ETHICAL REVIEW REGULATIONS

Faculty of Behavioural and Movement Sciences and Education
Vrije Universiteit
Amsterdam
Scientific and Ethical Review Board
Faculty of Behavioural and Movement Sciences
Van der Boechorststraat 1
1081 BT Amsterdam

Chairman:
Prof. Christian Olivers

Secretary:
Barbara Goudriaan

E-mail:
vcwe.fgb@vu.nl

Version of November 2015
Based on: Ethical Review Regulations of the Faculty of Psychology and Education, Faculty of Movement Sciences, Vrije Universiteit Amsterdam, 2005, 2014; Guidelines for ethical review of psychological research and safe procedures for psychophysiological research (Richtlijnen ethiek psychologisch onderzoek en richtlijnen hygienisch werken psychofysiologisch onderzoek). Department of Psychology, Faculty of Social and Behavioural Sciences, University of Amsterdam. March 2003; various documents cited in the Literature list.
Dutch legislation lays down procedures for the ethical review of medical research involving human subjects. However, much of the research that is performed in the field of behavioural research (psychology, pedagogics, and movement sciences) does not fall under the current definition of medical research and is therefore not reviewed by medical ethics committees supervised by the Central Commission for Research involving Human Subjects in the Netherlands (CCMO). Moreover, it is well known that unambiguous interpretation and hence practical implementation of the Dutch Medical Research Involving Human Subjects Act (WMO) are far from easy. However, there is a growing expectation that behavioural research projects should also undergo formal ethical review before they are implemented. Legal guidelines for such review procedures may be formulated in the not too distant future. In the meantime, the Faculty of Behavioural and Movement Sciences at Vrije Universiteit Amsterdam will make use of the guidelines given below, and research performed within the faculty will on request be subject to ethical review by the faculty’s Scientific and Ethical Review Board (VCWE) in accordance with these guidelines.
1. **ETHICAL PRINCIPLES CONCERNING SCIENTIFIC RESEARCH INVOLVING HUMAN SUBJECTS**

1. Where relevant, the research shall be planned and carried out in accordance with the provisions of Dutch legislation, the ethics code of the American Psychological Association (APA), the professional code for psychologists of the Dutch Institute for Psychologists (NIP), the scientific integrity code of the Royal Netherlands Academy of Arts and Sciences (KNAW) and the Principles of Good Academic Teaching and Research (*Code voor Wetenschapsbeoefening*) published by the Association of Dutch Universities VSNU. The relevant literature may be found on the VCWE website.

2. The recording of personal data shall be in accordance with the requirements of Dutch legislation and the VSNU Code of Behaviour on Personal Data.

3. In the case of conflict between the above-mentioned regulations and guidelines, the following procedure suggested by the APA should be followed: The researcher gives a clear description of the conflict involved and takes reasonable steps to resolve it, taking the Universal Declaration of Human Rights into account. (Introduction to the APA Ethics Code, article 1.02).

4. During the preparation of any research project, the acceptability of the research shall be assessed with reference to the applicable ethical principles laid down in section 2 below.

5. Researchers are also responsible for ensuring that any investigation carried out by others under their supervision or responsibility is ethically acceptable.

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

7. 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. Research carried out in a public space is not in principle covered by this requirement.

8. In the case of online research in the Netherlands or abroad 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). Moreover, when personal data is being stored on servers of American companies, the participant will have to be notified prior to participation through explicit informed consent. This because the US Government can demand or force access to the data, even when these are stored in Europe.

9. Researchers shall take measures to ensure that the rights and welfare of test subjects and other persons involved in the research are not infringed.

10. When research involves test subjects with specific problems, the researchers shall consider these problems, in consultation with experts in the field in question, before starting the research.
2. APPLICATION OF THE ETHICAL PRINCIPLES

2.1 Personal data

Personal data are defined as any information relating to an identified or identifiable natural person.

1. Researchers come into contact with personal data when they perform research involving human subjects. They must handle such personal data appropriately, in compliance with Dutch legislation (see reference section on the VCWE web page).

2. The privacy of test subjects must be respected; personal data must thus be regarded as confidential. Personal data that could lead to the identification of test subjects must be stored in such a way that the linkage between the test subject and the research results cannot be traced.

3. 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.

4. 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 data will have to be shared with the therapist(s) or trainer(s). Here too the participant has to give permission.

5. If the researcher makes long-term use of a systematic database containing directly identifiable personal data, he or she should check whether this database 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.)

