VU VRIJE UNIVERSITEIT AMSTERDAM | Faculteit der Gedrags- en Bewegingswetenschappen | Vaste Commissie Wetenschap en Ethiek / Scientific and Ethical Review Board

CODE OF ETHICS FOR RESEARCH IN THE SOCIAL AND BEHAVIOURAL SCIENCES INVOLVING HUMAN PARTICIPANTS

As accepted by the Deans of Social Sciences in the Netherlands, January 2016

Including local guidelines as laid down by the Faculty of Behavioural and Movement Sciences

Version: Nov. 15 2016

Preamble

This Code of Ethics for the Social and Behavioural Sciences is intended as a guideline for research in the social and behavioural sciences involving human participants not covered by the Medical Research Involving Human Participants Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, WMO).

Research in the social and behavioural sciences is diverse in its nature and execution, and in many respects it differs greatly from biomedical research.[1] This requires an independent guideline for ethical review of research involving human participants, taking the existing diversity into account.

This diversity not only concerns the broad spectrum that constitutes the social and behavioural sciences, but also the research methods applied. Methods comprise surveys and interviews, focus groups, direct observation, physiological manipulation and recordings, standardised tests, descriptive methods, economic analyses, statistical modelling, ethnography and evaluation. In some disciplinary branches of the social sciences, in particular in psychology, minimal physical interventions are also used[2]. As contemporary research is becoming increasingly interdisciplinary, it is impossible to draw a strict line between research in the social and behavioural sciences and other types of research. This complicates devising clear ethical guidelines to be applied to all forms of research.

However, the following basic principles may be applied to the implementation of all research and, consequently, to the review of ethical aspects of research in the social and behavioural sciences in order to protect research participants:

- Avoidance of exploitation;
- Just distribution of benefits and burden;
- Respect for persons:
    1. Participants are treated as autonomous agents;
    2. Participants with diminished autonomy are entitled to protection;
- Respect for human dignity;
- Scientific validity;
- Scientific, social and/or educational relevance;

[1] In its broadest sense, this also includes the humanities.

[2] Some types of behavioural interventions and treatment programs are examples of research that could be considered to fall under the regimen of the WMO, and thus should be evaluated by an METC. According to the CCMO, it is to the local METC and the Ethics Review Committee to decide who is reviewing what.

- Respect for rights and specific interests of (specific groups of) research participants, and/or the community/society

These ethical principles may be operationalised by translating them into tools and procedures that can vary, depending on the field and context of the research.

For the researcher this means:

- S/he is expected to demonstrate awareness of the ethical issues raised by the methodology in his/her research, and to describe the measures taken to address these issues appropriately;
- S/he must address all relevant ethical issues e.g. informed consent, incidental findings, data protection, privacy issues, comprehension of the information provided, voluntariness, assessment of risks and benefits (nature and scope) and selection of participants. Also a proper assessment is required of the potential risks (for individuals and communities/society alike), and a plan is needed to minimise potential harm;
- S/he must evaluate the potential harm with respect to the scientific, social and educational relevance of the research;
- S/he publishes, communicates and/or teaches on the research findings in such a way, that different audiences are being informed in an appropriate manner, that is, in line with the corrects standards for the type of publication/communication and with ample account for the capacities of the intended audience.

Additional note

In the following sections the general Code as determined at the national level is presented on the left, while the local implementation of the code at the Faculty of Behavioural and Movement Sciences at the Vrije Universiteit is explicated on the right, based on the principle “apply or explain” (see article A.1 of the Code).

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A. GENERAL

National Code	Local implementation (FGB)
1. All Institutes[3] of Social and Behavioural Sciences at Dutch Universities should in principle comply with the guidelines below. If an Institute decides to divert from these guidelines, the Institute must be able to explain why this has been decided.	**1.1. Compliance** FGB complies with the guidelines, except on some aspects. Deviations are indicated and explained.
2. Research in the social and behavioural sciences involving human participants must be carried out in accordance with a tailored protocol.[4]	**2.1. Protocol** The ethics review form asks for descriptions of the purpose, importance, design, dependent measures and analysis plan of the research, and whether it is part of an externally reviewed research program. Some research may follow standardized protocols and thus no individual document will be available for each subproject (as is e.g. the case with umbrella approvals). **2.2. Academic quality** The academic quality of research is primarily the responsibility of the researcher and his/her supervisors and/or collaborators. However, the VCWE bases its activities on the assumption that pointless research on test subjects is by definition unethical. Hence, it also reviews the main aspects of the academic quality of the research proposals submitted to it.
3. Approval of the research protocol must be obtained from an ethics review committee established for that purpose either by the Institute where the research is conducted, or the body that carries the main responsibility for the research.	**3.1. Obligations** **Here FGB deviates:** Ethical review by the VCWE is not compulsory, and has no legal status (unlike ethical review by a medical ethics committee). The VCWE cannot be held accountable for the consequences of the research. Acting in an ethical way – and *demonstrably* doing so – is primarily the responsibility of the researcher. The VCWE facilitates this by offering the possibility of getting research proposals appraised by parties other than the researchers themselves. Review by the VCWE may thus be regarded as a service. However, all researchers within the Faculty are expected to exercise due care in their research work, in accordance with guidelines such as those given in the present regulations. **Submission of research proposals to the VCWE is seen as the most effective, and hence the preferred, form of review within the faculty.**

[3] In this code, the word "Institute" is used to designate the organizational entity. Depending on the local structure, the "Institute" can be a faculty, a research institute, a Research or Graduate School, or any other organizational entity that has established an Ethics Review Committee.

[4] I.e. a document addressing the rationale, background, objective(s), design, methodology, statistical considerations and organisation including all relevant ethical aspects of a trial involving human participants such as participant information, informed consent, debriefing information and agreements of external research locations.

3.2. Medical ethical review: METC

Researchers must submit their research protocol to the Medical Ethics Committee (METC) when the research is subject to the provisions of the Medical Research Involving Human Subjects Act (WMO). According to the CCMO, a study falls under the scope of the WMO if both the following conditions are met:

I. It concerns medical-scientific research and
II. Participants are subject to procedures or are required to follow rules of behaviour

Since Condition II is almost always met in behavioural research (except in observation studies in natural environments), the crucial judgement is whether the study is medical in nature. Here the VCWE uses the following criteria:

a. The study involves a **medical research question**
b. The study involves a considerable **medical risk** (more so than in daily life)
c. The study involves **medical acts** (as registered by law).

See the Appendix for more clarification on these assessment criteria.

It is the responsibility of the principal investigator, project leader and/or research supervisor to determine with reference to these regulations whether a given research proposal falling under their authority needs to be submitted to the medical ethics committee for review. The VCWE can be asked for advice and an educated opinion (see also the flow diagram in the Appendix).

