Ethics Review Application - Full Procedure

Start of Block: Welcome

Q1 **Welcome! Use this form to apply for ethical review of your research at the Faculty of Social Sciences at Vrije Universiteit Amsterdam.**

Please complete this form in one seating. Your responses will be stored for one month, so if you break off the application you can resume within one month.

At the end of the form you will get a pdf of your responses. Please save this document for your records.

Q2
Before you proceed, make sure you have prepared the following materials:

- ○ Informed consent form for participants (if applicable) (9)
- ○ Debriefing for participants (if applicable) (11)
- ○ Data management plan (10)

End of Block: Welcome

Start of Block: Researcher

Q3 **Your name:**

- ○ First name (1) _____
- ○ Family name (2) _____

Q4 **Your email address:**

_____

Q5 **Your VU net ID:**

_____

Q6 **Your position:**

▼ Postdoc (3) ... Other (please note that master students and PhD students are NOT allowed to submit an application) (7)

Display This Question:

If Your position: = Other (please note that master students and PhD students are NOT allowed to submit an application)

Q64 Please describe your position:

_____

Q8 **Department:**

▼ Communication Science (1) ... Sociology (6)

End of Block: Researcher

Start of Block: Research project

Q9 **Title of your research project:**

_____

_____

_____

_____

_____

Q65 **Intended starting date of the research project: [dd - mm - yyyy]**

_____

Q50 **Which type of project most adequately describes this application?**
For example, the application could concern a MSc student project which is part of the PI's larger research project. In this case "Master project" applies.

- ○ Bachelor project (1)
- ○ Master project (2)
- ○ PhD project (3)
- ○ Postdoc / Senior level project (4)
- ○ Other: (5) _____

Q51 **What is the funding source?** Please specify funding source (1: VU University; 2: NWO/ERC; 3: foundation support / contract research) and the name(s) of the funding agency and grant number(s). In case of multiple sources please mention them all.

_____

Q52 **Is the research conducted in collaboration with researchers or institutes outside the VU?**

- ○ No (4)
- ○ Yes, with: (5) _____

End of Block: Research project

Start of Block: Third party

Q11 **Has a *third party* requested an ethical review?**
A third party may be a funder (e.g., NWO, ERC), a journal, or another party outside VU Amsterdam.

- ○ No (1)
- ○ Yes, name of third party: (2) _____

End of Block: Third party

Start of Block: Eligibility

Q12 **Has the proposed study already been approved by another review committee?** For eample by NWO, NIH, EMGO+, or the review committee of another faculty.

- ○ No (1)
- ○ Yes, by (name of review committee) (3) _____

Q13 **Is this a revision of a previous proposal?**

- ○ No (1)
- ○ Yes, proposal # (2) _____

Display This Question:

If Is this a revision of a previous proposal? = Yes, proposal #

Q14 **If you are submitting a revision, please upload a letter describing how you have dealt with the committee's comments. In this case, the revision letter suffices and you do not need to fill in this form again. Upload the revision letter here:**

Skip To: End of Survey If If you aresubmitting a revision, please attach a letter describing how you have dealtwith the comm Is Displayed

Q15 **Do you have a non-WMO statement ("niet-WMO-plichtig verklaring") for the proposed research?** A non-WMO statement means that the research is not subject to the provisions of the Medical Research Involving Human Subjects Act (WMO), and hence does not need to be reviewed by the Medical Ethics Committee (METC). Such review is not required for all research (though it is required in the grey area between behavioural and medical research). A non-WMO statement must be issued by the METC. The approval procedure for research with a non-WMO statement is shorter than when ethics review is required, and is free of charge. For further details, see the METC page of the VUmc website, https://www.vumc.nl/afdelingen/METc/ [NL] https://www.vumc.com/branch/internalmedicine-cru/qualityassurancecru/medicalethicscomite [EN]

- ○ No (1)
- ○ Yes (2)

