



ADVICE

Case: CWI 2019-01

in the matter of the complaint submitted by

Complainant: [REDACTED], Scientific Director (hereafter: SD or the Complainant) of the Institute of Psychology,

against

Defendant: [REDACTED], University Lecturer in [REDACTED], Institute of Psychology.

In these proceedings, the Academic Integrity Committee of Leiden University and LUMC (hereafter: the Committee) was composed as follows:

- Dr. M.Y.H.G. Erkens, LL.M., acting as the chair
- Prof. F.R. Rosendaal
- Prof. E.J.J. Groenen
- Prof. D.P. Engberts

secretaries:

- Y.T.R. Mees ten Oever
- W.J. de Wit, LL.M.

The origin and course of the proceedings

The Complainant submitted a notice of complaint against the Defendant by letter of 27 February 2019 regarding suspected violation of academic integrity. The complaint was initially submitted by the Scientific Director (SD) of the Institute of Psychology. At a later date, three more staff members of the Institute also gave notification that they support the complaint, namely [REDACTED], [REDACTED] and [REDACTED]. These 'co-complainants' are all members of [REDACTED].

On 27 March 2019 a statement of defence was submitted on behalf of the Defendant.



An initial hearing took place on 11 April 2019. In view of the complexity and scope of the complaints, at this hearing there was discussion about the procedure that would be followed. During this session, at which the Complainant, the Defendant and her legal counsel, [REDACTED], were present, the identity of the co-complainants was also made known.

On 28 May 2019 the three co-complainants were heard separately from each other; they were assisted by the SD of the Institute (the Complainant).

One day later, on 29 May 2019, the Defendant was heard in the presence of her legal counsel.

The reports of these hearings were sent to the individuals concerned for correction. These reports were then sent reciprocally to the Defendant and the Complainant and co-complainants. This did not lead to any substantial changes.

In June and July 2019 the Committee spoke with five people who work within the Institute of Psychology. These staff members were invited to provide further information and to answer questions, so that the Committee could gain a better insight into the reported violations of academic integrity and their background. These interviews were confidential, and the statements therefore do not serve as evidence.

Admissibility

The notice of complaint meets the requirements stipulated by the Academic Integrity Complaints Regulations of Leiden University & Leiden University Medical Center (hereafter: the Regulations) and is therefore admissible.

Legal framework

In Article 1 of the Academic Integrity Complaints Regulations of Leiden University & Leiden University Medical Center (hereafter: the Complaints Regulations), violation of academic integrity is defined as follows:

‘An act or omission in conflict with the Netherlands Code of Conduct for Scientific Integrity and, if the complaint concerns an LUMC employee, the LUMC Research Code.’

Article 5 of the Complaints Regulations specifies the Committee’s tasks:

5.1. The Committee investigates Complaints and issues recommendations to the Executive Board.



The complaints relate to actions that took place before 1 October 2018. Therefore, pursuant to Chapter 1, Article 19 of the Netherlands Code of Conduct for Research Integrity, the Netherlands Code of Conduct for Academic Practice 2014 (hereafter: the Code of Conduct) is applicable.

The Code of Conduct states, *inter alia*:

Preamble [...]

2. The Code presumes the autonomous setting in which universities operate, which is a fundamental aspect of academic freedom. It is a university's responsibility to promote this freedom within the framework of its curricula and research programmes.

3. At the same time, the Code presumes that a university is a collaborative venture of diverse parties. This includes academic staff and academic practitioners in training, such as students and PhD students, as well as bodies that commission research and valorisation, such as the government, civil society organisations, businesses, research-funding organisations and users. The integrity of each academic practitioner is an essential condition for maintaining these stakeholders' faith in science and scholarship. Integrity is the foundation of good and reliable academic practice.

[...]

Principles and elaborations

1. Honesty and scrupulousness

Principle: Academic practitioners are honest and forthright about their research and its applications. Scientific and scholarly activities are performed scrupulously and should remain unaffected by the pressure to achieve. [...]

1.4 Authorship is acknowledged. Rules common to the academic discipline are observed.

1.5 Academic practitioners do not republish their own previously published work or parts thereof as though it constituted a new contribution to the academic literature. When republishing previously published findings, they indicate this with a correct reference to the source or by another means accepted within the discipline.

In many disciplines it is permissible and even customary to reprint short texts from works published with or without co-authors without a source reference when it concerns brief passages of introductory, theoretical or methodological explanation.



1.6 Scrupulousness is expressed through precision and nuance in academic instruction and research, in publishing research results and in other forms of knowledge transfer.

Assessment of the complaints

The notice of complaint presents a number of complaints, grouped into five types of complaints. The names for the types of complaints are derived from the notice of complaint. In this Advice, the Committee addresses the complaints of each type separately.

1. Research without prior approval of the Psychology Research Ethics Committee (*Commissie Ethiek Psychologie*; hereafter: CEP)

The Complainant and co-complainants submitted that the Defendant conducted research a number of times without requesting prior approval from the CEP. They say that in some cases an attempt was made to compensate for this by requesting approval retrospectively. The following four examples were adduced.

- a. The Complainant and co-complainants point out that on 2 March 2017 an article was submitted to the journal *Neuropsychologia*, with the title [REDACTED] [REDACTED] ([REDACTED] & [REDACTED]). The data for this article were collected by the Defendant between 21 November 2016 and 2 January 2017. The protocol of this research study was submitted to the CEP in February 2017, i.e. only after the data had been collected. The Complainant and co-complainants shared the relevant raw research data with the Committee.
- b. The Complainant and co-complainants refer to the research study that was published in *Brain, Behavior, and Immunity*, [REDACTED] [REDACTED] ([REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED]). This is the first study with probiotics, and a further two studies followed. In the application to the CEP for this research study, the Defendant stated that ‘Yakult’ would be administered to the participants. However, in the study the Defendant administered different probiotics. In later email communication with the CEP, the Defendant asks whether she is permitted to repeat the study with elderly people; she again refers to Yakult in this communication, although she had administered different probiotics in the actual study.
- c. In November 2017 a PhD candidate of [REDACTED], [REDACTED], conducted a study



under the supervision of the Defendant during the (second) ‘Summer of Love’ festival in Amsterdam. A researcher from a different university, who had loaned a so-called ‘God Helmet’ for this study, spoke to one of the members of the CEP about this research. However, the CEP had never approved a proposal for a study in which the ‘God Helmet’ would be used.

