Code of Ethics for Research involving Human Participants
Faculty of Science
Vrije Universiteit Amsterdam

Based on:

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, 23 May 2018 2
And the local implementations such as formulated by the Vaste Commissie Wetenschap en Ethiek

Including local guidelines as laid down by the Faculty of Science, Vrije Universiteit Amsterdam

Preamble

The Code of Ethics of the Faculty of Science, Vrije Universiteit Amsterdam (VU), provides guidelines for research involving human participants, which is not covered by the Medical Research Involving Human Participants Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, WMO). It intends to support researchers and ethical review boards in their ethical reflection.

The Faculty of Science encompasses 12 departments: Athena, Chemistry and Pharmaceutical Sciences, Computer Science, Earth Sciences, Ecological Science, Environment and Health, Health Sciences, Physics and Astronomy, Molecular Cell Biology, Institute for Environmental Studies, Mathematics and Neurosciences[1]. The research of these departments is highly diverse in nature and execution. For example, the Faculty of Science is involved in research in environmental sciences, (life style) informatics, neuroscience, genetics research, health sciences, and science, technology & society studies. However, in many types of research human participants are involved. The diversity not only concerns the broad spectrum of scientific disciplines, but also the wide range of research methods applied, from surveys to participant observation, and from minimal physical interventions to ethnography. This requires an independent guideline for ethical and scientific review of research involving human participants, taking the existing diversity into account.

The VU Faculty of Science complies with the guidelines from the National Code of Ethics, which is subscribed to by all academic institutes that fall under the Deans of Social Sciences (DSW)[2]. This code is selected because the National Code of Ethics provides guidelines for research in the broad field of social and behavioural sciences involving human participants and research at the VU Faculty of Science involving human participants shares many characteristics with the social and behavioural sciences. However, the code adopted by the Ethical committee of the Faculty of Science (BETHCIE) diverts on some aspects. To make this visible, deviations or supplements of the BETHCIE are indicated by a line in front of the text. Wherever the national Code of Ethics mentions the “social and behavioural sciences”, we interpret this as “the type of research as conducted with human subjects within the Faculty of Science” which is somewhat broader, basically including any type of research involving human participants. We do not mention this explicitly throughout the document.

Apply or Explain
The Code of Ethics of the VU Faculty of Science does not intend to dictate the same specific measures and procedures to all researchers of all disciplines at all times. It offers general ethical guidelines that should be considered as default, but that require critical assessment and deliberation to be applied in concrete situations. The guidelines laid down below must be read in this light. Particular situations may require researchers to depart from the code. However, subscribing to the code is non-committal and in all cases researchers are expected to be able to clearly explain their considerations and to account for their choices. Thus, the guiding theme here is *apply or explain*” (see article A.1 of the Code).

Principles
The Code of Ethics is based in the following principles:

- Researchers respect the dignity of humans and their environment by avoiding exploitation, treating participants and their communities with respect and care, and protecting those with diminished autonomy.
- Researchers strive towards a minimization of harm, and a just distribution of benefits and burden, with respect for the potentially conflicting interests of diverse (groups of) participants, communities, and society.
- Researchers adopt an ethical attitude in which they are mindful of the meaning, implications and consequences of the research for anyone affected by it.
- Researchers demonstrate the ethical attitude by (i) active reflection on the ethical issues that may arise during, or as a consequence of, their research, (ii) initiating a proper assessment of the potential drawbacks of the research for individuals, communities and society, and (iii) monitoring for any developments that may impact upon ethical aspects of the research.

[1] On January 2019.
[2] At the VU, the Faculty of Social Sciences and the Faculty of Behavioral and Movement Sciences also comply with the guidelines from the National Code of Ethics.

- Researchers are able to account for, and communicate on their ethical reflection vis-à-vis different stakeholders, such as the participants and their communities, the own organization, scientific peers, students, funding agencies, and society.
- Researchers conduct research that is scientifically valid, and that will plausibly lead to relevant insights in the field of the social and behavioural sciences.