Q16 **Does the proposed research meet at least one of the following criteria?** a) The research question is medical in nature
b) There is a medical risk
c) The research involves medical acts Ad a). The research question is medical in nature. The study makes use of test subjects with the objective of answering a question relating to a disease or medical condition, which may include psychiatric complaints such as depression and schizophrenia. It should be noted that not all studies involving patients need have a medical objective. An example taken from the field of psychology is the study of cases involving specific neurological damage as a proxy for a cognitive model. Ad b). There is a medical risk to participants, in other words there is an immediate or predictable chance that they will suffer physical and/or mental harm or inconvenience. The inconvenience may be an integral aspect of the study, but is limited to the duration of the investigative session – for example, inflicting slight pain or a temporary increase in social pressure. The risk of harm is naturally greater in the case of patients – that is, people with pre-existing physical or mental conditions, who may be more vulnerable than others – but is not restricted to them. Mentally incompetent adults (for example

people suffering from Alzheimer's disease, who have learning difficulties or are unconscious) may also be at greater risk of physical or mental harm. On the other hand, not all patient groups need be vulnerable in the context of the proposed study, so research involving patients will not necessarily lead to a higher risk. Thus, persons with a complaint or disability that was diagnosed in the past but who can cope well with this condition and who are not mentally incompetent are not necessarily at higher risk. For example, this consideration would apply to the study of a new teaching method in a class where some or all of the children are dyslexic, the trial of a new educational approach for children with ADHD, investigation of the movement of Paralympic athletes who are wheelchair users and study of how diabetes patients perceive pictures of everyday food products. As long as the proper precautions are taken, such studies will involve little or no risk. It follows that not all studies involving patients need be referred to the METC. After all, such studies involve selected patients. Some of the patients in the sample may be at risk, even if they were not selected for this; this can however be dealt with by suitable choice of the exclusion criteria. Ad c). The study involves medical interventions – invasive procedures, or procedures performed by healthcare professionals whose name appears in the Dutch BIG register of healthcare professionals set up under the Professions in Individual Healthcare Act (Wet op de Beroepen in de individuele Gezondheidszorg; http://wetten.overheid.nl/BWBR0006251/2014-02-15#HoofdstukIV Invasive procedures include the taking of blood, tissue or DNA samples (unless through saliva), the giving of injections, the administration of substances in more than normal daily amounts and the withholding of medication or other medical treatment. The use of non-invasive methods, such as the taking of saliva samples and EEG, galvanic skin response, pulse rate or blood pressure measurements, does not require ethical review. fMRI measurements do currently require ethical review if they are carried out at VU University Amsterdam Medical Center (VUmc); the Spinoza Centre for Neuroimaging has its own review procedures.

- ○ Yes, at least one of these criteria applies (1)
- ○ No, none of these criteria apply (2)
- ○ I am not sure, and would like the committee's advice on this (3)

End of Block: Eligibility

Start of Block: Background: research questions and relevance

Q17 **What is the main research question or objective of the research?** Give a brief description of what you want to achieve in your research project. What is your research hypothesis or hypotheses?

_____

_____

Q18 **What is the importance of this question or objective?** Give a brief description of the background and impact of your research on theory and/or practice.

Q19 **What benefit do participants and society at large derive from the study?** Is the load imposed on participants balanced by any benefits? These may be not only financial rewards (money or credits) but also knowledge, insights into one's own abilities and limits, general knowledge about the research and its results, the feeling that one is helping to develop a new treatment that may actually benefit each participant personally, a free course, a new skill. Describe the actual benefits participants derive from taking part in the study, and *mention whether the benefits derived depend on anything (for example the participant's level of performance).*

End of Block: Background: research questions and relevance

Start of Block: Study design

Q61 **What is the study design?** Give a brief description of the study design and procedure, including stimulus material, conditions and interventions, between vs. within subject measurements, whether the study is experimental or quasi-experimental, etc.

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_____

End of Block: Study design

Start of Block: Data and methods

Q20 **During the study, what type of data will be analyzed?** More than one option may apply. Select at least one.

- ☐ personal interviews (1)
- ☐ paper-and-pencil questionnaires (2)
- ☐ online surveys (e.g. on Qualtrics, Survey Monkey) (3)
- ☐ observations (4)
- ☐ field notes (5)
- ☐ photos (6)
- ☐ videos (7)
- ☐ social media messages (8)
- ☐ other: (9) _____

Q21 **Which option(s) best describe your research population(s)?** More than one option may apply. Select at least one.