- d. The Complainant and co-complainants point out that the chair of the CEP observed some irregularities in a grant application to the Spanish BIAL Foundation, relating to a longitudinal study of microdosing with psychedelic truffles (fungi that produce psychedelic effects when ingested). The Defendant states in her email correspondence with the SD about this application that the CEP had previously given its approval for a similar study. When the chair of the CEP was asked about this, it was found that the approval had only been given for part of the study.

1.1 Standpoint of the Defendant

- a. With regard to the research study that resulted in the article in *Neuropsychologia*, the Defendant points out that while the proceedings of the Committee are still ongoing, she is unable to access the proposals from 2016 for which she submitted applications to the CEP, which makes it impossible for her to rebut the complaint. She says that it is not possible, from the raw data that are included in the dossier, to identify the specific study to which they belong. The Defendant points out that the application in question is undated, so it is not clear when it was submitted and when approval was given for it. The Defendant emphasises that the research studies are non-invasive and that the methods used have been generally approved by the CEP since 2015. The Defendant remarks that in the past two years and three months, she has submitted 78 applications to the CEP.
- b. The Defendant points out that she had the CEP’s approval to use Yakult for the research. Further email correspondence with the chair of the CEP at that time reveals that the Defendant requested and received approval to use a different product (Ecologic Barrier). The Defendant points out that Ecologic Barrier is included in the list of food supplements that are permitted and can be administered (*Guidelines for administration of food supplements*).
- c. The Defendant states that the application for the research study during the ‘Summer of Love’ festival was submitted by [REDACTED] and the study was conducted by [REDACTED] and [REDACTED], both of whom are PhD candidates of [REDACTED]. The Defendant points that she was not the co-supervisor (in Dutch: *co-promotor*) or day-to-day supervisor of these PhD candidates and therefore bore no responsibility for their research activities.



The event on 17 November 2017 followed on from the ‘Summer of Love’ festival that was held on 26 May 2017. Follow-up research was conducted at the second event, using a ‘God Helmet’. The studies that were conducted during the event were approved by the CEP (CEP [REDACTED]). The Defendant emphasises that [REDACTED] was the Principal Investigator of that research study. The Defendant’s role extended no further than bringing the two Leiden University researchers into contact with a researcher from the University of Amsterdam (UvA). She says that [REDACTED] was going to write an addendum to supplement CEP [REDACTED] for the use of the ‘God Helmet’, but he was ill and therefore did not do this.

The Defendant points out that she explained the process to the chair of the CEP. The chair of the CEP said at the time that there had been no incorrect conduct on the part of the Defendant.

- d. With regard to the BIAL grant, the Defendant remarks that the revised microdosing protocol (CEP [REDACTED]) was approved and its status was not ‘pending approval’ or partial approval. The Defendant refers in this connection to an email dated 9 August 2018 from the secretary of the CEP and the ‘Approval Microdosing’ from the CEP’s digital application system of April 2018. In addition, on 13 August 2018 the SD gave official support, in writing, to the application for the BIAL grant. This document also included the statement that the research study had been approved by the CEP on 23 April 2018. The Defendant surmises that confusion may possibly have arisen because of a misinterpretation of terminology. The Defendant states that it is clear to all the parties that the CEP did not give approval to study the participants at home. However, this was not relevant in this study, which was explained repeatedly to the chair of the CEP.

1.2 Assessment by the Committee

By virtue of internal rules of the Institute, the CEP has the task of ethical review of research with human subjects that will be conducted by staff members of the Institute of Psychology.

This means that all applications for research with human subjects to be conducted by staff members of the Institute of Psychology must be reviewed by the CEP and that without its approval, research must not be conducted. The CEP consists of seven members, each from a different unit of the Institute. A form must be filled in for every research study and submitted to the CEP. The research can only actually be conducted after the CEP has given its approval. Researchers are aware of this, which means they must take account of the time required for review by the CEP when making their preparations.



With regard to the four reported violations of academic integrity, the Committee has observed the following.

a. (*Heart rate variability*)

The Complainant and co-complainants have provided the Committee with a CEP application form, requesting approval for research on the effect of heart rate variability on cognitive performance.

The (digital) file name of the application form, Accepted_CEP [REDACTED] _Applicationform CEP_(...).docx, shows that the application was made in 2017, because the numbering of the application is linked to the year in which it was submitted. Furthermore, the application includes a model consent statement, with the title '*Toestemmingsverklaring* (consent statement), Februar [sic], 2017, Leiden'. The Committee therefore has no reason to doubt that the application was submitted in February 2017, as adduced by the Complainant and co-complainants.

The Committee also has no doubt that this application relates to the research study that is described in the article in *Neuropsychologia*, which was submitted to the journal on 2 March 2017, because the description in the application is almost entirely the same as the research study that is presented in the journal, and the CEP does not know of any other application that would correspond with this publication.

The Defendant stated that it is not possible to identify, from the raw data, the specific study to which they relate, and that it has therefore not been demonstrated that the data from the research study were obtained without prior approval of the CEP.

The Committee does not agree with the Defendant in this regard. The Committee has no reason to doubt that the information presented by the Complainant and co-complainants is correct. A further consideration is that one of the co-complainants, [REDACTED], personally collaborated in conducting the research. Moreover, it is not plausible that the data collection began after the CEP's approval was given in February 2017, since the article was actually submitted on 2 March 2017. There would then have been insufficient time to collect and analyse the data, and write up the results as an article.