The VCWE can provide an assessment of the academic quality of a research proposal priori to submitting to the METC, as the METC often requests this.

Research regarded by the METC as subject to the provisions of the WMO but not approved by the METC may not be submitted to the VCWE (since the mandate of the METC for WMO research is superior to that of the VCWE).

Research that has been approved by the METC does not have to be reviewed by the VCWE.

3.3. Research outside the faculty and external collaborations

a. When research is performed **outside the researcher's normal research establishment**, the researcher shall ensure that prior permission for the research has been obtained from the host establishment or any other relevant organizations, and that the research **meets the requirements both of the Faculty and of the host establishment**, taking into account the below:

b. **Research performed at another research or care institute** must comply with the ethical guidelines of that institution. This responsibility lies primarily with the

		external institution. If the external institution has no procedures for ethical review, then the research should be submitted to the VCWE. c. For **multicenter research**, the responsibility for ethical review is primarily with the institute at which the PI or penholder works. Depending on the nature and context of the collaboration, ethical review for different parts of the research can be obtained separately from multiple institutes (e.g. behavioural studies in one institute, and physiological studies in another). d. If ethical assessment has been obtained from an external institute, while the responsible researcher works at FGB, **the researcher is responsible for checking the external institute's guidelines against those provided here for gross deviations**. When in doubt, the researcher should ask the VCWE for advice. e. In principle, **any assessment from another Faculty or Institute of Social and Behavioural Sciences is deemed valid,** since these institutes subscribe to the present code – see Article M.1. **3.4. Archive or literature research** For archive or literature investigations that do not involve the retrieval or coupling of personal details, or that involve data that is publicly available (legal), no ethical review is necessary. **3.5. Animal testing** Plans for animal testing need to be submitted to the Dierexperimentencommissie (DEC).
4.	**The review on ethical aspects shall be conducted with due regard to relevant international, European and national laws, rules (including grant or editorial rules) and guidelines, including local habits and customs in both the country of the researcher/applicant and the country where the research is to be conducted.**	**4.1. Legislation and guidelines** Relevant sources here are the Dutch legislation (or that of the country where the research is conducted), the ethics code of the American Psychological Association (APA), the professional code for psychologists of the Dutch Institute for Psychologists (NIP), the Central Committee for Research on Humans (CCMO), and the scientific integrity codes of the Royal Netherlands Academy of Arts and Sciences (KNAW) and the Association of Dutch Universities (VSNU). Links are available on the VCWE website. **4.2. Conflicting rules** In the case of a **conflict between regulations and/or guidelines**, the following procedure, as suggested by the APA, should be followed: The researcher provides a clear description of the conflict, and takes reasonable and where possible documented steps to resolve it, taking the Universal Declaration of Human Rights into account. (Introduction to the APA Ethics Code, article 1.02).
5.	**A positive review of the research protocol shall be obtained only if:**	**5.1. Researcher responsibility** Researchers are responsible for ensuring that any

a. **It is reasonably plausible that the scientific research will lead to relevant insights in the field of the social and behavioural sciences.**[5]

b. **It is reasonably plausible that the insights, mentioned under a. cannot be gained by means or methods of scientific research other than research involving human participants, or by alternative means of research of a less intrusive nature.**

c. **It is reasonably plausible that the interests being served by the research are in proportion to the difficulties and risks imposed on research participants.**

d. **The research meets the requirement of a sound methodology of scientific research.**

e. **The research is carried out in suitable locations or Institutes, and carried out or directed by persons with the necessary expertise in the field of scientific research.**

f. **The research is carried out in external organisations with the demonstrable permission of the responsible authorities of the organisation in question.**

g. **It is reasonably plausible that the fees offered to research participants do not have a disproportionate effect on whether or not they consent to their inclusion in the research.**

h. **The person conducting the scientific research and the Institute where the research is carried out receive a compensation not exceeding what can be considered reasonably proportionate to the**

investigation carried out by themselves, or by others under their supervision or responsibility, is ethically acceptable, and thus meets the requirements listed here and in the sections below. Submitting the protocol to the VCWE aids in meeting this responsibility.

Researchers shall take measures to minimize the risk of physical or mental harm to participants, to minimize intrusiveness, and to ensure that the rights and welfare of participants are not infringed. When research involves participants with known or suspected vulnerabilities, researchers shall consider these problems before starting the research. For this, researchers must either have, or invoke, the necessary expertise.

Researchers and their assistants shall only perform those tasks for which they have been properly trained and prepared.

5.2. Emergency situations

In some research settings, situations may arise in which the participant may need urgent medical, psychological, or any other type of help – even when the research itself is not clinical in nature. Although risk of occurrence may be low (e.g. no higher than for the person's daily activities), where consequences may be substantial, the researcher should have a protocol in place that specifies:

1. Which incidents may occur (as far as can be foreseen)
2. How to act upon such incidents
3. Who will be informed (e.g. 112, a clinical psychologist or doctor involved in the project, VU security?)

All those actively involved in the research should then be familiar with the protocol.

5.3. Equipment

Research equipment should be certified and safe. In case of custom-made equipment carrying potential risks, it should be approved by the Veiligheidscommissie (movement sciences; Chair Jos de Koning j.j.de.koning@vu.nl). Those using the bridge (Loopbrug) should be aware of its special requirements (again, to be obtained from the Veiligheidscommissie).

5.4. Children and mentally incompetent

Children under 16 and people who are mentally incompetent may only be involved in research if there is no other way of obtaining the data required, and if the aim of the research is to gain scientific insights or to improve treatment methods.

5.5. Teaching purposes

In principle, research activities conducted for the purpose of **teaching only**, where students participating in the course merely **test or practice on each other,** does not need to be

[5] Including research that is executed within the context of education with students as participants.

nature, extent and purpose of the research. **i. The processing and storage of data is safe-guarded in accordance with the applicable laws and regulations.** **j. The research meets any other requirements that can reasonably be set.**	submitted for ethical assessment. This is under the assumption that teaching activities will employ established methods that are known to have little to no ethical implications. Ethical assessment does apply when students practice on people that do not participate in the course (i.e. research participants, whether they are students or not), or there is reason to believe that the activity has more far-reaching ethical implications. **Thesis work (Bachelor or Master) also typically involves working with research participants and thus ethical assessment applies.**
6. An ethical review committee may suspend or revoke a positive review of a research protocol if there are reasonable grounds to assume that continuation of the research would lead to the imposition of unacceptable difficulties or risks on the human participants involved.	

