

## **reaction cETO with questions and remarks**

Dear Gjalt-Jorn,

The cETO reviewed your application and has the following questions and remarks:

In general:

- The cETO can only review and approve the part of the research that takes place in the Netherlands.
- There is no WMO obligation for this research. The research focuses solely on the explanation of everyday health behavior.
- The researcher must ensure that Maastricht University (collaboration) only gains access to anonymized data.

Course credit:

- No payment for participation is awarded, but students of the Dutch Open University can earn course credit.": will participants lose course credit when they withdraw data?
- Providing course credit might suggest that participation is not entirely voluntarily.
- How will you obtain email contacts from potential participants? Did enrolled students agree to be contacted for research reasons
- It is not clear how the researchers will collect sensitive participant data necessary for the credit points. How will this information be disentangled from the questionnaire responses? How can you ensure anonymity?

Data storage:

- Please specify where and how data will be stored and who will have access to the data.

Online survey:

- What other information such as timestamps etc can be obtained from the online survey and in what way will it be used?

Information letter:

- The information letter and the declaration of consent must state that participation is voluntary and that the subject can withdraw at any time during the research without reason.
- Please add that participants can ask questions before, during and after the research
- Please add own contact details
- Please explain what happens to the personal data and research data; how and where the data is (safely) stored and who has access. How is the anonymization regulated?.
- Please specify how many credit points participants will obtain
- Please specify whether there are any benefits for participants
- Please refer to [www.ou.nl/privacy](http://www.ou.nl/privacy)

- The cETO is under the impression that potential participants do not have a reflection period. It seems like they must give permission immediately after reading the information letter. Is this correct? The cETO wishes to emphasize that this is not desirable.
- Please add “research data is stored in a safe manner by the Open University for 10 years”.
- Please add: By agreeing to participate you indicate that you have read and understood this text, that you are 18 years of age or older, you know the Open University stores the research data for 10 years, that you have given your consent freely, you know you can end the questionnaire without reason and do you consent to use your data, which will be collected anonymously, for scientific research.

Tip: there is a spelling error in the advertisement / informed consent document: In deze studie word (wordt) gemeten hoe u staat tegenover twee gedragingen om de zogenaamde determinanten van dat gedrag te meten.

CETO would like to receive a response to the remarks as mentioned above.

You can respond to this via 'reply' under the reaction of the cETO and react to the questions and comments. If and where necessary, it is possible to make adjustments via the edit in the application itself and / or upload new documents since it is in draft mode again.

The request is then to 'Submit' the application to the supervisor again, after giving the response. The supervisor then receives a message and can approve the response.

If there are any questions, please let me know.

Kind regards

*NAME REMOVED FOR PRIVACY REASONS*

secretary cETO

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Dear *NAME REMOVED FOR PRIVACY REASONS*, dear cETO,

Herewith we provide the additional information you have requested. For clarity, we have:

- Removed your remarks, as they did not require a response (but obviously retained your questions, to which we respond below);
- Colored your original questions green.

### **Response to cETO requests for additional information**

- No payment for participation is awarded, but students of the Dutch Open University can earn course credit.”: will participants lose course credit when they withdraw data?

No, it is made clear to respondents in the corresponding course that they can indicate that they do not give permission to use their data, in which case their data are removed from the dataset before it is made public (and analysed). Inclusion of this question is in fact a prerequisite for inclusion of any study in the Virtual Lab of this course (PB0202).

- How will you obtain email contacts from potential participants? Did enrolled students agree to be contacted for research reasons

No email contacts are obtained at any point. Students choose which study or studies they wish to participate in, and therefore have to 'opt-in' to be able to participate.

- It is not clear how the researchers will collect sensitive participant data necessary for the credit points. How will this information be disentangled from the questionnaire responses? How can you ensure anonymity?

No sensitive participant data is collected; as we explained in response to your section "VI Additional information" (specifically, question "Is there any additional information relevant to the cETO's assessment?"), "Note that this study falls under the approved research line "determinant studies", approved by the cETO at the 11th of May 2017 (reference code U2017/03081/FRO). However, explicit ethical permission is required as a reference case for requesting ethical approval in other countries. Regarding data management: the data will be collected anonymously and made public (cf. the CIBERlite studies and repositories at <https://osf.io/2uwxp/> [4] and <https://osf.io/pemfz/> [11] for examples)". Data are collected anonymously. Awarding of the course credit works through the Virtual Lab workflow, which the principal investigator will happily inform you about, but which is quite technical and so will not be explained here. Regarding this study, as I said, the data are collected anonymously, and therefore, at no point whatsoever will any identifiable data be collected, and as such, the GDPR does not apply to the data collected for this study.

#### Data storage:

- Please specify where and how data will be stored and who will have access to the data.

Our apologies for having left this implicit in our answer to your section VI. Like in the other two CIBERlite studies (see the corresponding Open Science Framework repositories linked to in the original request for ethical approval), the data will be published at the Open Science Framework. As we explained, the data are collected anonymously, and therefore, there is no processing to anonymize the data. There is processing, however, to remove the data from those participants who want their data removed. The exact workflow can clearly be seen in the OSF repository for the other two CIBERlite projects (should you want to inspect this, see the Rmd file in the "results-analysis-scripts" directory in those repositories).

