]
3. [REDACTED]
[REDACTED]

Findings

1. [REDACTED]

This application was honoured. In the application there was no reference to preliminary results, nor to one study published earlier ([REDACTED]). This concerns a small study in which 26 test subjects carried out a simple test. Although it is not possible to verify the original research data, there is no reason to assume that malpractices took place, in particular because, in contrast to the findings in the applications where malpractice was demonstrated, this was a modest investigation in terms of its design and implementation.

2. [REDACTED]

This application, which was honoured, was already examined in 2019, and it was established that non-existent research results were presented as 'preliminary results'.

3. [REDACTED]
[REDACTED]

This application, which was not honoured, was already examined in 2019, and it was established that non-existent research results were presented as 'preliminary results'.

Judgement

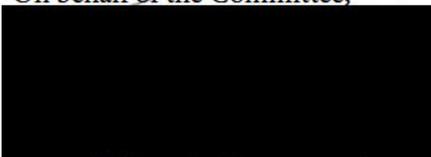
No malpractices were established in [REDACTED] applications submitted by [REDACTED], apart from those that were reported in the advisory report of the Academic Integrity Committee in 2019.

Conclusion

The Committee advises the Executive Board to have seven articles withdrawn, and to notify the editors of the relevant journals of the malpractices in eight articles. With regard to subsidy applications, the Committee advises that [REDACTED] should be informed of the findings.

Leiden, 2 August 2021

On behalf of the Committee,



Prof. F.R. Rosendaal
Chair



W.J. de Wit, LL.M.
Secretary