B. INFORMED CONSENT PROCEDURE

National Code	Local implementation (FGB)
1. During the process of obtaining informed consent from participants, the researcher(s) must provide information that is comprehensible for the target population, and made available beforehand as much as possible (so the subject can make a well thought decision) regarding the: **a. voluntariness of participation;** **b. nature, purpose and duration of the research;** **c. procedures, including the expected duration and the extend of strain for participants;** **d. reasonably foreseeable factors that may be expected to influence participants' willingness to participate, such as potential risks, discomfort, adverse effects and benefits;**	In addition to the national requirements: **1.1. Data collection** Clear Information is provided on the nature of the data that is being gathered, including personal data, and how such data will be treated. **1.2. Children and mentally less competent** In case of minors (under 16) and mentally less competent, information is provided at the level of competence of the participant as much as possible. In addition, information is provided to the legal representatives (usually the parents). **1.3. Personal feedback** Researchers shall inform prospective participants about which feedback or personal score they may or may not receive. Examples are feedback about a social interaction, a school test, or a score on a clinical test. **1.4. Incidental findings** Incidental findings are findings that are clinically relevant (whether physical or mental in nature) to the participant, and are (likely) unknown to the participant.

e. right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation; **f. recording of voices and images, where applicable (see also H);** **g. confidentiality protection and limitations;** **h. procedures for incidental findings;** **i. applicable insurance guarantees (see also I);** **j. period of time to which the consent applies;** **k. re-use of specified data in the current, future or other research, where applicable;** **l. incentives for participation;** **m. names and details of the responsible researcher and contact person(s) for questions about the research and rights of research participants;** **n. participants should be informed on the fact that/told that data will be stored and encrypted for a certain period of time.**	The researcher is responsible for - Providing an educated estimate on the probability of a clinically relevant finding – that is, a finding with implications for the physical and/or mental wellbeing of the participant. - Implementing a protocol on how to deal with such findings, in case there is a reasonable chance of such a finding. - Clearly communicating the implications of this protocol to the participant or the legal representative, through informed consent. Note: This does not mean that the researcher is obliged to search for such findings, or is responsible for detecting them. The protocol needs to specify - Who does the primary assessment/analysis - What is this person's expertise (even if limited) - Which additional expertise is being invoked when necessary - At which stage/moment this will be done - Which findings will be reported back - To whom findings will be reported (participant, specialist, GP, aid worker, etc.) - How this is being reported back (private meeting, letter, etc.). In case of a reasonable chance of incidental findings, the information to the participant (informed consent) needs to specify the possibility of incidental findings, how and to whom this will be reported, and that they cannot participate if they do not want to be informed. Note: Other institutes (VUmc, SPINOZA, etc.) may have slightly different procedures.
2. Participants, particularly children and vulnerable adults, including their legal representatives, must be given ample opportunity to understand the nature, purpose and anticipated consequences of research participation, so they are able to give informed consent to the extent to which they are capable to do so.	**2.1. Time period of information** How long before participation the participant should receive the relevant information will depend on the nature and context of the research. For simple behavioural "walk in" experiments in the lab, it typically suffices to explain things right before the task. For studies with wider ethical implications, a longer respite is required, with two weeks being more typical. **2.2. Mode of information** Whether information can be conveyed verbally or should be provided in written form also depends on the nature and context of the research. For simple behavioural "walk in" experiments in the lab, it typically suffices to explain things

	verbally. For studies with wider ethical implications, written information is required, to prevent misunderstandings and to provide participants with the opportunity to re-read and reconsider. Young children, however, are best addressed verbally (plus consent is obtained from their parents or legal representatives, see later). **2.3. Compensation** Participants may be offered a proportionate compensation. Researchers shall not offer excessive or inappropriate financial or other incentives in an attempt to recruit participants. When test subjects are offered professional services such as treatment or teaching as an incentive for participation in research, researchers shall clearly specify the nature of these services and the possible risks, obligations and restrictions associated with these services. **2.4. Dependency** If participants are in a relationship of dependency or subordination to the researchers (for example, if they are psychology students), the researchers shall take steps to protect the participants against possible adverse effects of declining to take part in the study or of ending their participation prematurely. If a certain course requires participation in a research project or such participation is required to gain the necessary credits, students shall be offered a number of alternatives. If students do not wish to act as test subjects as a matter of principle, they shall be offered the option of taking another course. NB: The scheme providing credits for participation in research by first-year students, as set up through Sona Systems includes such alternative choices.
3. Researchers must keep adequate records of when, how and from whom informed consent was obtained, unless this could or proves to be detrimental to participants (see also C.) and/or where the formal registration of the informed consent has a negative effect on the execution of the study.	**3.1. Standard informed consent forms** Standard informed consent forms can be downloaded from the VCWE website. **3.2. Audiovisual recordings** Researchers shall obtain permission from participants or their legal representatives for the use for research purposes of audiovisual recordings (photos, audio and/or video recordings) made of them or recordings of their behaviour collected in any other way. **3.3. Teaching and presentations** Researchers shall request permission separately for the use of material such as audiovisual recordings in presentations or for educational purposes. (This is not necessary for anonymized research data as such). **3.4. Children and mentally incompetent** Children under 16 and people who are mentally incompetent (regardless of age) may only be involved in research if there is no other way of obtaining the data required, and if the aim

of the research is to gain scientific insights or to improve treatment methods. In these cases, informed consent must be obtained from the legal representative(s). Minors who are 12 years or older must also provide informed consent. Minors under 12 and mentally incompetent (regardless of age) should either be asked for their willingness to participate, and/or monitored for signs of unwillingness (in which case the research should be paused or cancelled). In case of children, it is sufficient in principle for one parent to provide consent, unless the nature of the investigation calls for consent to be received from both.

3.5. Default: Active consent

The standard approach assumed here is *active* informed consent, in which *the participant has to perform an action* to signify his or her willingness to take part. This should preferably be done by signing a form, but a digital method such as ticking a box, pressing a button or clicking on a link can be an acceptable alternative. Important is that this action is performed *after* the relevant information has been provided.

3.6. Dispensation

a. *Passive consent* (opt-out). With passive informed consent, the participant or his or her legal representative has to perform an action to indicate that he or she (or the represented) does *not* wish participation to occur. Passive informed consent is in principle undesirable, firstly because there is no way of knowing whether the relevant information has been received, and secondly because the participant (or his or her legal representative) may have been unable to perform the action required to indicate non-consent. This can lead to infringement of personal autonomy and privacy. There are however circumstances where passive informed consent may be acceptable. For example in situations where the research fits within the context of a generally accepted activity, such as research into learning performance in school, evaluation of a service provided (hospital, company), or research into workflows and performance in work organisations. The researcher needs to explain in a convincing manner that 1) the context and importance of the research make passive consent acceptable, and 2) sufficient action is taken to inform the participants or their legal representatives, for example through various and repeated approaches. **Note: if the research involves new collection or new use (including linkage) of personal data, active consent is required, in compliance with the Wet Bescherming Persoonsgegevens.**

b. *No consent: Protecting the interest of the participant.* In exceptional cases, the requirement for informed consent may be dispensed with.