The VU Faculty of Science encompasses 12 departments of very different nature (see above), of which many conduct research featuring human participants. We expect researchers from the VU Faculty of Science to conduct research that is scientifically valid, and that will plausibly lead to relevant insights in their field of research.

The ways in which these principles are safeguarded may vary to some degree depending on the field of research. Moreover, raising ethical awareness of scientists requires them to be stimulated, by way of the questions and considerations put to them in the ethical review procedure. The Code of Ethics forms the basis of such review procedures, of which the detailed implementation may vary.

A. DEFINITIONS

BETHCIE: The Ethics Review Committee of the Faculty of Science.

Board: The faculty board of the Institute the Dean plus the Director of Research, Director of Education and Managing Director.

CCMO: The Central Committee for Research on Humans (*Centrale Commissie Mensgebonden Onderzoek*)

Code of Ethics: The Code of Ethics For Research in the Social And Behavioural Sciences Involving Human Participants, as laid out here.

Ethics Review Committee: A committee of experts assigned by the Board with the task to review research plans on ethical aspects, and advise the Board accordingly.

Ethics Committee for Information Sciences (ECIS): The Ethics Committee from the UvA Informations Institute and the VU Computer Science department

Institute: A university faculty, research institute, or graduate school in the social and/or behavioural sciences that subscribes to the Code of Ethics.

METC: Medical Ethical Review Committee (*Medische Ethische Toetsingscommissie)*

Participant: A person that partakes in, or is subject to, research in which data on or from this person are being collected. Data collection may occur at the level of individual participants, but also at the level of a group, community, or organization.

Personal data: Data that can lead to the identification of a person. Note that the law also distinguishes *sensitive* personal data, to which additional rules apply ("bijzondere persoonsgegevens"; Algemene Verordening Gegevensbescherming).

Research plan: A document addressing the rationale, background, objective(s), methodology, planned analyses, and all relevant ethical aspects of a research project involving human participants. Note: This does not deny or decry exploratory or unexpected research directions.

Social and Behavioural Sciences: The fields of science that study the patterns and causes of human behaviour, as individuals and as part of groups, communities, cultures and societies. In its broadest sense, this also includes the humanities and life sciences.

WMO: The Medical Research Involving Human Subjects Act (*Wet Medisch Onderzoek*)

B. GENERAL PROCEDURES

1. All Institutes of Social and Behavioural Sciences at Dutch Universities subscribe to the guidelines laid out in the Code of Ethics. If an Institute diverts from these guidelines, the Institute must be able to explain why this has been decided.

BETHCIE complies with the guidelines, except on some aspects. Deviations (including specifications) are indicated with a line in front of the text (as is done here) in this document and explained where deemed necessary.

2. Research in the social and behavioural sciences involving human participants, or any research concerning ethical issues, for example, the use and publishment of medical data, must be carried out in accordance with a research plan.

2.1. Protocol
The ethics review form asks for descriptions of the purpose, importance, design (quantitative, qualitative, observational, with or without active intervention), 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 may be available for each subproject.

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 BETHCIE 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. The research plan identifies and weighs the potential costs and benefits to all stakeholders, with an emphasis on the consequences for the participants and their communities.

4.Ethical review by the BETHCIE has no legal status (unlike ethical review by a medical ethics committee). However, all researchers within the VU Faculty of Science involved in research not falling under the Medical Research Involving Human Subjects Act (WMO) pertaining to human are expected to exercise due care in their research work, in accordance with guidelines such as those given in the present regulations. Furthermore, all researchers must check their research proposals on ethical issues by completing the online 'Self-Check' before starting the research. The 'Self-Check' concludes whether further ethical review by the BETHCIE is required. Submission of research proposals to the BETHCIE is seen as the most effective, and hence the preferred, form of review within the VU Faculty of Science.