- [ ] Patients - A patient is a person (including children) with a physical or mental illness who is being treated or managed by a physician or care worker shortly before, during or shortly after the period covered by the research, and is thus currently in need of care. (1)
- [ ] People with an impairment or disability - An impairment is not necessarily under current medical care, but could still lead to vulnerability. Think of physical disability, dyslexia, ADHD, etc. (2)
- [ ] Mentally incompetent adults - Think of Alzheimer, the unconscious, etc. This should almost always be submitted to the METC, unless you have a non-WMO statement. (3)
- [ ] Persons selected from a wider population on the basis of a deviant or clinical score on a test or questionnaire - These are not a priori patients, but may still be vulnerable given their score. (4)
- [ ] Children (age 0-11) (5)
- [ ] Adolescents (age 12-17) (6)
- [ ] Elderly (age > 65) (7)
- [ ] Healthy adults (age 18-65) (8)
- [ ] Other: (9) _____

Q22 **What are the inclusion and/or exclusion criteria?** Describe the criteria used in the selection of participants, and the reasons for these criteria. Who is allowed to participate and who is not, and why?

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_____

_____

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Q23 **How are the participants recruited?** Give a brief description of the way you approach potential participants. *Please include any recruitment material you may have (e.g. flyers, adverts) by uploading it in the next question.*

Q62 **Please upload any recruitment material you may have (e.g. flyers, adverts) here.**

Q24 **How many participants do you expect to need, and what is your basis for this estimate?** One possible approach is power analysis, but this is not obligatory. State the number of participants required for the study as a whole, and for the various subgroups. You can also mention whether you will be performing an exploratory or pilot study, and whether you intend to use Bayesian methodology.

Q25 **Research location(s)**
Where will the research be conducted?

_____

_____

Q26 **Is some or all of the research performed abroad?** For example through online tools such as Mechanical Turk and Crowdflower, but also through collaboration with a foreign institute at which (part of) the data is being collected. NB: Online research using tools such as Mechanical Turk is regarded as being based on voluntary participation meeting standard conditions (anonymity, voluntary, on the basis of informed consent, participants can stop whenever they want to, adequate debriefing).

- ○ No (1)
- ○ Yes, in (name country): (2) _____

Q27

Approximate starting date of data collection: [dd – mm – yyyy] The committee does not review projects in which the data collection has already started, or will start before the committee has had a chance to assess the proposal. The committee aims for a response time of a few weeks but cannot (yet) guarantee this.

_____

Q28 **Approximate end date of data collection: [dd - mm - yyyy]**

_____

End of Block: Data and methods

Start of Block: Procedure

Q29 **What are you going to measure?** Describe exactly which variables you are going to measure and how you will measure them (operationalizations).

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Q30 **Are you going to use stimuli that might be disagreeable or stressful for the participant?** For example questions, illustrations, statements, etc. that deal with emotionally charged or taboo topics. Or stress-inducing instructions.

- ○ No (1)
- ○ Yes, or potentially so (2)

Display This Question:

If Are you going to use stimuli that might be disagreeable or stressful for the participant? For exa... = Yes, or potentially so

Q31 **Please describe the used (potentially) disagreeable or stressful stimuli below:**

_____

_____

_____

_____

_____

Q32 **What is the *maximum* load you impose on the participants?** The load imposed on the participants should take their vulnerability into account. Describe clearly the pressures put on the participants and/or the tasks they have to perform. Take mental as well as physical stress into consideration. If the study consists of several components, do this for each component –

and please include follow-ups, if any. The following details should be included:
- Nature of the load
- Frequency of the load (how many sessions, and how much time between sessions)
- Duration of the load (per session and total)

Q33 **What feedback does the participant receive?** Is some of the information given painful or embarassing, or can the facts reported have far-reaching consequences for the participant? If so, what kind of support does he or she receive?

Q34 **What do you estimate the risk of physical or mental harm to be?** According to the guidelines of the Central Commission for Research involving Human Subjects in the Netherlands (CCMO), research is not permitted if the associated risk of harm to participants is higher than what may be expected in daily life. If unusual methods or interventions are used, please provide evidence from the literature or elsewhere, if possible.