   The most important case is when informed consent is not in the interest of the participant. This often concerns the

consent from parents or legal representatives. A particular case in which one can decide not to inform the parents is when **the child explicitly opts for anonymity**. This occurs for example in the context of on-line self-aid sites. In such cases, contacting the parents would be more intrusive to the child's privacy than not contacting them. The wish for anonymity therefore needs to be respected, and can only be violated in exceptional cases, when: 1) Not informing the parents, health care professionals, or authorities clearly goes against the child's interests. For example when the child needs urgent medical or psychiatric care. 2) Not informing the parents, health care professionals, or authorities will bring serious harm to others. For example when the child indicates it will commit or has committed a serious crime.

There are also cases where the child is known, but involving parents or legal representatives may still be damaging to the child, e.g. in cases of research into abuse. Note that in such cases gathering or using personal data for the research should be prevented, since doing so also requires parental consent.

b. *No consent: Observations.* See also Article M. In principle no informed consent is needed for observation of behaviour in a public space such as a shopping street, underground station or university campus, as long as no personal data are collected and no information about specific individuals can be derived from the research data. This also excludes audiovisual recordings on which people can be recognized. Neither should the investigation be intrusive in other ways, e.g. through extensive following of a single person. What counts as intrusive will be determined by the context (nature of the research, environment, and people).

c. *No consent: Group studies.* Behavioural research often involves the studies at the level of group behaviour. Examples are network studies of social interactions (including bullying) in a class room, the effect of a teaching method on class performance, or the effects of a new management techniques on team work. In such cases, it may not be possible (and in some cases undesirable, as it may affect the group process) to obtain informed consent from every individual. In such cases, the researcher makes sure that:

   I. Informed consent is obtained from the responsible person, institution or authority, such as the management of the institution or company. In the case of Dutch schools, depending on the nature of the research, consent may have to be obtained from the school's representative advisory board, constituted in conformity with the provisions of the Education Act (Wet Medezeggenschap Onderwijs 2006, see www.infowms.nl). This would only be the case if the research affects any of the points listed in Article 10 (Instemmingsbevoegdheid medezeggenschapsraad) of that law. 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.

II. Individual privacy and autonomy is preserved. That is, no personal data are gathered without the active consent of the person or their legal representative. This means that data is anonymous also for the researchers (i.e. it is not sufficient to separate or recode participant details).

III. The relevant groups (including the parents or guardians of children used as test subjects) are as far as possible informed in advance of any interventions, procedures and observations, unless this seriously interferes with the objective of the investigation. The researcher shall provide evidence of the need to withhold such information and take measures to prevent negative consequences of withholding such information.

IV. 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.

V. The research results are reported only at group level. This also applies to reports made 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.

3.7. Weighing and procedures.

The researcher must make clear which deliberation underlies the decision to deviate from the standard consent procedure, or to apply the standard procedure even when this might be damaging to the participant. Such deliberation should involve:

a. The level of intrusiveness of the research.

b. The reasonable possibility of asking for consent

c. The risks of asking or not asking for consent

d. The capacity of a child to judge and represent its own interests.

e. Taking into account the context and societal importance of the research

f. Taking into account the extent to which the researcher is legally committed to confidentiality.

g. Discussing the issue (in confidentiality) with colleagues

	or others with adequate expertise on the matter. The VCWE recommends that the researcher involves others in his or her decision (intervision and participation), for example colleagues, teachers, social workers, health care professional, school parent boards, or the child itself. (e.g. health care professional, Jeugdzorg, lawyer). h. Adequate record keeping (with regard for privacy).
4. Supplemental informed consent (as circumstances indicate) must be obtained when research is conducted over an extended period of time, or when there is a significant change in the nature or focus of the research activities.	

C. DATA PROTECTION AND PRIVACY

National Code	Local implementation (FGB)
1. There are major risks relating to the disclosure of a person's identity and insufficient protection of private information in social and behavioural sciences research. This, in turn, may lead to discrimination, stigmatisation or psychological discomfort or harm. Thus, considerable effort should be devoted to safeguarding participants' privacy and the confidentiality of data processed in social sciences research. Furthermore, certain groups may be more vulnerable to harm from having information they provide linked to them (e.g. illegal immigrants, victims of home violence, prostitutes, people engaged in criminal activities and HIV-positive employees). In these cases, standard procedures for obtaining written informed consent may be more harmful to the participants than offering them protection and may, therefore, need to be replaced by other measures of protection including verbal informed	**1.1. Personal data** a. Personal data are defined as **any information relating to an identified or identifiable natural person**. One ought to be aware that other information may also lead to a person, such as ip address, employment details, or information emerging from linking multiple databases ("big data"). b. Researchers must handle such personal data appropriately, in compliance with Dutch legislation (see VCWE web page for relevant links). c. The privacy of research participants must be respected; personal data must thus be regarded as confidential. Personal data that could lead to the identification of research participants must be stored in such a way that the link between the participant and the research results is either removed or properly protected (password, encryption). Furthermore, information revealing *that* the participant took part should also be protected. This is especially important in the case of vulnerable groups or sensitive information. d. Personal details should be removed if the participant requests so. This does not hold for the research data, unless these inadvertently lead to the person. e. Researchers shall allow participants, on request, access to all data collected relating to them, insofar as it has not yet been fully anonymized or insofar as these data are not associated with identifiable personal information referring to other participants.

consent.

f. Researchers shall only use personal data for the purpose or purposes for which they are collected, as formulated in advance by the researcher and made known to the participants in the study in question, or for similar purposes.

g. Researchers shall not pass personal data on to third parties without the permission of the test subject in question. Personal data may only be passed on to third parties for the purposes of scientific research and with the written permission of the test subject in question. Sometimes the data are meant to improve the treatment (e.g. in psychology) or training (e.g. in movement sciences) of the participant. In this case the personal data will have to be shared with the therapist(s) or trainer(s). Here too the participant has to give permission.

h. If the researcher plans long-term use of a systematic database containing directly identifiable personal data, he or she must register the plan with the Privacy Offcier (Functionaris Gegevensbescherming) of the VU, to check whether this database complies with regulations of, and needs to be registered by, the Dutch Data Protection Authority (College Bescherming Persoonsgegevens) as laid down in Dutch legislation. (Certain exceptions are made for scientific research – see section 5, References, below.)

i. Researchers shall take appropriate technical and organizational measures to avoid unauthorized access to or processing of personal data. These measures may include the use of lockable cabinets, passwords and/or encryption, but also registration of those persons who have access to the data.

j. It is to be expected that a general guideline covering all the above-mentioned points, and others, as applicable to VU University Amsterdam as a whole will become available in the form of a Data Management Plan, including a Privacy Protocol (not clear yet, sept. 2016).