5. The BETHCIE differentiates between (i) a light (e.g., assessment of a protocol concerning secondary data analyses, studies that do not raise ethical concerns based on the list of control questions as published on the VU webpage of the BETHCIE), and (ii) a comprehensive ethical review process. The assessment procedures and criteria as employed by BETHCIE are illustrated in the flow chart in the Appendix. Research not involving human subjects is not reviewed by the BETHCIE.

5.1 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 WMO. According to the Central Committee for Research on Humans (Centrale Commissie Mensgebonden Onderzoek; CCMO), a study falls under the scope of the WMO if <u>both</u> 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 BETHCIE uses the following criteria:

a. The study involves a medical or clinical research **question**
b. The study involves a considerable medical health risk for the participant (more so than in daily life)
c. The study involves **medical intervention or treatment** (as registered by law).

See the Appendix[3] 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 METC for review. The BETHCIE can be asked for advice and an educated opinion (see also the flow diagram in the Appendix).

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

[3] Appendix, Step 7.

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

5.2 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 BETHCIE.
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 the researcher has obtained ethical assessment from an external institute, the researcher must submit his research proposal, including the assessment of the external Ethical Committee, to the BETHCIE for light review. Nevertheless, the BETHCIE can conduct comprehensive review when deemed necessary.
e. In principle, **any assessment from another Dutch Faculty or Institute of Social and Behavioural Sciences is deemed valid,** since these institutes subscribe to the present code – see Article M.1.

5.3 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.

5.4 Secondary analyses of existing data sets

For secondary analyses of existing data (i.e., data that have been collected in previous studies by the same researcher of by other researchers at the same or different universities), ethical review is in principle not necessary. However, the BETHCIE can produce a "niet-WMO" statement and/or conduct a light ethical review upon request (e.g., some external data bases require local approval from an ethical committee before data are made available).

5.5 Animal testing

Plans for animal testing need to be submitted to the Dierexperimentencommissie (DEC).

6. The ethics review must occur before the research commences. In exceptional circumstances an important research opportunity may arise without the possibility of a timely research plan and/or ethics review. In such cases the review must occur as soon as is reasonably possible. In the meantime, the researcher remains responsible for acting in accordance with the ethical principles as laid out in this Code.

7. The Ethics Review Committee evaluates the research plan based on the guidelines as laid out in the Code of Ethics, specifically the local implementation thereof. Based on this evaluation the Ethics Review Committee will either issue or withhold approval or a positive advice.

8. The ethics review is conducted with due regard to relevant international, European and national laws, rules and guidelines. In case the research is conducted in a country other than the Netherlands, the principal investigator is responsible for ensuring that the research is conducted with due regard for local laws, habits and customs.

8.1 Legislation and guidelines

Relevant sources here are the Dutch legislation (or that of the country where the research is conducted) and the CCMO, as well as the scientific integrity codes of the Royal Netherlands Academy of Arts and Sciences (KNAW) and the Association of Dutch Universities (VSNU), European Code of Conduct, Dutch Code of Conduct for Research Integrity. Links are available on the BETHCIE website.

8.2 Conflicting rules
In the case of a **conflict between regulations and/or guidelines**, the following procedure 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.

In the case of research abroad, including online research using crowdsourcing websites such as Mechanical Turk, Crowdflower or Qualtrics, the BETHCIE 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 servers are located in Europe.

9. In case of unclear or conflicting laws or values, the nature and circumstances of the dilemma are clearly documented, together with a plan to come to a well-founded resolution.

10. An Ethics Review Committee may suspend or revoke a positive review of a research plan if there are reasonable grounds to assume that continuation of the research would lead to unacceptable harm or burden to the human participants involved.

11. Research must be covered by the regular legal liability insurance of either the Institute where the research is conducted or the body with primary 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.

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 typically not necessary for standard low risk research. The insurance policy documents can be obtained from the BETHCIE.

C. SCIENTIFIC RELEVANCE, NECESSITY, AND VALIDITY

1. The research as described in the Research Plan will plausibly lead to relevant insights in the field of the social and behavioural sciences.

2. Research may also be conducted for training purposes, without necessarily leading to new insights, as long as the participants involved are made aware of the training purpose (e.g., students testing on fellow students).