End of Block: Procedure

Start of Block: Informed consent

Q35 **Every investigation must be performed on a voluntary basis. Does your informed consent procedure comply with *each of the guidelines as mentioned under Instructions?* (if applicable for the population under investigation)?** a) Mentally competent people aged 12 or older give personal informed consent.
b) In case of children or adolescents younger than 18 years of age, informed consent is also provided by at least one of the parents (or legal guardian). Depending on the research, in some cases consent from both parents may be called for.
c) In case of mentally incompetent adults aged 18 or older informed consent is given by the legal guardian
d) It is clearly explained to participants that they are free to withdraw from the study at any time, without stating a reason.
e) In case specific data (e.g. audiovisual material) is being used for the purpose of teaching or presentation, then separate explicit consent for this is asked.
f) The informed consent is actively given.
Explanation of active/passive consent: *Active consent* means that the participant and/or parent/guardian must perform a recorded action to indicate consent. A signature is the best form of active consent, if possible, but clicking on a button or link, replying affirmatively to an E- mail or the like (digital informed consent) also counts as active consent. Participation is regarded as indicating implicit consent (as long as the relevant information has been received). *Passive consent* means that the participant is assumed to wish to take part if no indication is given to the contrary. Since this conclusion is based on an assumption, care must be taken to ensure that this assumption is well based. For example, participants should be provided with the relevant information repeatedly and in different ways before a lack of response can be assumed to indicate passive consent. Moreover, closer attention must be paid to certain aspects of the investigation such as the load placed on the participant and the use of deception in the case of passive consent.

- ○ No (1)
- ○ Yes (2)

Q36 Upload the information you provide to participants in the research before they decide to participate (e.g., the invitation for the study).

Q37 **Would you like to claim exemption from individual informed consent because you are performing a group study?** Research may study the effect of a change in a situation on a large group of people. Examples of this are studies of the general interactions between children in a class, of the effect of teaching methods on pupils' out-of-school behaviour, of the effects of a management techniques on shop-floor productivity, of the effect of road signs on driving behaviour and of the effect of the street scene on shopping behaviour. When studying group behaviour, it may not be possible to obtain informed consent from every individual – and it may not even be desirable to do so, since this could influence their response. Nevertheless, it may not be possible to collect the desired data in any other way. In such cases, the researcher may request exemption from the duty to obtain individual informed consent for the collection and use of data, under a number of conditions: 1. No informed consent is needed for simple observation of behaviour in a public space such as a shopping street, underground station or university campus, as no personal data are collected and no information about specific individuals can be derived from the research data.

2. In other cases, informed consent is obtained from the responsible institution or authority, such as the management of the institution or company or the council of the municipality where the measurements are performed. In the case of Dutch schools, consent is obtained from the school's representative advisory board, constituted in conformity with the provisions of the Education Act (Wet Medezeggenschap Onderwijs 1992).

3. The study consists mainly of observation of the group in question in its daily setting. If the effect of a procedure is being studied, this procedure was set up and implemented by the institution in question, or was approved by the institution and implemented with its permission and under its supervision.

4. Interventions and/or procedures occur at group level and are not aimed at specific individuals. It goes without saying that the effect of an intervention can vary from one individual to another. For example, a measure may be applied to a whole class but the behaviour of some children may change more than that of others.

5. The research results are reported only at group level. This also applies to the institution where the research was performed. "Groups" in this context may be subgroups, as long as the data provided cannot be traced back to the individuals concerned.

- ○ No, not applicable (1)
- ○ Yes, I would like to claim exemption (2)

Display This Question:

If Would you like to claim exemption from individual informed consent because you are performing a g... = No, not applicable

Q38 Upload the informed consent form here.

End of Block: Informed consent

Start of Block: Deception and debriefing

Q39 **Is some form of deception used before or during the research?** In principle, participation in any investigation is on a voluntary basis, which presupposes that the participant knows what kind of study he or she is taking part in. In some cases, however, it is necessary to give participants false or misleading information about the nature of the investigation, for example if giving correct information could influence the outcome of the study. Withholding details of the investigation (such as full information about the experimental conditions) that could influence the outcome but are not otherwise relevant for participation does not count as deception.