1.2. Data collected and/or stored externally

a. When personal data are stored outside the university, e.g. with another institute or a commercial company, the researcher has to check whether storage and processing complies with Dutch and European privacy regulations.

b. Storage in other countries, especially non-european countries, is discouraged. For example, currently it is unclear whether storage of personal data on servers of American companies (e.g. Qualtrics) and institutes complies with European legislation, even when the servers are based in Europe. This because under current legislation the US Government can demand or force access to the data, even when these are stored in Europe. As a temporary workaround, the participant will have to be notified of where the data is stored and the potential (though unlikely) implications, prior to

participation through informed consent.

1.3. Data publication and presentation

Researchers shall ensure that the presentation of research data in any form occurs on an anonymized basis.

1.4. Research using existing databases

Research involving research data from, or re-analysis of, existing databases does not require informed consent from the original participants as long as data are anonymized, and the new use or purpose does not lead to disclosure of the person's identity, or increases the risk thereof. Re-use which also involves personal data is restricted to the original researchers or research group, and must comply with the original research goal as formulated at informed consent. Sharing personal data with external researchers (see next point), or re-using them for a rather different purpose than originally formulated requires informed consent from the participant. What counts as a different purpose is best considered together with the VCWE.

1.5. Data sharing

In the same vein, research data may be shared with other scientists or experts, as long as data are anonymized, and the new use or purpose does not lead to disclosure of the person's identity, or increases the risk thereof (e.g. through data cross-linkage). The researcher must ensure that participants' privacy is protected. Databases shall be anonymized before data are shared with other experts, such that the data cannot lead to specific persons. Identifiable personal data on participants may only be shared if the researcher has obtained prior written permission for this from the participant through a Data Transfer Agreement, in which also the purpose for which the data is being shared is made clear.

1.6. Duration

Research data – anonymized where necessary – shall be stored for at least 10 years after publication, in line with international scientific guidelines. Unpublished data may be deleted earlier. Personal data of participants is kept for as long as has been agreed with the participant. If nothing has been agreed on duration, personal data is in principle kept for as long as is necessary for the research project.

D. DECEPTION

National Code	Local implementation (FGB)
1. A study may not employ deception unless the use of deception techniques can be	**1.1. Explain** The researcher should document and explain the nature

	justified by the study's significant prospective scientific or applied value and where there is no alternative procedure for effectively collecting the data.	of the deception and explain why it is required. **1.2. No deception about adverse consequences** Test subjects shall not be misled about possible risks, inconveniences, and intrusiveness associated with participation in the study (see next point, Article M.2). **1.3. Withholding information** Withholding information on the research question/hypothesis as such (to prevent influencing the participant) does not count as deception (see also Article E.1.).
2.	**Prospective participants may not be deceived about research that is reasonably expected to cause physical pain or severe emotional distress. Special consideration must also be given towards additional safeguards required for the preservation of participants' welfare.**	
3.	**Any deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than by the time of the conclusion of the study data collection. Participants must also be informed that they have the right to withdraw their data without any negative consequences.**	

E. WITHHOLDING INFORMATION

	National Code	Local implementation (FGB)
1.	**Information for participants may be withheld from participants only when it is necessary to preserve the integrity of the research, or if it is shown to be in the public interest. In case information for participants has been withheld, participants will be provided information following**	**1.1. No information shall be withheld on the (potential) risks or burden of a study.** Deception can be a necessary tool in psychological research. However, it should only be applied when necessary, and shall not be used to misinform on potential harm, risk, or stress.

their participation in such a manner and to such an extent that, to their judgment, the informed consent remains intact.	

F. RESEARCH IN PUBLIC DOMAIN

National Code	Local implementation (FGB)
1. Unless informed consent has been obtained, research based on observations of public behaviour must be restricted to situations where people being studied would reasonably expect to be observed by strangers. Research in public places must also consider local cultural values and the privacy of persons who, even when in a public space, may consider themselves unobserved.	**1.1. Observation in public places** In principle no informed consent is needed for observation of behaviour in a public space such as a shopping street, underground station or university campus, as long as no personal data are collected and no information about specific individuals can be derived from the research data. This also excludes audiovisual recordings on which people can be recognized. Neither should the investigation be intrusive in other ways, e.g. through extensive following of a single person. What counts as intrusive will be determined by the context (nature of the research, environment, and people).

G. DEBRIEFING

National Code	Local implementation (FGB)
1. Appropriate information regarding the nature and aims of the research, other than that provided when obtaining informed consent, must be provided to the participants. Reasonable steps must be taken to correct any misconceptions participants may have that the researcher is aware of.	**1.1. General debriefing** Depending on the nature of the research, participants may be debriefed verbally or in writing. This includes contact details for further questions (written). Researchers shall give test subjects the opportunity to receive information on the nature, results and conclusions of the study in the form of a general research report not containing any individual data. This report will be presented in a way that is clearly comprehensible to the test subjects. **1.2. Personal feedback** Any feedback on personal scores is provided with due regard to the context of the test and the expertise of the researcher. Researchers must not overstate the meaning of an outcome, and must not go beyond their own expertise in interpreting an outcome. In case of outcomes with potential implications for mental or physical health adequate expertise should be

	invoked. **1.2 Incidental findings** See Section B, 1.4.
2. Reasonable measures must be taken to reduce the risk of harm when scientific/ human interests or values justify delaying or withholding such information.	
3. Reasonable steps must be taken to minimize and repair any harm, should researchers become aware that research procedures have proven detrimental to a participant.	

H. RECORDING VOICES AND IMAGES IN RESEARCH

National Code	Local implementation (FGB)
1. Informed consent must be obtained from research participants prior to recording their voices or images for data collection unless (1) the research consists solely of naturalistic observations in public places, and the recording will not be used in a manner that could cause personal identification or harm, or (2) the research design includes deception, and consent for the use of the recording was obtained during a debriefing (See also D.2).	

I. INSURANCE

National Code	Local implementation (FGB)
1. Research must be covered by the regular legal liability insurance of either the Institute where the research is conducted or the body with primary	All research activities at the VU are in principle covered by the liability insurance. In addition, there is a dedicated insurance available for research participants ("proefpersonenverzekering"). The latter is required for METC approval, but may be useful for other research too. It is

	responsibility for conducting such research, assuming the research is part of the regular activities of that Institute. If the latter is not the case, separate insurance must be obtained for research participants.	typically not necessary for standard low risk research. The insurance policy documents can be obtained from the VCWE.