6. 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.

7. It is to be expected that a general guideline covering all the above-mentioned points, and others, and applicable to VU University Amsterdam as a whole will be prepared in the course of 2014 in the form of a Data Management Plan including a Privacy Protocol.

2.2 Recruitment of participants and informed consent
1. Test subjects are people whose actions or ideas could be influenced by an investigation. Groups of people who are simply observed in a public space are not considered to be test subjects.

2. Before a research project starts, researchers shall inform test subjects and/or their legal representatives about the expected course of the investigation. If possible, each participant should receive this information in the form of a letter or leaflet. This letter or leaflet shall comply with the guidelines of the Central Commission for Research involving Human Subjects in the Netherlands (CCMO) as laid down in the Handleiding voor de toetsing van medisch-wetenschappelijk onderzoek met mensen, 2002 (Guidelines for assessment of medical research involving human subjects), see the VCWE website. The information provided to test subjects about the objectives of the research and the procedures used shall be presented in clearly understandable language. Test subjects who are illiterate shall be given the necessary information verbally, and their informed consent obtained as described in subsection 5 below.

3. Researchers shall inform prospective participants that their participation is voluntary and that they can refuse to take part in the study or end their participation in the research at any time, without having to give any reason for their decision. Researchers shall further inform prospective participants about major factors that might affect their willingness to take part in the study, such as possible risks and inconveniences involved, possible adverse effects of participation and limits on confidentiality, and they shall reply to any further questions about the research that prospective participants may have. Finally, researchers shall inform prospective participants about the feedback procedures to be employed and the nature of the personal research results provided to each test subject.

4. Prospective participants shall be given enough time to read through the information provided, ask the researcher questions and consider whether they wish to take part.

5. The researcher will now ask each prospective participant for his or her consent for participation in the research, on the basis of the information provided in the relevant letter or leaflet together with the information provided verbally by the researcher. 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 is an acceptable alternative. The main thing is that the consent should be given after the relevant information has been provided.

6. 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. It must furthermore be stipulated that the mental and physical load imposed on the test subjects must be minimal. Researchers will provide relevant information, insofar as this is possible. Informed consent from legal representatives is required in all these cases (see also subsection 6 above).
7. When children under 12 are involved in research, the consent form shall be signed by the child’s legal representative. When children aged 12 or over are involved, the consent form shall be signed by the child as well as his or her legal representative. Young people aged 16 or over do not need consent from a legal representative. It is sufficient in principle for one parent or guardian to give consent, unless the nature of the investigation makes it preferable for consent to be received from both. In the case of test subjects who are mentally incompetent, consent must be obtained from the legal representative irrespective of the age of the test subject. Researchers shall also obtain the consent of the test subject himself- or herself wherever possible.

8. **Dispensations:**

   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. 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 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.

   b. **No consent.** In some cases, the requirement for informed consent may be dispensed with. The first case is involves research on groups of subjects; see section 2.4, Group research. The second case is when informed consent is not in the interest of the participant. In exceptional cases one could for example decide not to ask parents or legal representatives for informed consent when this may be damaging to the child, e.g. in cases of abuse. Furthermore, a child may explicitly choose for (and prefer) anonymity, e.g. on-line, on a self-aid site. In such cases, contacting the parents would be more intrusive than not contacting them. For these reasons, the VCWE does not categorically exclude the possibility of no consent. Researchers must however provide convincing arguments that the interests of the participant and research outweigh the disadvantages of no consent.

   c. **Weighing.** The researcher must make clear which deliberation underlies the decision, and whom has been involved in this. The VCWE will pay attention to:

      i. The level of intrusiveness of the research
      ii. The reasonable possibility of asking for consent
      iii. The risks of asking or not asking for consent
      iv. The capacity of a child to judge and represent its own interests.
      v. The societal importance of the research

Here too decision will be determined by the context of the research. Explanation and record-keeping are therefore very important. Moreover, 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.

9. A particular case in which one can decide not to inform the parents is when the participant explicitly opts of anonymity. The wish for anonymity needs to be respected, and can only be violated in exceptional cases, e.g. when:
   a. 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.
   b. 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.
   c. In these cases, the researcher has to:
      i. First discuss the issue with the child and try to come to an adequate solution
      ii. Check to what extent the researcher is legally committed to confidentiality.
      iii. Discuss the issue with colleagues or others with adequate expertise on the matter (e.g. doctor, Jeugdzorg, lawyer).
      iv. Keep adequate records.