For the sake of completeness and clarity, the Committee asked an external expert whether the raw data supplied to the Committee formed the basis, or at least could have formed the basis, of the publication in *Neuropsychologia* in 2017. The external expert came to the conclusion that the raw data correspond with the said publication. The Committee therefore has no doubt that the Defendant conducted research without



prior approval of the CEP, while this was indeed necessary.

b. (*Probiotics*)

The Committee will now consider the point that on 10 July 2013 the Defendant submitted an application to the CEP for research in which Yakult is administered. This application was approved by the chair of the CEP on 29 July 2013.

On 23 September 2013 the Defendant asked the chair of the CEP whether it was permissible to replace Yakult with Ecologic Barrier. On the same day, the chair replied that this was permitted.

Since it has been found that the CEP gave its approval for Ecologic Barrier to be administered, the complaint relating to this research study must be considered to be unfounded. On this point, the Defendant did not violate academic integrity.

c. (*God Helmet*)

With regard to the research with the 'God Helmet', the Committee has observed the following.

On 25 May and 17 November 2017, two 'Summer of Love' festivals took place, organised by the Psychedelic Society of the Netherlands (PSN). A large number of the people attending each festival voluntarily ingested 'truffles', which have a hallucinatory effect.

At the festival on 25 May 2017, at the invitation of PSN, Leiden University researchers conducted research on participants who were under the influence of truffles. In the documents, this research study is also referred to as the [REDACTED]. The researchers submitted an application to the CEP for this, which is registered under number CEP [REDACTED]. This application was approved and the research then took place on 25 May 2017.

On 17 November 2017 the PSN organised the second 'Summer of Love' festival in the 'Cultural Freeport Ruigoord' near Amsterdam. Psychedelic truffles were also ingested during this festival, and research was again conducted on their effects. A new element in the research was the use of a 'God Helmet'. This is an ordinary motorcycle helmet with a few wires on the outside; before the experiments took place, the participants were informed that there is a weak electromagnetic field within the helmet, with the possible consequence of greater susceptibility to psychedelic experiences. Another difference compared with the previous research study was that the participants ingested a larger dose (not microdosing) of hallucinatory truffles. The fact that the second research study in November 2017 differed substantially from the research study in May 2017 is also evident from the explanation about the research



study included in a report of the chair of the CEP (Appendix 3: Notice of complaint). The Committee's opinion is that a new application should have been submitted, or at least an addendum should have been written to supplement the CEP [REDACTED] application, because of the substantial changes in the research design, as described above.

By chance, one of the members of the CEP was informed by a fellow researcher from another university that Leiden University researchers had conducted research at this festival with the 'God Helmet'. However, this CEP member was not aware of a research proposal relating to this. The chair of the CEP investigated the matter, and found that no approval had been requested for this research in November 2017.

The question under consideration is whether the Defendant bore responsibility for the research study on 17 November 2017. The Committee has observed that the Defendant is referred to as the 'Principal Investigator' (PI) on page 1 of the application for the research study on 25 May 2017, with number CEP [REDACTED], which was conducted during the 'Summer of Love' festival.

A great deal of information was supplied in the documents and during the oral hearing on this point, which allegedly demonstrates that people other than the Defendant bore the responsibility for the research study on 17 November 2017. For instance, various PhD candidates were named, who were involved and hence were said to be responsible for the research study on 17 November 2017. The Committee finds this implausible: these are young researchers, while the Defendant is an experienced senior researcher, who is accustomed to acting as the Principal Investigator. Since a separate CEP application was not submitted for the research study on 17 November 2017 and this built upon the study conducted on 25 May, the Committee concludes that the Defendant, who was named as the PI on the application for 25 May 2017, was also responsible for the research study on 17 November 2017.

The Defendant's involvement in the research study on 17 November 2017 is evident from, *inter alia*, an email from the Defendant on 6 November 2017 to a researcher at the University of Amsterdam (Appendix 3: Notice of complaint), which mentions the use of 'large doses' instead of the microdosing previously used during the research study on 25 May 2017.

With regard to scrupulousness, the Committee's considerations are as follows. Conducting research with people who are under the influence of e.g. drugs or psychotropic drugs is fundamentally different from research with healthy human subjects who are in possession of their full cognitive capacities. It is not possible to



know in advance what the consequences will be if drugged individuals are exposed to research with the ‘God Helmet’, which has (consciously and deliberately) been asserted, contrary to reality, to possibly have a certain hallucinatory effect.

In view of these circumstances, the Committee deems it unscrupulous that no application was submitted for the research study on 17 November 2017. The Committee’s opinion is that the Defendant can be criticised for, in any case, not having sufficiently ensured that the application for the research study on 17 November 2017 was submitted to the CEP for review in due time and in full. The next question is whether this negligence results in violation of academic integrity (see below, under ‘Opinion’).

d. ([REDACTED])

With regard to the BIAL grant, the following has become evident.

On 29 July 2018 the Defendant, together with [REDACTED], asked the SD [REDACTED] to sign a statement showing that the Institute of Psychology supports a grant application to the BIAL Foundation. The project’s title was: [REDACTED]

On 2 August 2018 the SD replied that the Institute Board wishes to support the application but it assumes that the study is classed as ‘medical research’ within the meaning of the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*; hereafter: WMO) and that the protocol will be submitted to the Medical Research Ethics Committee (*Medisch Ethische Toetsingscommissie*; hereafter: METC) (see 2.2 for a more detailed explanation).

On 5 August 2018 the Defendant informed the SD that permission from the METC was not needed. She further wrote:

‘The study for the BIAL grant is placebo-controlled and longitudinal, as participants will take 6 microdoses over the course of approximately 2 weeks.

Attached are the following documents:

1. Approval of the CEP on date [REDACTED] (CEP [REDACTED])
2. Accepted ethical protocol CEP [REDACTED]: [REDACTED]

[REDACTED]
[REDACTED].’



On 6 August 2018 the SD replied that the research study still needed to be approved by the CEP.

To this, the Defendant replied that the CEP already had already given its approval for this research study on 23 April 2018 (CEP ██████████).