J. RESEARCH IN OTHER COUNTRIES

	National Code	Local implementation (FGB)
1.	**The research must comply with all relevant European and national legislation, and with due regard of all relevant accepted international standards.**	In the case of research abroad, including online research using crowdsourcing websites such as Mechanical Turk, Crowdflower or Qualtrics, the VCWE can only state whether the research complies with the faculty's own guidelines. The researcher is responsible for estimating whether (or if possible for ensuring) that local guidelines are complied with and for taking measures to ensure that respondents do belong to the intended population (for example by stating this requirement clearly when obtaining informed consent). Note that when personal **data is being stored on servers of American companies**, the participant will have to be notified prior to participation through informed consent. This because under current legislation the US Government can demand or force access to the data, even when these are stored in Europe.
2.	**The research projects must benefit all stakeholders, with an emphasis on benefits for research participants and their communities. Special initiatives to support local communities (e.g. benefits generated by the research) can help to achieve this goal.**	
3.	**If local resources are used, adequate compensation must be provided.**	
4.	**Potentially vulnerable populations must be able to provide genuine informed consent. This requires taking into account any potential cultural differences, economic and linguistic barriers and levels of education and illiteracy.**	

5.	**Even if adequate scientific and ethics infrastructure is not available, the relevant local and independent approval needs to be provided in accordance with the customs and traditions of the society concerned.**	

K. ETHICS COMMITTEE

	National Code	Local implementation (FGB)
1.	**The social and behavioural sciences ethics committee must consist of at least five members, to be appointed by the board of the Institute where the research is conducted. The ethics review committee acts as an advisory body to the board of the Institute.**	**1.1. Composition** The VCWE consists of ten members, including the chairperson, and the vice chair. It is also provided with a secretary, who is a member of the faculty's administrative and support staff. Since the VCWE has to review the academic, ethical and social aspects of the various research proposals submitted to it, its composition is chosen to reflect the range of research performed within the faculty. In practice, each research section within the faculty will have one representative on the Board. New members are selected and nominated by the VCWE and approved by the Faculty Board for a period of four years in all cases. The VCWE determines the selection procedure for its chairman and secretary, and the nomination procedure for new members. Formally, the board advises the Faculty Board. However to optimize the work flow, the Faculty has chosen to grant the VCWE the mandate to advise researchers directly, without the intervention of the Faculty Board.
2.	**In order to guarantee the independence of the ethics review committee, the committee must have at least one member who is not on the scientific staff of the Institute where the research is conducted. All other committee members must be tenured staff of the Institute.**	**Here the VCWE deviates** **Currently there is no board member from outside FGB** The various ethical committees at the VU (FSW, FGB, FEW) are currently looking into ways of organizing overarching or shared support (November 2016).
3.	**The committee should preferably consist of one member who is an expert in ethics/philosophy, and one an expert in judicial matters, having preferably at least a Master of Law degree. The expertise of the other members**	**3.1. Juridical and ethical advice** The board currently has a member with a philosophy and ethics background. Furthermore, Henk Sportel, h.sportel@vu.nl has been assigned as the juridical advisor for all ethical committees at the VU (FSW, FGB, FGW, and FEWEB).

	of the committee must cover the major research lines of the Institute. The board may appoint substitutes for the expert members.	
4.	**The board will appoint one of the members as committee chair; the board may also appoint a vice chair.**	
5.	**The board appoints an executive secretary to the ethics review committee. The executive secretary is responsible for all procedural aspects with due regard to the committee and its mission. The executive secretary may be a member of either the Institute's academic staff or support staff, and could also cover the legal expertise as mentioned in ad 3.**	
6.	**The chair, vice chair (if appointed) and executive secretary constitute the executive board of the ethics review committee.**	
7.	**The ethics review committee may be extended (temporarily or permanently) by non-voting advisors.**	**7.1. Ad hoc reviewers** During busy times, the VCWE may make use of ad hoc reviewers, who are not full members of the committee, but who are knowledgeable researchers within the faculty.
8.	**The board of the Institute is responsible for the adequate instrumentation, administrative and financial support of the ethics review committee. This also applies to the proper recording of all ethical reviews performed by the committee.**	
9.	**The committee's working method and related procedures must be specified in a set of regulations.**	**9.1. General** The Board shall determine its own review procedure, which shall be laid down in a document to be submitted to the Faculty Board and the regular meeting of department heads (AHO) for approval. Reviewing occurs on the basis of the ethical principles laid down in this document, which is available from the VCWE website as well as from the Chair and Secretary.

9.2. Submission

Research proposals are submitted via the online VCWE portal. Students (Ba/Ma/Msc) are not allowed to submit applications. PhD students can submit but the supervisor or principal investigator must be inclouded in the proposal (and must therefore also be named and registered as user in the system).

Proposals will not be reviewed when the research has already commenced or been completed.

The portal stores all details of proposals submitted, thus reducing the amount of information to be provided when a revision is submitted.

9.3. Submission documents

Submitting an application consists of filling in an online form on the following main points:

- Is the research medical in nature? (Is it subject to the provisions of the Medical Research Involving Human Subjects Act (WMO)?)

- Risks and physical/mental load to which test subject is subjected

- Information to be supplied to test subject

- Data gathered and stored

- Research protocol

Where relevant, the following documents shall be uploaded together with the online form:

- Material used to recruit test subjects (such as information leaflets and media advertising)

- Informed consent form for participants. The information provided to test subjects and the informed consent form must comply with the guidelines applying to medical research involving human subjects.

- In case of children or mentally incompetent test subjects: consent form signed by parents, guardians or other legal representatives.

- Statement issued by the METC that research is not subject to the provisions of the Medical Research Involving Human Subjects Act (WMO) – only required in cases of doubt whether the research in question is medical in nature.

- Information about insurance, if applicable (most research performed within the faculty is covered by the third-party insurance of VU University Amsterdam).

9.2. Review Procedure

Each research proposal is initially reviewed by two members of the VCWE and the Chair, who shall not be related to the

project, and shall not be from the same section as the applicant. If the applicant is from the same section as the Chair, the Chair will be replaced by the Vice Chair.

Reviewing occurs continuously, online, through the VCWE portal.

The assessment criteria and procedure used by the VCWE during the review of research applications can be found in the Appendix.

If the committee members or the Chair are of the opinion that there are substantial ethical issues that need broader discussion, extra committee members or external expertise will be invoked, or the research proposal will be discussed in the VCWE meeting.

9.3. VCWE meeting

The VCWE meets monthly, except July, August and January (unless necessary), and when there is little to discuss. Currently the meeting is held **every first Thursday of the month**. The purpose of the meeting is to discuss overarching scientific and ethical issues, as well as issues related to specific proposals (to the extent they have not been dealt with during the online review process). If a member (including the Chair) is involved with a particular project or he/she is from the same section as the applicant, he or she shall refrain from taking part in the discussion and decision, and shall leave the room. The Chair may be replaced by the Vice Chair.

9.4. Duration of the review procedure

The applicant immediately receives an automatic confirmation of receipt when submitting a proposal. He or she can track the status of the proposal in the online portal. The VCWE aims for a turnaround time (i.e. time until first assessment) of two full weeks, with a maximum of four weeks. Note that during busy times (especially spring time with its Ba and Ma projects) this may take longer. Please plan ahead.