3. The same insights cannot plausibly be gained, or not to the same level, by alternative means of research that are less intrusive to human participants.

4. It is plausible that the insights gained from the research are in proportion to conceivable burden and risks imposed on research participants.

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

6. The research makes use of a sound methodology.

6.1 Researcher responsibility
Researchers are responsible for ensuring that any investigation carried out by themselves, or by others under their supervision or responsibility, is ethically acceptable, and thus meets the requirements listed here and the

sections below. Checking the research protocol on ethical issues by completing the 'Self-Check' and/or submitting the protocol to the BETHCIE aids in meeting this responsibility.

Researchers must 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 must consider these problems before starting the research. For this, researchers must either have, or invoke, the necessary expertise. The BETHCIE evaluates whether the proposed study is ethically acceptable.
Researchers and their assistants may never perform tasks for which they have not been properly trained and prepared.

6.2 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 must have a protocol in place that specifies:
a. Which incidents may occur (as far as can be foreseen)
b. How to act upon such incidents
c. 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. The BETHCIE verifies the existence and sufficiency of the emergency protocol, and provides an example of such a protocols on its webpage.

6.3 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. (For rules concerning informed consent, see below).

6.4 Research with a teaching purpose
In principle, research activities conducted for the purpose of **teaching only**, where students participating in the course merely **test or practice on each other,** do 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 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.

6.5 Ethical questions concerning content of courses
At the VU Computer Science department, courses are taught that share or teach ethically sensitive information (courses on e.g., digital warfare, computer hacking, and practicals testing security or safety of servers,firewalls or computer processes). Although these undertakings do not concern research, ethical review of the course may be requested from an Ethical Review Committee. As described under B4, teachers from the VU Computer Science department may request such review from ECIS. The BETHCIE will comply with the decision of the ECIS, and the BETHCIE shall not review the decision of the ECIS.

D. INFORMED CONSENT

1. Participants, or their legal representatives, must be given ample opportunity to understand the nature, purpose and anticipated consequences of research participation, so that they will be able to give informed consent to the extent to which they are capable of doing so. Specifically, the information provided in advance addresses (where applicable):
a. the voluntariness of participation;
b. the nature and purpose of the investigation, including if the data collection is meant only for training purposes;

c. any reasonably foreseeable factors regarding the nature, purpose and duration of the research that may influence participants' willingness to participate (such as extent of strain, potential risks, and discomfort);
d. the right to decline to participate and withdraw from the research at any time, without any negative consequences, and without providing any reasons;
e. any recording of voices and images (where applicable);
f. confidentiality protection and the limitations thereof;
g. procedures for incidental findings (where applicable);
h. additional insurance guarantees (where applicable);
i. period of time to which the consent applies;
j. time and nature of data storage;
k. re-use of specified data in the current, future or other research, including conditions of sharing of data with others;
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.

1.1 Participant Information Forms
The BETHCIE stimulates the use of a standardized Participant Information Form (Proefpersonen Informatie Formulier: PIF) that addresses all points described above. An example of such a form can be downloaded from the website.

1.2 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.

1.3 Children and mentally less competent
In case of minors (under 16) and mentally less competent participants, 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).

1.4 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.

1.5 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. 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, PIF) needs to explicitly specify the possibility of incidental findings, whether, how and to whom these will be reported, and that participants can choose to participate even if they do not want to be informed on such incidental findings.
The main researchers are responsible for putting a procedure in place detailing how relevant incidental findings are treated and whether/when/to whom these are reported.

Note: Other institutes (VUmc, SPINOZA, etc.) may have slightly different procedures.

2. When personal data are being registered or collected, consent must be obtained in accordance with the law (NL: Algemene Verordening Gegevensbescherming, EU: General Data Protection Regulation).

3. In case of a mentally incompetent participant, informed consent is obtained from the legal representative(s). It is good practice to also ask the participant for consent whenever possible.