The chair of the CEP had meanwhile been included in the email correspondence and stated that permission had only been given for part of the research study, i.e. only the part in which participants ingest the microdosing on site and under the supervision of the involved party, the Psychedelic Society of the Netherlands (PSN), but not for asking participants to complete an online 'mood' questionnaire as a way to monitor ingestion at home, because of the risks and uncertainty about the responsibility in case of possible side effects.

The Committee concludes that this research proposal has had the attention of the CEP. During the period before the research proposal was submitted, the SD did not follow a clear and consistent line of policy. The issue of the ethical review was not discussed to a conclusion in terms of the principles involved. The course of events reveals a certain unwillingness of the Defendant to comply with the applicable procedures. Although this is regrettable from the perspective of professionalism and collegiality, it does not in itself result in violation of academic integrity.

Looking at the situation as a whole, the Committee comes to the conclusion that a picture with little transparency arose in relation to the Defendant and her research activities, in consequence of a great number of research protocols in rapid succession and often overlapping. The SD and the CEP were aware of this, and appear to have been incapable of introducing clarity and transparency into the situation. In any event, at a certain point the SD issued a statement of agreement for the research study, while he did not have a comprehensive view of its scope, or at least the interpretation that could be given to it.

The Defendant can be criticised for consciously and deliberately giving the impression that the research proposal had been approved by the CEP, while this was only partly the case.

1.3 Opinion

As can be seen from the above, the Committee's opinion is that the Defendant repeatedly started to conduct research without the prior approval of the CEP. The Committee deems this to be improper conduct and in conflict with the rules in force within her own Faculty. The defence that the research was non-invasive, and that the



CEP had approved similar research in the preceding period, is not valid. Questions about burden and risks should have been asked, in order to assess whether the protocol needed to be reviewed not only by the CEP but also by an METC. The CEP was established by the Institute to ensure that research with human subjects that is not required by law to undergo review is still subjected to ethical review. In this context, every new protocol should be re-submitted for review, and the researcher is not free to decide whether the CEP can be expected to grant its approval for a new protocol on the basis of previous decisions. The fact that the Defendant submitted 78 applications to the CEP in just over two years does not change this, and in fact it could be remarked that this large number appears to be at variance with responsible research practice. Nevertheless, the conduct in this regard cannot be classed as violation of academic integrity, since this is a specific rule of an institute, which does not have general applicability and has not been clearly laid down in codes and formal rules; failure to comply with this specific rule does not necessarily have an evident effect on the research product.

1.4 Additional consideration for the sake of completeness

With regard to the research study with the 'God Helmet', the Committee's considerations are as follows. As noted above, the consequences cannot be known in advance if individuals in an abnormal – and possibly to be characterised as psychopathological – state are exposed to conditions that can quite easily have an escalating effect in a context that is unsuitable for monitoring and safeguarding the safety of human subjects.

A further point is that the research study was actually conducted by young, relatively inexperienced researchers, who had not been specifically instructed in relation to possible emergency situations. Moreover, there is no evidence that medical expertise was present while the research study was being conducted.

In view of these circumstances, the researchers should in any event have considered whether the research proposal should have been submitted to the METC. The report of their research study should in any case have shown that this was considered, and why the decision was made not to do this.



2. Blood samples were taken without prior permission of the Medical Research Ethics Committee (METC)

The Complainants point out that in 2016 the Defendant administered probiotics in a research study with elderly participants and took blood samples without the permission of the accredited METC of the Leiden University Medical Center (hereafter: LUMC).

The Complainants also remark that the total of 246 blood samples from this research study were stored by a Joint Programming Initiatives (JPI) partner outside the Netherlands, while the 'informed consent' forms signed by the participants state that the tubes will be destroyed.

2.1 Standpoint of the Defendant

The Defendant explains that the research study in which blood samples were taken took place in 2016 and was part of a research study that was conducted together with researchers outside the Netherlands. The Defendant points out that she obtained approval from the CEP for this research study and submitted an application to the METC of the LUMC for taking blood samples. The Defendant states that the international partners had very quickly received permission in their own institutions to take blood samples in this research study, but the permission of the METC in Leiden was taking a long time. The Defendant was under pressure to start the data collection because it had to start at the same time (in all the centres, i.e. also those of the international partners). Because the Defendant had the approval of the CEP and after three months had still not heard anything from the METC, she started the research study without the required permission. As soon as it became clear that the METC was not going to grant permission for taking the blood samples, the Defendant immediately stopped taking those samples.

The Defendant admitted this error and offered transparency by providing the head of the [REDACTED] unit and the SD with all the required information about that research study.

2.2 Assessment by the Committee

Research that is subject to the Medical Research (Human Subjects) Act (*Wet medisch-wetenschappelijk onderzoek met mensen*; hereafter: WMO) must be reviewed by an METC that is accredited by the Central Committee on Research Involving Human Subjects (*Centrale Commissie Mensgebonden Onderzoek*; hereafter; CCMO) and must not be conducted without its approval. The Committee states first and foremost that taking blood samples is an activity reserved for medical professionals and performing this activity entails that a research study is classed as medical research



within the meaning of the WMO. Before such a research study may be conducted, permission must be given by the METC.

It has been established that the Defendant participated in an international research study in the context of a Joint Programming Initiative (JPI). Part of this research study involved taking blood samples from elderly participants to whom probiotics and tryptophan were administered.

The Defendant submitted a protocol for this to the METC. However, on 23 February 2016 the METC notified her by letter that additional information was required before a decision about the application could be given. After the METC asked a second time for additional information, the request for permission was withdrawn, without the METC having granted permission.

The Defendant admitted that she had taken blood samples from a total of 106 participants in the period from 15 February to 16 March 2016.

The Committee has not found that the Defendant was under pressure from the other partners to press ahead with the research study. At the hearing, [REDACTED] explained that, on the contrary, Leiden was in the lead with this research and blood samples had been taken from more than 100 participants before the other partners had started with this. This is confirmed by the Minutes of the Kick-off Meeting of the JPI project on 23 and 24 March 2016. These show that it was only in Leiden that blood samples had already been taken. The other partners were experiencing problems with the funding, or had not yet been granted permission by their ethics committees.