Revisions (of not yet approved positively assessed proposals) and **Amendments** (of already positively assessed proposals) are typically reviewed more rapidly, depending on the nature of the changes.

9.5. Decision: advice

The applicant may receive a positive advice, a positive advice provided some minor adjustments (no need to re-submit), a request for major changes (resubmit) or outright rejection (this research should not be done). A special type of decision is Defer to METC, when the committee is of the opinion that the research should be submitted to the Medical Ethical Committee.

9.6. Validity duration of advice

	A positive advice is valid for 5 years.

L. COMPLAINTS PROCEDURES

National Code	Local implementation (FGB)
1. The ethics review committees of the Institutes are advisory bodies established by the boards of those Institutes. Any negative advice issued by an ethics committee may be accepted or disregarded by said board. When a board issues a negative decision, an objection can be filed with the same board. An appeal can be lodged against such a decision in accordance with the 's university's regulations.	
2. Each ethics review committee has adopted a publicly available procedure regarding complaints from participants regarding/on all aspects of being included or excluded in a study that has been reviewed by the said committee.	**2.1 Complaints procedure** **a. Complaints concerning a researcher or research project** If it is believed that a member of the faculty is not complying with the ethical principles laid down in this document, or is behaving unethically otherwise when performing academic work, a written complaint backed up by arguments and where possible documentation can be submitted to the VCWE, vcwe.fgb@vu.nl. The VCWE will then give the person against whom the complaint is made the opportunity to respond, before coming to a decision. The VCWE will send its decision in writing to the person making the complaint and the person against whom the complaint is made, with a copy to the head of the department in question and the Faculty Board. The VCWE may advice the Faculty Board on whether the research project in question should be allowed to continue. If the researcher or the research project concerns a VCWE member, then the committee will treat the complaint without this member. The member will be absent from the relevant (part of) the meeting, and will be excluded from the committee's internal communication on the matter. The member, like any other researcher, will be allowed to respond. Moreover, a chair or senior member of any of the other ethical committees at the VU will take seat to independently monitor the decision process. If the researcher or the research project concerns the VCWE

	Chair, then the same rules apply, plus the Chair will be replaced by the Vice Chair. In case of grave violations of ethical or scientific integrity, the VCWE will advise the board to file a complaint with the central committee for scientific integrity http://www.vu.nl/nl/over-de-vu/wi/index.aspx **b. Complaints concerning the VCWE itself** In case the complaint concerns the decisions or functioning of the VCWE itself, the first step is to explain the problem to the VCWE chair, through vcwe.fgb@vu.nl. If this is for some reason not preferred, or turned out unsatisfactory, a complaint can be filed with the Faculty Board.

M. GENERALIZED VALIDITY OF THE ETHICS ADVICE

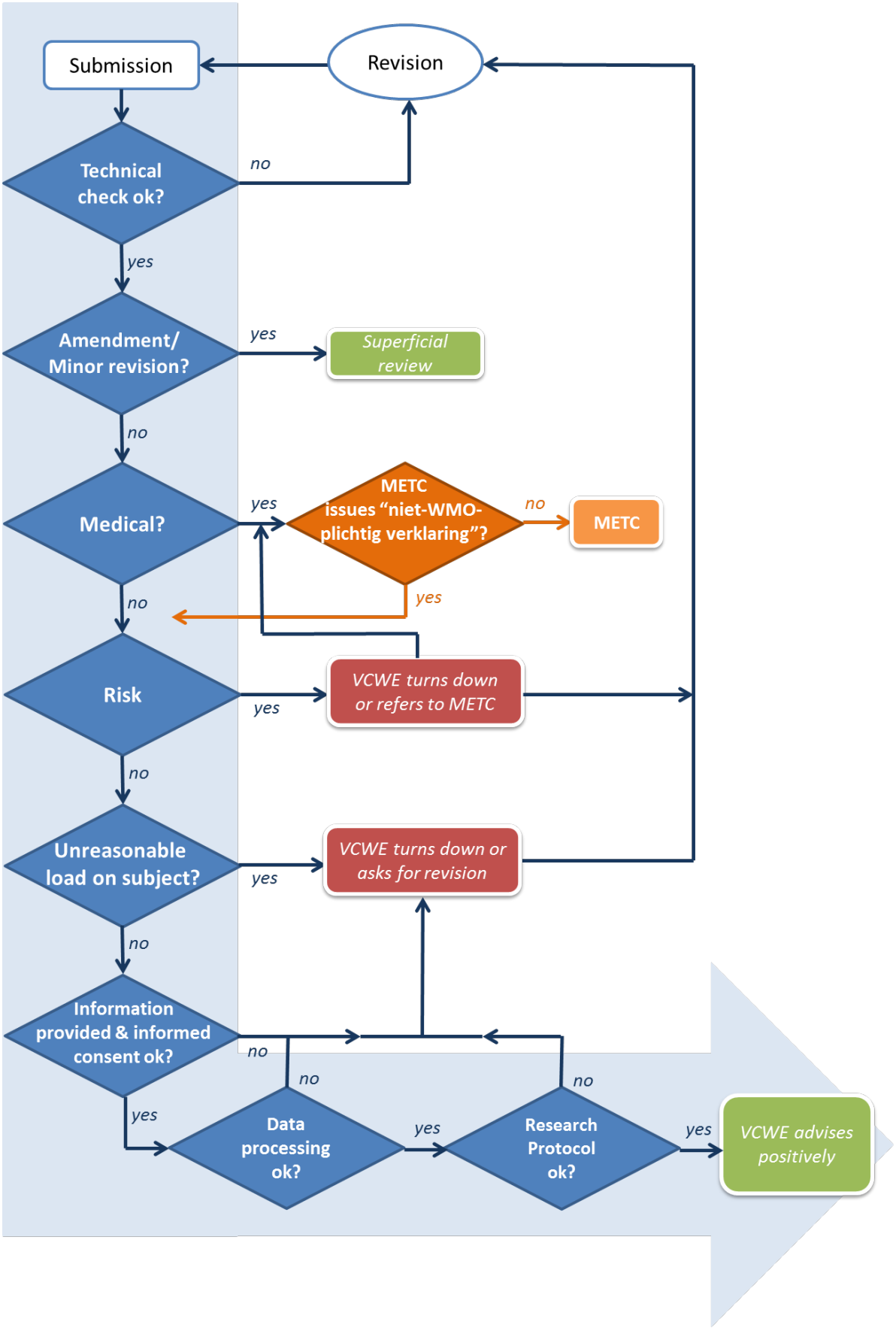
National Code	Local implementation (FGB)
1. If an ethics committee of an Institute of Social and Behavioural Sciences reaches a decision, this decision is deemed valid by all other Dutch Institutes of Social and Behavioural Sciences. This means that if a researcher moves from one university to another and the research program moves with her/him no additional review is necessary. It is due diligence to report the continuation of the study and its ethics approval at the new workplace.	
2. In case of research projects executed in multiple Institutes of Social and Behavioural Sciences, it is deemed sufficient to perform the ethical review by a single ethics committee only.	