#### Online survey:

- What other information such as timestamps etc can be obtained from the online survey and in what way will it be used?

This is a very generic question; what exactly do you mean by ‘etc’? Timestamps can be obtained, and can be used, for example, to verify whether a participant was serious when completing the survey. However, there are probably other things one can do with timestamps. I am not sure what you mean to ask with this question? I suggest that if this answer is not the answer to your question, you contact the principal investigator (Gjalt-Jorn) directly to prevent further delays in data collection.

#### Information letter:

- The information letter and the declaration of consent must state that participation is voluntary and that the subject can withdraw at any time during the research without reason.

We have revised the sentence “You can cease participation at any time.” to “Participation is voluntary, and you can cease participation at any time.”.

- Please add that participants can ask questions before, during and after the research

We have revised the sentence “If you still have any questions, you can always ask these through [ciberlite@u-bc.eu](mailto:ciberlite@u-bc.eu).” to “If you ever have any questions, you can always ask these through [ciberlite@u-bc.eu](mailto:ciberlite@u-bc.eu).”.

- Please add own contact details

These are included – this email address forwards to both researchers’ email addresses, so as to ensure full transparency of the process and swift responses to any queries.

- Please explain what happens to the personal data and research data; how and where the data is (safely) stored and who has access. How is the anonymization regulated?.

As we explained in section VI in the original proposal, no personal data are collected, and therefore, there is no anonymization. All data from participants who give permission for publication of their data will be made public following the procedure outlines above.

- Please specify how many credit points participants will obtain

In the Virtual Lab, this is already shown to participants in the study overview. I have the feeling that the cETO is not familiar with how our virtual lab works. Would it be a good idea if I come give a brief overview once? In any case, for now, please see <https://oupsy.nl/vl1.5/studies> for this overview.

- Please specify whether there are any benefits for participants

There are none, and therefore, these are not listed. That is, one could always add potential benefits like enjoyment through completing the questionnaire, or long-term benefits as this study

will contribute to more effective behavior change intervention development, but these are so far removed from participants' reality that listing them doesn't seem reasonable.

- Please refer to [www.ou.nl/privacy](http://www.ou.nl/privacy)

The OU privacy policy does not apply, because no personal data are collected. Only anonymous data are collected (i.e. facts). Linking to this page nonetheless confuses participants by implying that the privacy policy is in any way relevant to their participation to this study.

- The cETO is under the impression that potential participants do not have a reflection period. It seems like they must give permission immediately after reading the information letter. Is this correct? The cETO wishes to emphasize that this is not desirable.

No, this is not correct. As explained above, this is a Virtual Lab study, and therefore, participants have a reflection period that lasts as long as they want. Perhaps it would be a good idea if I drop by some time to explain how the Virtual Lab works (for future reference)?

- Please add "research data is stored in a safe manner by the Open University for 10 years".

This statement is not true for this study. Research data will be made public in perpetuity (as it should be, pursuant to the Open Science policies of the Open University, which mean that unless there are good reasons to do otherwise, all products of the scientific endeavor are made public as soon as possible and in perpetuity). We have amended the statement as followed and added that instead. We have included the sentence "Conform the Open Science policies of the Open University, the data in this study will be made public in that repository." After the sentence "The repository for this project is <https://osf.io/mh9fs/> - the repository for the overarching international project is <https://osf.io/pr9dz/>".

- Please add: By agreeing to participate you indicate that you have read and understood this text, that you are 18 years of age or older, you know the Open University stores the research data for 10 years, that you have given your consent freely, you know you can end the questionnaire without reason and do you consent to use your data, which will be collected anonymously, for scientific research.

This text has been amended to reflect the different conditions (i.e. being an Open Science study, data are collected anonymously and published immediately and in perpetuity, not only for 10 years, and not (only) at the Open University), and now reads: "By agreeing to participate you indicate that you have read and understood this text, that you are 18 years of age or older and participate voluntarily, and do you consent to use your data, which will be collected anonymously, for scientific research."

Tip: there is a spelling error in the advertisement / informed consent document: In deze studie word (wordt) gemeten hoe u staat tegenover twee gedragingen om de zogenaamde determinanten van dat gedrag te meten.

Great, thank you very much for this correction! This has been implemented.

Thank you for all comments and improvements. We hope that in this response, we have managed to clarify all remaining points, and make all adjustments that you deem necessary to provide your approval. If you have any remaining questions, given that data collection was planned to commence at the third of January, I request you contact the principal investigator, Gjalt-Jorn, directly, so any remaining issues can be swiftly explained/resolved.

Again, thank you very much for your effort and corrections, kind regards

Gjalt-Jorn Peters and Rik Crutzen

(more accurately; on behalf of Rik Crutzen; the urgency of this response combined with other engagements have prevented him from reading this response, but we are generally in agreement about these matters)