2.3 Opinion

The Committee's opinion is that the Defendant, as she has admitted, acted incorrectly and in contravention of the WMO by not submitting research that needed to be reviewed, according to the WMO, to an METC. The Committee deems this conduct to be a violation of academic integrity.

The Committee's opinion here is therefore different from that concerning failure to submit research to the CEP. This difference can be explained as follows. The review of medical research is organised in line with the Declaration of Helsinki for protection of human subjects, and is a central aspect of medical research. The Act that prescribes review is restrictively formulated, in the sense that such research is not permitted unless a number of conditions have been met, including review (and the subsequent approval) by an accredited review committee (METC), which is supervised by a national committee (CCMO). The importance that society attaches to compliance with



this Act is demonstrated by the fact that a prison sentence is named in the Act as a sanction for research that does not meet certain conditions, including review. The review procedure is clear, has strict protocols and is clearly described for everyone, for example on the website of the CCMO. The Code of Conduct states (Preamble, paragraph 4) that ‘the overarching principle is that every academic practitioner is bound by the frameworks established by Dutch and international legislation’. Since the purpose of a medical ethics review is to protect human subjects, specifically also against pressure perceived by researchers, the Committee severely condemns the Defendant for this violation.

3. Plagiarism (irregularities with publications)

The Complainants point out that the Defendant published a book as the editor, consisting of 23 chapters, [REDACTED] (2017) [REDACTED]. She is the author or co-author of 18 chapters. For these 18 chapters, she used material that was written (or jointly written) by others, without these people being named as a co-author.

- a. A check with a plagiarism scanner reveals that the chapters with the titles [REDACTED], [REDACTED], [REDACTED] and [REDACTED] have a large overlap with other sources.
- b. For five chapters, the Defendant instructed students to write review articles for her course [REDACTED]. These manuscripts were used for the book. In four of these chapters, the Defendant named herself as the first author and the students as co-author, although she made hardly any changes to the manuscripts for the book.
- c. In three chapters ([REDACTED], [REDACTED] and [REDACTED]), the Defendant copied her own work almost verbatim, without stating that it had already been published previously.

3.1 Standpoint of the Defendant

- a. The Defendant explains that her book is a revised compilation of articles that she had previously published. The initial articles were written with others, but the revised version was written by the Defendant. The chapters are not identical, but are rather an updated version of previously published articles. In agreement with the publisher, this is clearly stated at the beginning of each chapter by indicating that it is ‘adapted from’.
- b. The Defendant states that she did indeed instruct students to write manuscripts, *inter alia* to ensure that students were able to publish their work. In fact, she even received compliments for this from the Director of Education of the Institute of



Psychology. She decided the sequence of author names on the basis of the quality of the articles. Hardly any changes were made to the definitive manuscripts because this had already been done while they were being written.

- c. The Defendant considers the assertion that in three chapters she copied her own work almost verbatim, without stating that it had already been published, to be incorrect. After all, 'adapted from' is repeatedly stated. This was mistakenly omitted once, for the chapter [REDACTED].

3.2 Assessment by the Committee

The Committee firstly remarks that the Defendant is named as the author or co-author for all the previously published articles listed in the complaint. This can therefore not be characterised as plagiarism, in the sense of appropriating other people's results or publications.

However, pursuant to Article 1.4 of the Code of Conduct, authorship should be acknowledged, and rules common to the academic discipline should be observed. Article 1.5 of the Code of Conduct also stipulates that academic practitioners must not republish their own previously published work or parts thereof as though it constituted a new contribution to the academic literature. When republishing previously published findings, they must indicate this with a correct reference to the source or by another means accepted within the discipline. In many disciplines it is permissible to reprint short texts from work published with or without co-authors without a source reference.

The Committee must therefore assess whether the Defendant acted in conformity with these rules.

- a. The Committee has observed that the four chapters [REDACTED], [REDACTED], [REDACTED] and [REDACTED] have a large overlap with previous articles. More detailed analysis of these chapters by the Committee reveals that the overlap with the previous articles is considerably larger than indicated by the plagiarism scanner. This analysis also gives insight into the meaning of the statement 'adapted from', as used by the Defendant.

The Committee remarks that the chapter [REDACTED] is substantively a copy, apart from one paragraph, of part of the original publication of [REDACTED], [REDACTED], [REDACTED] and [REDACTED] ([REDACTED]) [REDACTED], in the Journal of Psychiatric Research.



The plagiarism scanner indicates that only 50% is the same, because much of the overlap is not recognised. This is because in at least 180 places, words and parts of sentences from the publication have been replaced in the chapter with synonyms, although the content has remained the same.

There is a similar situation for the chapter [REDACTED]. The chapter is substantively a copy, apart from one sentence, of part of the original publication of [REDACTED], [REDACTED], [REDACTED] and [REDACTED] ([REDACTED]), [REDACTED], [REDACTED], in Neuroscience & Biobehavioral Reviews. Once again, in this chapter the fact that the content is the same is largely masked by the abundant use of synonyms and slightly changed sentence constructions.

The Defendant has pointed out that the chapters in the book are not identical to previous work and it is stated that they are an 'adapted from' version, with a reference to the original work. The Defendant considers that this gives sufficient acknowledgement to the contribution of the authors of the original work.

The Committee does not agree with the Defendant in this regard. After all, it cannot be said that the work has been adapted, changed or updated in such a way that a 'new' article is created: the articles have almost in their entirety been copied from the previous work. Although sections have been omitted from the original works, and synonyms have been used and the word order has been changed, these cannot be characterised as 'adapted versions'. The Defendant has thus not sufficiently acknowledged the contribution of the other authors. This is especially true for the chapters named under a., because the Defendant was not the first author of the original works. The Defendant has therefore violated academic integrity.