4. In case of minors younger than 12 years of age, informed consent is obtained from the parent(s) or legal representative(s). It is good practice to also ask the child for consent whenever possible.

5. In case of minors older than 11 and younger than 16 years of age, informed consent is obtained from both the minor and the parent(s) or legal representative(s).

6. In case of minors, consent from one parent is considered sufficient by default, unless the Ethics Review Board decides that a particular research plan requires consent from both parents.

7. From 16 years of aged, consent is only obtained from the participant. For some types of research it may nevertheless be good practice to inform the parents or legal representatives.

8. Participants, especially those of reduced mental competence, are monitored for signs of discontent (including nonverbal signs) prior to, during, and where possible after the research, and such signs are acted upon appropriately by alleviating the discomfort or ceasing the research.

9. When recording voices or images of participants, informed consent must be obtained unless the research consists solely of naturalistic observations in public places.

10. Information is provided to the participant sufficiently in advance. What qualifies as “sufficient time” depends on the nature of the research, with as a general rule: the higher the impact or burden, the longer the time period.

11. The information is provided, and consent is asked, in a manner comprehensible for the participant, taking into account factors such as age, cultural differences, economic and linguistic barriers, and levels of education and illiteracy.

11.1 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.

11.2 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).

11.3 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.

11.4 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 students do not wish to act as test subjects as a matter of principle, they shall be exempted from the research project.

12. By default informed consent is active, i.e. through a deliberate act of the participant ("opt-in"). Special circumstances may call for passive consent ("opt-out"), see section E.

13. Depending on the type of research, any deliberate and plausibly demonstrable act of consent can be valid, whether transferred through writing, digitally, verbally, or by other means.

14. 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, or when a study is conducted anonymously. In these cases, it must be explained how voluntariness is established instead.

14.1 Standard informed consent forms
Standard informed consent forms can be downloaded from the BETHCIE website.

14.2 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.

14.3 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).

14.4 Children and mentally incompetent participants
Children under 16 and participants 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 significant 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 participants (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.

14.5 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 (i.e., opt-in). 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.

14.6 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 organizations. 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.

c. *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).

d. *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 (Instemmings-bevoegdheid 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.

14.7 Deviate from standard protocol
The researcher must use the standard consent procedure. However, if the standard consent procedure is unfeasible in the planned study, the researcher can deviate from the standard consent procedure. In that case, the researcher must make clear which considerations underly the decision to deviate from the standard consent procedure. 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 BETHCIE 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).

15. Researchers who collect information about individuals who are not actively participating (i.e. third parties from whom no informed consent has been or can be obtained), must indicate how they protect the interests (including privacy) of those third parties.

16. Supplemental informed consent must be obtained when the research takes substantially longer than was announced, or when there is a significant change in the nature or focus of the research or the burden or risk it causes.

E. EXCEPTIONS: WHEN IS WITHHOLDING INFORMATION, DECEPTION, PASSIVE CONSENT, OR NO CONSENT ACCEPTABLE?

1. Information for participants may be withheld from participants only when the necessity to preserve the integrity of the research outweighs the interests of the participant, 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 their participation in such a manner and to such an extent that, to their judgment, the informed consent remains intact.

2. A study may not employ deception unless the use of deception techniques can be justified by the study’s significant prospective scientific or applied value and when there is no alternative procedure for effectively collecting the data.

2.1 Explain
The researcher should document and explain the nature of the deception and explain why it is required.

2.2 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).

2.3 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.).

2.4 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.

3. Information may not be withheld on, or participants may not be deceived about, procedures that can reasonably be expected to cause physical or mental harm.

4. Any deception or withheld information must be explained to participants as early as possible, immediately after participation, and no later than at the end of data collection. Participants must then also be informed that they have the right to withdraw their data without any negative consequences.

5. Passive consent ("opt-out") can be considered under special circumstances, but only if (a) active consent leads to substantial and demonstrable disadvantages with respect to the quality or aim of the research, and/or the interests of the participants (b) there is minimal burden and no risk for participants, (c) special care is taken to inform participants and/or their representatives of the study and the possibility to opt out, (d) the opt-out procedure is straightforward. Any opt-out procedure is to be reviewed by the Ethics Review Board.