- ○ No (5)
- ○ Yes (6)

Q40 **Is the participant in a relationship of dependency or subordination to the researcher or researchers?** The participants may for example be students taking a course given by the researcher or employees of the researcher.

- ○ No (5)
- ○ Yes (6)

Q41 **Are the participants (or the parents or guardians in the case of young children) debriefed?** Debriefing allows important extra information to be given about the nature and possibly the results of the research, and provides the participant with an opportunity to ask questions.

- ○ No (4)
- ○ Yes (5)

Display This Question:

If Are the participants (or the parents or guardians in the case of young children) debriefed? Debri... = Yes

Q42 **Upload the debriefing text here.**

End of Block: Deception and debriefing

Start of Block: Data management and archiving

Q43 **Will personal data be stored in this research?** Long-term storage of personal data in the Netherlands may require registration of the database where the data are stored by the Dutch Data Protection Authority (College Bescherming Persoonsgegevens). The registration of identifiable genetic material must always be submitted to the METC for approval. The presence of a particular markers does not count as personal data as long as this information is made anonymous. CPB Documentation: https://autoriteitpersoonsgegevens.nl/nl/over-privacy/persoonsgegevens [in Dutch]

- ○ No (4)
- ○ Yes (5)

Q44 **Does the way you store personal data comply with each of the following requirements, as mentioned under Instructions?** Instructions:
a) The permission of the participant or his/her legal representative has been requested for the storage of personal data
b) Personal data are kept separate from the research data, or the research data are anonymized in some other way
c) The connection between the research data and the personal data is at most indirect, for example via a code or participant number
d) Personal data are stored in a secure manner, for example by using a password and/or encryption
e) Access to the personal data is restricted to the relevant researcher, department of research group
f) Personal data are not shown to third parties or used for purposes other than research without prior written permission of the participant
g) Participants are allowed access to their stored personal data, and can have them deleted.

- ○ No (4)
- ○ Yes (5)

Q45 **Do you store audiovisual recordings (photos, video and/or audio recordings) of the participant?** Long-term storage of personal data in the Netherlands may require registration of the database where the data are stored by the Dutch Data Protection Authority (College Bescherming Persoonsgegevens). The registration of identifiable genetic material must always be submitted to the METC for approval. The presence of a particular markers does not count as personal data as long as this information is made anonymous. CPB Documentation: https://autoriteitpersoonsgegevens.nl/nl/over-privacy/persoonsgegevens [in Dutch]

- ○ No (4)
- ○ Yes (5)

Q46 **Where will the raw data be stored?** More than one option may apply. Select at least one.

- [ ] Locally, on a desktop / laptop (1)
- [ ] On a VU-server, path (e.g., G:\FSW\Ethical Review Board\Public\): (2) _____
- [ ] On an online platform (e.g. Qualtrics), account: (3) _____
- [ ] In a cloud, account: (4) _____

Display This Question:

If Where will the raw data be stored? More than one option may apply. Select at least one. = Locally, on a desktop / laptop

Q95 **Is the desktop/laptop on which the data will be stored provided by VU-IT?**

- ○ No (2)
- ○ Yes, the identification number (e.g. PC 034232) is: (1) _____

Q65 What is the storage facility for the data?

- ○ Laptop, owned by: (1) _____
- ○ Desktop, owned by: (2) _____
- ○ Other, namely: (3) _____

Q47 **Who will have access to the data or recordings in the absence of the applicant or principal researcher?** Provide names, positions and e-mail address of all persons who have access to the data or recordings. [Members of the Department, research group, PI, co-authors, public access]

_____

Q48 **Upload the anonymization procedure here.**

End of Block: Data management and archiving

Start of Block: Analysis

Q49 **What analyses do you intend to use?** Give a brief description of how you plan to analyze the data.

End of Block: Analysis

Start of Block: Questions or comments

Q63 **Do you have any questions or comments?**

End of Block: Questions or comments

Start of Block: Statement applicant

Q54 **I have completed this form truthfully.**

- ○ Yes (1)

Q55 **Date [dd-mm-yyyy]**

_____

Q94 **Submit form**

- ○ OK (4)

End of Block: Statement applicant