The Committee has observed that the Defendant asked [REDACTED] to read the chapter [REDACTED] before publication. In this version, [REDACTED] was named as the second author. When this version is compared with the chapter in the book, it can be seen that the name [REDACTED] no longer appears, although the text is identical apart from one exception: wherever 'we' is used in the draft version, 'I' is used in the chapter, and the verb forms have been changed accordingly.

With regard to the chapter [REDACTED], the Committee remarks that [REDACTED], [REDACTED], [REDACTED] and [REDACTED] are named as the authors on the original work, but that for the chapter in the book, in addition to the Defendant as the first author, three other authors, [REDACTED], [REDACTED] and [REDACTED]



██████████, are named. This is remarkable, since the chapter is almost entirely taken from the original work. There can consequently have been no contribution from ██████████, ██████████ and ██████████, and they are wrongly named as authors.

In both of the above cases, the Committee's opinion is that the Defendant's actions did not reflect academic integrity. The Defendant's conduct towards colleagues in a dependent position was not honest, respectful or responsible.

b. The Committee has found that in the case of the chapters based on 'student papers' (theses), the students were always named as the author or co-author. This therefore cannot be classed as plagiarism.

c. The chapters ██████████, ██████████ and ██████████ also show a large overlap with previous articles. In the case of these articles, unlike the ones listed under a., the first author of the article remained unchanged, therefore the original authorship was acknowledged.

3.3 Opinion

When compiling her edited book, the Defendant did not sufficiently acknowledge the contribution of the other authors. Moreover, in another chapter she included authors who did not make any contribution. She therefore violated academic integrity.

4. Data manipulation

The Complainants adduce that in two published articles the Defendant reported the data of fewer participants than the actual number whose data were collected, without stating why those participants were not included in the ultimate analyses.

a. The Complainants refer here to a publication from 2017 in the journal *Frontiers in*

Nutrition: ██████████, ██████████. *Overweight and Cognitive Performance: High Body Mass Index Is Associated with Impairment in Reactive Control during Task Switching*. *Front Nutr* 2017; 4: 51.

In this article, the data of 52 participants are reported, although 110 participants were tested.

b. Reference is also made to a publication in the international scientific journal *Experimental Brain Research*, also from 2017:

██████████, ██████████, ██████████. *The effect of gamma-enhancing binaural beats on the control of feature bindings*. *Exp Brain Res* 2017; 235: 2125-2131. In this article, the data of 40 participants are reported, although 87 participants were tested.



4.1 Standpoint of the Defendant

- a. The Defendant remarks that [REDACTED] was the 'corresponding author' of the article in *Frontiers in Nutrition*, and that she ([REDACTED]) supervised the data collection and analysed the data. [REDACTED] is therefore responsible for the data.
- b. With regard to the article 'The effect of gamma-enhancing binaural beats', the Defendant remarks that [REDACTED] was responsible for supervising the data collection for this research study and that discrepancies in numbers could be due to non-functioning equipment during the data collection.

The Defendant points out that because she has been suspended, she is not permitted to have any contact with her colleagues and therefore cannot further substantiate her defence.

4.2 Assessment by the Committee

- a. During the hearing, the Complainants explained that the data for the research study in *Frontiers in Nutrition* were collected by students, who saved the data in the E-Prime software. After this, [REDACTED] transferred the data to the statistical software SPSS. The Committee has observed that the original dataset of this research study consists of 110 participants. Furthermore, it can be seen from an exchange of emails on 22 November 2016 that the complete dataset, in SPSS, was supplied to the Defendant.

On 27 February 2017 the Defendant sent a first draft of the Methods and Results of the article, and also the data on which these analyses were based, to [REDACTED]. By that time, the SPSS dataset contained only 52 participants. A number of 52 participants was also reported in the article that was submitted to *Frontiers in Nutrition* on 23 May 2017 and accepted on 9 October 2017. No explanation is given in the article as to why participants were omitted from the analysis. The Committee has examined both the SPSS file that was sent to the Defendant and the SPSS file that she sent back. This examination reveals that the original dataset (n=110) contains the 'body mass index' (BMI) data of 106 individuals, with 26 of these having a BMI greater than 25 kg/m² (overweight) and 80 having a BMI less than 25 kg/m² (normal). The dataset on which the article is based has 26 participants in each group. The published article states that the participants were healthy adults aged 18-26 years (students), who were asked to take part in a research study. After they had gone through a procedure to determine their



suitability for participation, and after they had signed a consent form, a determination was made of their height and weight, which can be used to calculate the BMI. The distribution of overweight and normal participants does not correspond with this: according to Statistics Netherlands (*Centraal Bureau voor de Statistiek*; CBS), 15% of young people aged 16-20 years in the Netherlands are overweight, and 32% of those aged 20-30 years, therefore it is quite possible that 26 overweight individuals will be found in a random sample of 110 students, but not in a random sample of 52 students, as reported. Since the measurement of the BMI took place after the consent forms were signed, this means that individuals were selectively omitted by the Defendant after they had been included in the research study.

The first author of the article explained that she sent the complete dataset to the Defendant and received back a dataset with 52 participants. This reading is supported by the e-mail correspondence between [REDACTED] and the Defendant.

Furthermore, the Committee was provided with a thesis written by a bachelor's student ([REDACTED]) by [REDACTED], in which the aforesaid research study is described with 104 participants.

This shows, in the Committee's opinion, that the Defendant violated academic integrity. Research results were selectively omitted and this was not reported and substantiated in the article. In fact, it is not possible to think of any good argument to justify this, since there are no indications that anything was wrong with the measurement data of the missing participants, and analysis of a complete dataset yields more precise results than analysis of part of it.

The fact that the Defendant did not collect the data herself and is not the first author of the article does not change this. After all, it was the Defendant herself who excluded a number of participants. Moreover, the Committee has the impression that the Defendant, as a University Lecturer (US: Assistant Professor), should not place a PhD candidate in a situation where data are eliminated without stating the reasons. A further point, which became evident from various hearings, is that the atmosphere in the Defendant's research group was such that PhD candidates could not openly and safely discuss any comments that they might have.