CONDUCT OF RESEARCHERS

An area that is not covered by the national code of ethics is the expected conduct of researchers.

1. Researchers shall not make up data, omit relevant data or falsify data when publishing their research results.
2. Researchers shall indicate how they acquired their data, whether any data selection took place and if so how (for example when there are several dependent variables), and which methods were used to "clean up" and analyse the data.
3. If researchers discover serious errors in published data, they shall take steps to correct such errors by issuing an erratum, a retraction or by other appropriate measures.
4. Researchers shall not present substantial parts or elements of other researchers' work or data as their own, even if they do cite the other author's work or the source of the data from time to time.
5. Researchers shall only assume responsibility for the work they have actually done or to which they have contributed. They can only be named as author or co-author of a publication describing the work in question if this condition is satisfied, and only in this case can they claim that this work belongs to their oeuvre.
6. Being named as the principal author or co-author of a publication is an indication of the scientific or professional contributions of the persons in question, not their relative status. Acquiring a grant on the basis of a research proposal may be regarded as a major contribution, since a) the proposal describes the ideas on which the research is based and b) the research would not have been possible without the financial support provided by the subsidy. No one should be named as author merely because of his or her institutional position (such as head of department or group leader). Minor contributions to the research or to the writing of a publication shall be acknowledged in an appropriate way, for example in a footnote or the Introduction. The faculty further follows the guidelines for authorship laid down by the International Committee of Medical Journal Editors ICMJE (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html):
   The ICMJE recommends that authorship be based on the following 4 criteria:
   i. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
   ii. Drafting the work or revising it critically for important intellectual content; AND
   iii. Final approval of the version to be published; AND
   iv. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
7. A PhD student is normally named as the principal author of any article substantially based on his or her PhD thesis, if the article in question is published during or shortly after the doctoral study.
8. Researchers shall not publish data that have already been published as original data. This does not exclude republication of data where this republication is explicitly mentioned.
9. Researchers who receive publications or research proposals for review or assessment shall respect the confidentiality of the information contained in these documents and the copyright of the author or the person who submitted the proposal.

APPENDIX: Assessment procedure and criteria



Step 1: Technical check.

After the research proposal has been submitted to the VCWE, it is checked for completeness by the secretary of the Board. Have such details as the name of the principal researcher been included?

Step 2: Is this an amendment or minor revision?

In that case a superficial review by one member of the Board, often the chairman, is sufficient. In all other cases, the proposal will be reviewed by at least two members of the Board.

Step 3: Is the research proposal medical in nature?

Researchers must submit their research protocol to the Medical Ethics Committee (METC) when the research is subject to the provisions of the Medical Research Involving Human Subjects Act (WMO). According to the Central Commission for Research involving Human Subjects in the Netherlands (CCMO) (ccmo.nl), a study falls under the scope of the WMO Act if both the following conditions are met:

I. It concerns medical-scientific research and
II. Participants are subject to procedures or are required to follow rules of behaviour

Since Condition II is almost always met in behavioural research (observation studies in natural environments being one exception), the crucial judgment is whether **the study is medical in nature** or not.

Here, the WMO Act is difficult to interpret, as jurisprudence and various policy documents issued by the CCMO have shown. Moreover, the METC is the only body competent to give a ruling on whether a given research proposal is subject to the provisions of the Act or not. The CCMO has been trying to reach agreement with the various Dutch ethical review committees about which types of research require review by the appropriate METC and which do not. In the meantime, the VCWE makes use of the following criteria, while reserving the right at all times to refer research proposals to the METC in cases of doubt. A research proposal should in the first instance be submitted to the METC if one of the following criteria is met:

1. 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.
2. 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. The risk of harm should be distinguished from light mental or physical inconvenience which 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. Finally, these criteria apply to patients that have been deliberately selected for the study. Participants that coincidentally happen to be patients are not intended here, and if the research involves risk for such accidental patients then this should be dealt with by suitable choice of the exclusion criteria.

3. The study involves **medical acts or interventions** – i.e. invasive procedures, or BIG-registered procedures as listed under the Dutch Professions in Individual Healthcare Act (*Wet op de Beroepen in de individuele Gezondheidszorg*; http://wetten.overheid.nl/BWBR0006251/HoofdstukIV/Article36/geldigheidsdatum_06-06-2014). *Invasive procedures* include the taking of blood, tissue or DNA samples (if not through saliva swabs), 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.

Step 4. Irrespective of whether the research proposal is characterized by the METC as subject to the provisions of the Medical Research Involving Human Subjects Act (WMO) or not, and irrespective of the nature of the study population, the possibility of physical or mental harm to the test subjects must be considered.

The basic principle here is that participants should not be at greater risk during the study than they are in daily life. The permissible risk level is related to the importance of the study, and depends on two factors:

1. The vulnerability of the participants – for example, people with complaints or disabilities, children, the elderly, etc.
2. The physical and mental load imposed on participants during the study. This depends on the nature of the measurements made, the tasks participants have to perform and the duration of the study.

The greater the vulnerability of the research group, the lower the permitted load.

Mild physical or mental inconvenience within the context of the study, of short duration and not causing any real harm, does not fall within the scope of this consideration and can be justified if it is in the interests of the study and participants have been given prior notice of it.

Step 5. Is the load on participants excessive, even without an increased risk of harm?

An example of an excessive load on participants even in the absence of increased risk of harm is getting them to perform boring tasks for hours on end without a break. In such cases, the load imposed on participants must be weighed against the benefits they derive from taking part, such as monetary rewards, the opportunity to learn new skills, to gain new knowledge and insights, etc.

Step 6. Are prospective participants provided with the right information, and is the procedure for obtaining informed consent appropriate?

The various guidelines discussed above should be taken into consideration here. For example, have prospective participants been given all the information they require, and is that information correct? Has informed consent been obtained, and was that passive or active? If children are involved, has consent been obtained from their parents or guardians? If not, is the rationale convincing? Does the study involve deception, and can this be justified?

Step 7. Are the procedures used to collect and record data appropriate?

Here again, the relevant guidelines discussed above should be taken into consideration. Has a data management plan with privacy protocol been drawn up? What data are stored, and how? Is this done in a secure manner? Are video recordings made of participants? Is any information passed on to third parties?

Step 8. Has the relevance of the research been made clear?

It should be remembered that pointless research is unethical, and the relevant guidelines discussed above should be taken into consideration. How relevant is the research question? Under what conditions is the research to be performed? Are the investigative and analytical methods chosen adequate?