Here too the VCWE recommends that researchers set up regular *intervision* and/or *participation*.

10. 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.

11. 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.

12. Researchers shall not offer excessive or inappropriate financial or other incentives in an attempt to recruit test subjects.

2.3 Research procedures

1. Researchers shall comply with the requirements of Dutch legislation when performing research (see the VCWE website).

2. Researchers shall use methods and/or take measures that minimize the risk of physical or mental harm to participants. If this risk is high, the research should be submitted to the Medical Ethics Committee (METC). In this context, a high risk is taken to mean a risk that is higher than may be reasonably expected in daily life.
Researchers shall not use methods that compromise the dignity of test subjects or invade their private life more than is necessary to meet the objectives of the research.

Researchers shall ensure that all agreements made with participants – both those laid down in the introductory letter and information leaflet and those made verbally before, during or after the investigation – are met.

Researchers shall not make use of deception in the course of their investigations, unless such deception is justified by the scientific, educational or practical benefits expected to be derived from the study. Deception shall only be used if equally effective procedures not involving deception are not available. The researcher should be able to demonstrate this. Test subjects shall not be misled about possible risks and inconvenience associated with participation in the study. Any form of deception concerning a key feature of the design and performance of a study must be explained to test subjects as soon as possible – preferably at the end of their participation but in any case no later than the end of the study.

Researchers shall inform test subjects prior to the start of the study which personal research results will be passed on to them at the end of the study. Researchers shall further allow test subjects, 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. Researchers shall inform test subjects on this issue in a clearly understandable way, and shall try to correct any obvious misunderstandings test subjects may have at the end of the study in a clearly understandable way.

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.

If scientific or human considerations justify withholding or delaying the provision of information, researchers shall take appropriate measures to limit the risk of harm arising from such circumstances as far as possible. Researchers shall inform test subjects on this issue before the start of the research.

Participants’ privacy must be respected; hence, personal data must be treated as confidential. Personal data must be stored separately from research data, and protected against unauthorized use (see also section 2.1).

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

Data collected in the course of a study are usually stored after the objective for which the data was collected has been achieved and the research reporting process has been finalized. The researcher and the head of the research department are responsible for ensuring that the data are stored safely. Once again, the requirement holds that personal data must be stored separately from research data. If a test subject objects to use being made of his or her data, the data in question shall be deleted immediately unless they have already been used in publications. If data have been used in publications so that the researcher has to use replication techniques to ensure consistency, identifiable personal data shall be deleted and the remaining data anonymized. The research data – anonymized if necessary –
shall be stored for at least **10 years** after publication, in accordance with international scientific guidelines. If it is decided not to publish the data, they may be deleted earlier.

12. If data are requested by other scientists or experts, the researchers shall take steps to ensure that test subjects’ privacy is protected. Databases shall be anonymized before data are shared with other experts. Identifiable personal data on test subjects may only be shared if the researcher has obtained prior written permission for this from the test subject (see section 2.1). As long as all the relevant guidelines mentioned in this document are observed, informed consent is not required for research making use of completely anonymized databases or field observations that do not involve manipulation of test subjects.

13. Researchers shall obtain permission from test subjects 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. This requirement does not apply if the only recordings made were for the purposes of field observation in a public space and it is unlikely that the recordings can be used for identification of the persons involved.

14. Researchers shall request permission separately (for example by means of an opt-out procedure) for the use of audiovisual recordings in presentations or for educational purposes.

2.4 Group research

Behavioural research may study group processes such as the effect of changes 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’ in-school or out-of-school behaviour, of the effects of 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. 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 of the research (nature of the research, environment, and people). It should be noted that audiovisual recordings can lead to identification of individual persons. Such recordings may therefore only be used if the individuals concerned are unrecognizable or are made unrecognizable.

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, 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).

3. The study involves observation of the group in question in its daily setting, without any limitation of or interference with individual privacy or autonomy. 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. 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 interferes with the objective of the investigation. The researcher shall provide evidence of the need to withhold such information.

5. 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.

6. 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.

2.5 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. It is to be expected that a general guideline covering all the above-mentioned points, and others, and applicable to VU University Amsterdam as a whole will be prepared in the course of 2014 in the form of a Data Management Plan including a Privacy Protocol. Researchers will then be expected to comply with this guideline, which will be phased in gradually.

4. 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.