- b. It was explained at the hearing that the experiment underlying the publication for *Experimental Brain Research* was conducted by students in November 2016. Part



of the experiment was that participants were presented with sounds via headphones. After 60 participants had been tested, it appeared that there was a technical fault and 30 participants were added and tested. After the experiment had been completed, the student sent a dataset with 88 participants to [REDACTED], who was supervising this student in writing her thesis. It can be seen from emails that on 27 November 2016 the Defendant received the dataset, in Excel, with 88 participants. On 28 November 2016 the Defendant wrote to [REDACTED] and [REDACTED] that she would take on the task of analysing the data herself, and on the same day sent a file containing analysed data with 46 participants, as an SPSS file. The Committee has examined both of the files, and has established that there were no participants with a large number of missing values, which would perhaps have justified their exclusion (but even then, this needed to have been stated in the article).

It has also been established that on 5 January 2017 the Defendant sent a draft of the article 'The effect of gamma-enhancing binaural beats on the control of feature bindings' to [REDACTED], which referred to 40 participants. The Defendant is the first author of the article, with two PhD candidates as co-authors. It is not stated in the article that participants were omitted from the analysis.

For this study, too, a bachelor's student ([REDACTED]) wrote a thesis ([REDACTED] [REDACTED] [REDACTED]). This thesis also states the correct number of 88 participants .

4.3 Opinion

The Defendant has repeatedly selectively omitted research results and has not reported this or given reasons for it. She has thus violated academic integrity.

4.4 Consideration for the sake of completeness

For the sake of completeness, the Committee remarks that it is evident from the above that the Defendant performed the statistical analysis of a research study and wrote part of the report in just one day. This is difficult to reconcile with a thorough scientific approach.



5. Grant applications based on incorrect data

- a. The Complainant and co-complainants refer to an NWO Vidi grant for which the Defendant applied in 2012. This application was successful. In the application, the Defendant presents results of a 'preliminary study' with 40 participants, looking at administration of tyrosine (a food supplement) and genetic predisposition. These results support her application, but the data were not based on a data collection that was known to the University.

- b1. The Complainant and co-complainants refer to an NWO grant [REDACTED], for which the Defendant applied in 2014 but which was not awarded. In this application she describes results about probiotics and 'fairness judgements'. The Complainants state that these data do indeed exist, but that the Defendant eliminated participants from the analysis to obtain results that support the application. The results have not been published in any scientific journal.
- b2. Additionally, the Defendant refers in her application to an article that is 'under revision' (i.e. has been submitted to a journal and conditionally accepted, provided that changes are made by the authors), but this article is unknown.

- c. The Complainant and co-complainants refer to a Joint Programming Initiative (JPI) grant for which the Defendant applied in 2015. The application was successful. In this application, the Defendant refers to data relating to tryptophan (a food supplement), probiotics, placebo and moral judgements in elderly people. The Defendant writes in the application that tryptophan and probiotics had an effect on 'moral judgements'. At the time when the Defendant submitted the grant application, she had not yet collected these data. Some of these data (the data relating to probiotics) were collected later, but not published; this was because they were part of the study in which the Defendant took blood samples without permission, described in section 2. A further point is that the effect to which the Defendant referred in her application for the JPI grant was not found in the collected data.

5.1 Standpoint of the Defendant

- a. The Defendant explains in her statement of defence that she noted her expected results in the application, and these later turned out to be correct. The Defendant acknowledges that she should have stated that they were 'expected results' and there had not been a 'preliminary study', which would mean that results had actually been found in such a study. The Defendant points out that this happened in 2012, during an emotional period for her. She also asserts in her statement of defence that this was an isolated event, which took place more than 7 years ago.



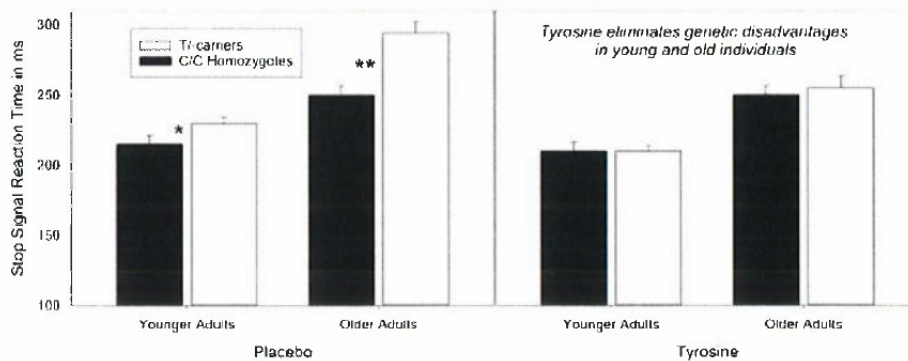
- b1. The Defendant explains in her statement of defence that the initial analyses of the data from the not yet completed ‘pilot study’ (which means the same as ‘preliminary study’) showed a result that was ‘close to being significant but had not yet reached conventional statistical significance’. She says that this was carefully reported by [REDACTED] [REDACTED] to [REDACTED], the sponsor of the research and the manufacturer of the probiotics used in the research study. The Defendant informed [REDACTED] about both the level of statistical significance and the fact that the data collection was still ongoing and the results could still change. This is also true for the proposal (where the provisional character of the data was emphasised). Once the data collection had been completed, the planned analyses were performed and the effect was ultimately not significant. Because the effect was still numerically visible, but was evidently too weak to be reliable, it was decided that the data first needed to be replicated again before they could be published. According to the Defendant, this is standard practice in research. The Defendant says that there was consequently no incorrect conduct on the part of herself or [REDACTED] in this situation. The planned repeat study was ultimately not conducted.
- b2. The Defendant points out that she should have stated that the article was ‘in preparation’, instead of ‘under revision’. The Defendant explains that account still had to be taken of criticisms of individuals who had to proofread the article. Changes were made to the article in consequence of the criticisms, and co-authors were added.
- c. The Defendant admitted that she should not have taken blood samples without the METC’s prior permission. When she ultimately did not obtain permission for the research study from the METC, she stopped the research study and paid back the JPI grant that she had received. She expresses regret for her conduct. The Defendant also refers to her defence in section 2, which relates to the JPI grant.

