Create Full ethical assessment

Title *

I General information

Intended start date *

Date

11/29/2018

E.g., 11/29/2018

Intended end date *

Date

11/29/2018

E.g., 11/29/2018

Principal investigator (supervisor in case of thesis) *

- Select a value -

Researcher(s) performing the research (first name, surname, email)

Source | Styles

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In what context will the research be performed? *

- Select -

II WMO obligation scan

Help

Does the WMO law apply? *

- (●) no (no WMO check necessary)
- ( ) I am not sure (Please fill in the WMO check below)

III Ethical assessment

The ethical assessment concerns:

- None -

Help

1. Provide a brief description of the study (preferably substantiated with references) (maximum 500 words description, references not included) of the:

A. research question and relevance/importance (scientific and societal)

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B. study design, participants (age, characteristics, required number (preferably and if applicable including power calculation))

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C. main statistical analyses

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2. Provide a brief description of the (measurement) tools (e.g. questionnaire, materials, apparatus) to be used

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Upload lists and measurement tools

Add a new file

Browse... No file selected. **Upload**

Files must be less than **2 MB**.

Allowed file types: **txt pdf doc xls docx xlsx**.

IV Information, recruitment and privacy

1. How will participants be recruited? (You may check multiple answers)

- ☐ Internet
- ☐ Information meeting
- ☐ Newspaper / magazine / advertisement
- ☐ By sending out an information letter
- ☐ Folder
- ☐ Other (explain below)

Explanation

Add information / advertisement / folder / etc. as an appendix

Add a new file

Browse... No file selected. **Upload**

Files must be less than **2 MB**.

Allowed file types: **txt doc xls docx xlsx pdf**.

2. How much consideration time will the participant / legal representative have to decide whether to participate or not?

- ○ 1 week
- ○ 2 weeks
- ○ Other, namely

3. Must participants or their legal representative (for minors or those that are non compos mentis) provide a written or online consent form?

- ○ Yes (upload the informed consent below)
- ○ No

Upload the informed consent

Add a new file

Browse... No file selected. **Upload**

Files must be less than **2 MB**.

Allowed file types: **txt pdf doc xls docx xlsx**.

4. Are participants or their legal representatives (for minors or those that are non compos mentis) informed in written (or online) form in advance about the nature of the study?

- ○ Yes (upload the information letter below)
- ○ No, explain why not and upload or describe materials that are used

Help

Upload the information letter

Add a new file

Browse... No file selected. **Upload**

Files must be less than **2 MB**.

Allowed file types: **txt doc xls docx xlsx pdf**.

5. If it is not possible to provide full disclosure prior to the study taking place, are participants informed in written (or online) form (and possibly verbally) about the objective of the study afterwards (feedback/debriefing)?

- ○ Yes (upload the debriefing below)
- ○ No, explain why not

Help

Upload debriefing (if applicable)

Add a new file

Browse... No file selected. **Upload**

V participants

1.a What study population falls under the study? (You may check multiple answers)

- ☐ Students of the Open University
- ☐ General population without any disorders (compos mentis)
- ☐ General population with disorders
- ☐ Patients (inpatient or outpatient care)
- ☐ Other (e.g. non compos mentis)

1 b. Among which age category are you going to perform your research and which corresponding consent forms are you going to use? (You may check multiple answers) Help (for examples of informed consent models to use)

- ☐ > 17 years and compos mentis - Informed Consent, model 1
- ☐ All ages and non compos mentis - Informed Consent, model 2
- ☐ 12 - 17 years and compos mentis - Informed Consent, model 3
- ☐ < 12 years - Informed Consent, model 4

2a. Name and type of organisation(s) from which the study population will be recruited (if applicable)

2b. Ha(s)ve the participating organisation(s) provided their written consent (consent is required for approval)?

- ○ Yes (please upload consent form below)
- ○ No, explain why not

Help

Upload written consent of participating organisation(s) (if applicable)

Add a new file

Browse... No file selected. **Upload**

Files must be less than **2 MB**.
Allowed file types: **txt doc xls docx xlsx pdf**.

2c Does the study concern a multi-centre study?

- ○ N/A
- ○ Yes
- ○ No

2d Does (part of) the study take place outside of the Netherlands? (for Belgium a no fault insurance needs to be taken out)

- ○ No
- ○ Yes (explain and name the countries that are involved)

If the study concerns Belgium participants a no fault insurance must be arranged. Please contact Henri.terHuurne@ou.nl

3 Incentive per participant in the study

- ○ None
- ○ Travel expenses
- ○ Remuneration (please explain)

4 (Maximum) load per participant in the study (complete)

Please answer in format hours:minutes

If it concerns more than one research session, complete the following questions.

A. Maximum number of hours:minutes (H:M) per session

Please enter Houres and minutes (H:M)

B. Maximum number of sessions a day:

C. Maximum number of days per session

VI Additional information

Is there any additional information relevant to the cETO's assessment?

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VII data storage procedure.

Here you find the data storage procedure.

☐ yes I have carefully read and understood the data storage procedure and confirm my adherence to the protocol (must be conducted by the principal researcher or student, depending on who is the applicant) PLEASE CONFIRM.

For students
For researchers

VIII Included forms

Check here whether the following forms were uploaded

☐ Advertisement

☐ Participants information letter (or online form) / if applicable the protocol of verbal information, including any written additional information about the study). (obligatory)

☐ Written feedback/debriefing (if applicable)

☐ List of the measurement tools used

☐ See previous point: questionnaires/interview questions etc. (depending on the research method) (obligatory)

☐ Participant (informed) consent form (obligatory)

☐ External institution declaration of consent (if applicable)

Other (such as participants insurance) (if applicable), namely:

IX Your application complete?

Please confirm that you have filled in all applicable fields in the form

☐ yes

X Final agreements

All researchers specified in the registration agree with the following provisions (check):

Ad 1.
All researchers specified in the registration are responsible at all times for respecting the regulations and legislation that apply to research involving human participants and the ethical guidelines that apply to research (in the relevant subject area) and if necessary will arrange participants insurance. If part or all of the study takes place outside the Netherlands the responsible researchers in the countries involved are responsible for respecting the regulations and legislation that applies to research involving human subjects in their country and the ethical guidelines that apply to research (in the relevant subject area). The principal researcher from the OU hereby declares to have informed his or her foreign colleagues about this matter;

☐ Yes

Help

Ad 2.
All researchers specified in the registration must guarantee that participants (compos mentis or non compos mentis, in a relationship of dependency with the researcher or not) can terminate their cooperation at any time without any consequences whatsoever;

☐ Yes

Ad 3.
The researcher commits to maximise the quality of the research, the (statistical) analysis and reporting;

☐ Yes

Ad 4.
By signing the researcher declares that the research information necessary for the assessment is complete and truthfully described; with particular attention to ethical aspects;

☐ Yes

Ad 5.
The undersigned declares that when performing the study he or she will act in accordance with:

- **The Personal Data Protection Act (and associated personal data code of conduct)**
- **The code of conduct for scientific practice.**

☐ Yes

You can save the (draft or final) application by using the save-button. The save button can be found at the end of the page (left). Note: fill in all obligatory fields (marked with a *) before you save the application (elsewhere the application will be lost).

Revision information

New revision

Revision log message

Provide an explanation of the changes you are making. This will help other authors understand your motivations.

Save