5. 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.

6. 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.

7. 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. Winning a subsidy 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/)

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.

8. 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.

9. 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.

10. 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.
3. ROLE OF THE SCIENTIFIC AND ETHICAL REVIEW BOARD (VCWE)

3.1 Objective and tasks

1. The VCWE of the Faculty of Psychology and Education at VU University Amsterdam aims to ensure that scientific research involving human subjects is performed in an ethically acceptable way.

2. The VCWE has the following tasks: 1) ethical review of proposed research, 2) assessment of complaints and 3) promoting ethical conduct of researchers.

3. The academic quality of research is primarily the responsibility of the researcher. 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. If the academic quality has already been checked elsewhere, the VCWE will only perform a superficial assessment of this aspect.

4. Ethical review by the VCWE is not compulsory, and has no legal status (unlike ethical review by a medical ethics committee). The VCWE has the task of facilitating such review – that is, it offers the possibility of getting research proposals appraised by parties other than the researchers themselves – but it can never be held accountable for the consequences of the research. 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.

5. In principle, research activities conducted for the purpose of teaching, where students participating in the course merely test or practice on each other, does not need to be 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 is still recommended when students practice on people that do not participate in the course, or there is reason to believe that the activity has more far-reaching ethical implications.

3.2 Composition

1. The VCWE consists of ten members, including the chairman. 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 (sub)department within the faculty will have one representative on the Board.

2. Each research proposal is in general reviewed by two or three members of the VCWE. However, complicated cases are discussed by the Board as a whole.
3. New members are nominated by the VCWE and approved by the Faculty Board for a period of four years in all cases.
4. The VCWE selects new members for approval by the Faculty Board and determines the selection procedure for its chairman and secretary, and the nomination procedure for new members.

3.3 Procedures

1. The Board (that is, the Scientific and Ethical Review Board or VCWE) performs its tasks on the basis of the ethical principles laid down in this document, which are open to inspection by all members of faculty staff and all test subjects involved in a given research project. (For example, a copy of these Ethical Review Regulations is available on request from department heads and can be viewed by visiting the faculty website.) All members of faculty staff must comply with these principles.

2. The Board shall review all proposals for research involving human subjects performed by academic staff of the Faculty of Behavioural and Movement Sciences of Vrije Universiteit Amsterdam, guest researchers within the faculty. Research performed at another research or care institute must comply with the ethical guidelines of that institution. The responsibility then lies primarily with the external institution. However, if the institution has no procedures for ethical review, then it is recommended to submit the research to the VCWE.

3. The Board shall determine its own review procedure. The full Board shall meet at least once in two months. It shall lay down its review procedure in a document to be submitted to the Faculty Board and the regular meeting of department heads (AHO) for approval. Further details of the review procedure are given in section 4 below.

4. If a member of the Board is involved in a research proposal, he or she, or a member of his/her department, shall not take part in the review of that proposal. If the proposal is discussed during a meeting of the Board, he or she shall not be present during the discussion. Similar considerations apply to the chairman: if he or she is involved in a given research proposal, he or she shall not take part in the review of that proposal, and shall not play the role of chairman during its review. The chair shall be passed on to another member of the Board, and the original chairman shall be absent during any Board discussions of the proposal.

5. The Board shall acknowledge receipt of a research proposal within one week, and shall provide the applicant with an opinion on the proposal within no more than 4 weeks of receipt. The applicant shall be informed in good time of any delays in this procedure.

6. After review, the VCWE gives the researcher (and if applicable his or her research supervisor or project leader) an opinion as to whether the proposed research complies with the guidelines. The research and its ethical implications remain the responsibility of the researcher.

7. A positive advice by the VCWE is valid for 5 years.
8. The Board shall be provided with a secretary, who is a member of the faculty’s administrative and support staff. The secretary’s tasks shall
include keeping a record of the research proposals received for review, and sending the Board’s opinion on each proposal to the applicant.

9. The Board can call on the assistance of other experts in its review of the research proposals.

10. 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.

11. There is a complaints procedure for research involving human subjects and for other research performed within the faculty. If it is believed that a member of faculty staff is not complying with these ethical principles when performing academic research, a written complaint backed up by reasoned argument may be sent to the VCWE. The VCWE will give the staff member against whom the complaint is made the opportunity to reply before coming to a decision. The Board 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. If the VCWE concludes that the complaint is well founded, it may advise the Faculty Board whether the research project in question should be allowed to continue.