5.2 More detailed investigation

During the hearing with the Defendant, the Committee announced that it would also investigate other grant applications, and in this context named an application to the European Research Council (ERC). This relates to an application with the title [REDACTED] (proposal number [REDACTED]), which was submitted in 2016 for a ‘Consolidator Grant’ in the European Commission’s H2020 programme. The Faculty gave its approval for a requested amount of 2 million euros. The application was not successful.

The application included the following figure, to which reference was made in the text as 'preliminary results':

Figure 3. Mean stopping time (stop-signal RT) as a function of intervention



(Placebo vs. Tyrosine), C957T polymorphism at DRD2 gene (C/C homozygotes vs. T/- carriers) and age group (younger adults vs. older adults). Asterisks indicate significant (* $p < .05$; ** $p < .01$) effects of the gene on stopping time.

This figure refers to an experiment in which a genetic variant (C957T polymorphism at the DRD2 gene) was measured in 120 individuals (60 'older' and 60 'younger'), and then after randomisation half of the individuals were administered tyrosine and half were administered a placebo. After this, all 120 individuals performed a reaction time test. According to the application, this is an unpublished preliminary study, which is said to support the idea behind the research proposal. A study of this kind is not known at the University. It can also not be found in publications of the Defendant, although she has published similar studies, such as one where the same polymorphism was measured in 166 students (Cortex 2016; 82: 217-224), whose average age was 20-21 years, and one (Eur Neuropsychopharmacol 2018; 28: 933-944) in which 26 young people were tested after ingesting tyrosine. In a recent publication ([REDACTED], in press), two polymorphisms were measured in 194 young people, and psychological tests were performed without administration of tyrosine. Randomising and genotyping 120 individuals, as reported in the ERC application, is a major undertaking and it is inconceivable that such a research study would be conducted and not published. In the same application, the Defendant describes a randomised experiment with genotyping and tyrosine versus placebo administration in individuals aged 55 years and over. Nothing can be found in the literature about this experiment either.



5.3 Opinion

The Committee's opinion is that, in grant applications, the Defendant repeatedly presented results of experiments that had not been conducted, and also manipulated results to present a favourable picture of reality. This occurred not only in an application from 2012, but also in applications from 2014 and 2016, therefore the defence that in 2012 it was an isolated event during an emotional period does not appear to be valid. This violates academic integrity. In addition, it can be seen from the Defendant's defence that statistical tests were continually performed during the course of an experiment, and the research population was supplemented in order to increase the chance of obtaining a statistically significant result. This is known as 'p-hacking', i.e. incorrect use of statistical methods. The Committee's opinion is that this violates academic integrity.

5.4 Consideration for the sake of completeness

The Committee adds the following remark with regard to the research study that was published in Cortex. In the article, it is stated that the research study was approved by the CEP, but the METC is not mentioned. During the study, genotyping using buccal swabs took place and tyrosine or a placebo was orally administered, after which the participants performed reaction time tests.

The Committee considers that it cannot be said in advance whether this research study must be characterised as pharmaceutical research, but it must certainly be characterised as research within the meaning of the WMO. The Defendant should therefore have had the research proposal reviewed by the METC.



6. Recommendations

Before proceeding to formulate its recommendations, the Committee feels it is important to remark that in this entire dossier, the appropriate channels for early detection of possible violations of academic integrity did not function.

1. The Committee recommends that the following two articles should be retracted:

- [REDACTED], [REDACTED], [REDACTED]. The effect of gamma-enhancing binaural beats on the control of feature bindings.

Exp Brain Res 2017; 235: 2125-2131.

- [REDACTED], [REDACTED]. Overweight and Cognitive Performance: High Body Mass Index Is Associated with Impairment in Reactive Control during Task Switching.

Front Nutr 2017; 4: 51.

2. The Committee recommends that the relevant grant-providing bodies for the following applications should be informed about the content of this advice. They are:

- NWO 2012, [REDACTED]
[REDACTED]
- NWO 2014, [REDACTED]
- Joint Programming Initiatives (JPI 2015)
- ERC 2016 [REDACTED]
[REDACTED] (Proposal number [REDACTED])

3. The Committee recommends that this advice, together with a summary in English, should be sent to:

- NWO
- [REDACTED], the Defendant's current employer
- Faculty Board of the Faculty of Social and Behavioural Sciences
- Scientific Director of the Institute of Psychology
- Board of the Institute of Psychology
- Psychology Research Ethics Committee (CEP)
- Medical Research Ethics Committee (METC) of LUMC
- University of Bonn (JPI partner in BIAL Grant)
- University of Mannheim (JPI partner in BIAL Grant)
- University of Extremadura (Badajoz) (JPI partner BIAL Grant)



4. The Committee advises the CEP to investigate whether it is functioning in accordance with its objectives, and more in particular whether all the research proposals that should be reviewed are actually submitted to it, and whether its decisions are followed in practice.

5. The Committee advises the Executive Board to instruct the Faculty Board of the Faculty of Social and Behavioural Sciences to investigate all of the Defendant's articles. This investigation should relate to both whether approval had actually been obtained from the body that was required to approve the research study reported in each article (CEP/METC) and to the veracity and completeness of the data and analyses presented.

6. Finally, the Committee remarks that the Defendant can be reported to the judicial authorities for conducting research without METC approval, and fraud in acquiring grants.

Conclusion of the Committee

In view of the above, the Committee concludes that the Defendant did not comply with the requirements applicable with respect to academic integrity.

Established on 11 November 2019

On behalf of the Committee,



Dr. M.Y.H.G. Erkens, LL.M.
Chair



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



Prof. F.R. Rosendaal
Chair