12. A copy of the ethical guidelines of the Faculty of Behavioural and Movement Sciences is available on request from the secretary of the Board, and these guidelines can also be viewed on the VCWE web page.

13. Research that has to be reviewed by the Medical Ethics Committee (METC) must be submitted to the METC in accordance with its procedures. Research regarded by the METC as subject to the provisions of the Medical Research Involving Human Subjects Act (WMO) but not approved by the METC may not be submitted to the VCWE (since the mandate of the METC is always superior to that of the VCWE). However, researchers can ask the VCWE to give an educated guess as to whether a given research proposal requires review by the METC (see flow diagram in section 4 below). The VCWE can also express an opinion on the academic quality of a research proposal if the METC requests this.

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

15. For multicenter research, the responsibility for ethical review is primarily with the institute at which the PI or penholder works. Nevertheless, if research has been positively reviewed elsewhere, the researcher has to make their own judgment whether the research complies with the faculty guidelines, by comparing it to this document. Most institutes will have adopted similar criteria, but when in doubt, the researcher may submit the proposal to the VCWE.

16. Plans for animal testing need to be submitted via the faculty’s coördinator (G.C. Baan) to the “Dierexperimentencommissie VU” (Secretariaat DEC, Dienst voor Veiligheid en Milieu, Transitorium, room 0D-38, van der Boechorststraat 1, 1081 BT Amsterdam).

17. For literature or archive 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.
4. SUBMISSION AND ASSESSMENT OF RESEARCH PROPOSALS

Submission

Research proposals are submitted via the online VCWE portal.

Applicants must be registered as users before they can submit a research proposal. Students without a doctorate are not allowed to make applications. In the case of research performed by a PhD student, the research supervisor or principal investigator must therefore also be named and registered as user in the system. The PI is seen as carrying main responsibility for the research.

The proposal needs to be submitted at least 4 weeks before the start date. Proposals will not be reviewed after when the research has already commenced or been completed.

The online submission procedure consists of a number of steps, where information has to be provided about the following 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 storage
- Research protocol

The questions asked during online submission are listed in Appendix I. The portal stores details of proposals submitted, thus reducing the amount of information to be provided when a revised proposal is submitted.

Proposals shall be accompanied by the following documents, if possible and relevant:
1. Application form for ethical review, including research protocol
2. Material used to recruit test subjects (such as information leaflets and media advertising)
3. 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.
4. In case of children or mentally incompetent test subjects: consent form signed by parents, guardians or other legal representatives.
5. 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.
6. Information about insurance, if applicable (most research performed within the faculty is covered by the third-party insurance of VU University Amsterdam).

Assessment

The assessment form used by the CVWE during the review of research applications is given in Appendix II.
The assessment criteria and procedure are summarized in the flow diagram given below.
**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?**

In principle, all medical research proposals are subject to the provisions of the Medical Research Involving Human Subjects Act (WMO) and must be reviewed by the appropriate Medical Ethics Committee (METC). However, the Act is difficult to interpret, as jurisprudence and various policy documents issued by the Central Commission for Research involving Human Subjects in the Netherlands (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 in 2014 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 guidelines, 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 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. 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 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?
5. REFERENCES

5.1 Relevant legislation

- Wet van 26 februari 1998, houdende regelen inzake medisch-wetenschappelijk onderzoek met mensen (Wet medisch-wetenschappelijk onderzoek met mensen).
- Wet van 6 juli 2000, houdende regels inzake bescherming van persoonsgegevens (Wet bescherming persoonsgegevens).
- Wet van 3 december 1992, houdende medezeggenschap in het onderwijs, niet zijnde hoger onderwijs (Wet medezeggenschap Onderwijs).

5.2 Relevant guides to legislation

- CCMO-Notitie psychologisch onderzoek en de WMO, 2008 (niet gepubliceerd)

5.3 Selection of other literature consulted

- Gedragscode gezondheidsonderzoek, Stichting Federatie van Medisch Wetenschappelijke Verenigingen.
- American Psychological Association Ethics Code
- NIP Beroepscode voor Psychologen
- KNAW code voor wetenschappelijke integriteit
- VSNU code voor wetenschapsbeoefening
- VSNU Gedragscode Persoonsgegevens

5.4 Important addresses:
Central Commission for Research involving Human Subjects in the Netherlands
www.ccmo.nl

Dutch Data Protection Authority
www.cbpweb.nl