6. Observation of people in public spaces may occur without consent. Such research must be conducted with respect for privacy. Data collection occurs fully anonymously (no personal data can be registered) and unobtrusively, in accordance with local cultural values, and restricted to situations where people being studied can reasonably expect to be observed by strangers. By law, the collection of any personal data requires informed consent.

6.1 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).

6.2 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.

6.3 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.

7. Observation of specific groups or organizations (not necessarily in public spaces), including participant observation, occurs with informed consent from either the group members, or from an appropriate representative – a person who can be demonstrably or reasonably considered to represent the interests of the group (e.g. a teacher, a village elder, a team leader, a coach, or a chosen representative). Here too, observation must occur with respect for privacy, and local cultural values.

8. Whenever personal data on individuals are collected, the law dictates active informed consent from the individual. However, the law allows for deviations when there is a justified cause ("gerechtvaardigd belang"; Algemene Verordening Gegevensbescherming). Such a justified cause is to be established in consultation with the Institute's legal office.

9. When data are to be re-used for new research purposes, but informed consent from the original participants can no longer be obtained, a Research Plan detailing the nature and importance of re-use, and

including the implications for privacy, shall be submitted for review to the Ethics Review Committee, who shall decide whether re-use is justified.

F. COMPENSATION

1. Any compensation or benefits offered to research participants and/or their communities is fair.

2. Compensation does not have a disproportionate effect on whether or not participants decide to participate in a particular study or activity, nor should the amount of compensation cause or contribute to inflation beyond normal levels.

3. If local resources of a community are being used, adequate compensation is provided.

4. The person conducting the research and the Institute where the research is carried out receive a compensation not exceeding what can be considered reasonably proportionate to the nature, extent and purpose of the research.

G. DATA PROTECTION AND PRIVACY

1. The processing, storage, and publication of data that can lead to the disclosure of a person's identity is safe-guarded in accordance with the applicable laws and regulations, notably the Algemene Verordening Gegevensbescherming (NL) / General Data Protection Regulation (EU).

2. Special care and restraint is adopted with regards to highly sensitive personal data ("bijzondere persoonsgegevens"), as specified by the same laws.

3. Special care is taken to protect those who may be extra vulnerable to harm from being identified and/or having information linked to them, e.g. those who are in a position of dependence (whether psychological, social, economic, political, or otherwise), easily stigmatized, discriminated against, prosecuted, or met with violence. For example, protecting someone's privacy may have implications for the way informed consent is being registered.

3.1 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 BETHCIE webpage 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 participant.
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.
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.
g. Researchers shall not pass personal data on to third parties without the permission of the participant 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 participant 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 Officer (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 as a whole, will become available in the form of a Data Management Plan, including a Privacy Protocol (not clear yet, sept. 2016).

3.2 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.

3.3 Data publication and presentation

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

3.4 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 additional informed consent from the participant. What counts as a different purpose is best considered together with the BETHCIE.

3.5 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.

3.6 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.

4. When data are to be re-used for new research purposes, but informed consent from the original participants can no longer be obtained, a Research Plan detailing the nature and importance of re-use, and including the implications for privacy, shall be submitted for review to the Ethics Review Committee, who shall decide whether re-use is justified (see also Section E).

H. ETHICS REVIEW COMMITTEE

1. An ethics review committee of an Institute is an advisory body established by, and reporting to, the Board of the Institute.

2. Any advice issued by an ethics review committee may be accepted or disregarded by the Board.

3. The ethics review committee must consist of at least five members, to be appointed by the Board of the Institute where the research is conducted.

3.1 Composition
The BETHCIE consists of seven core members, including the chair person and the vice chair. Since the BETHCIE has to review the academic, ethical and social aspects of the research proposals submitted to it, its composition is chosen to reflect the range of research performed within the VU Faculty of Science. The VU Faculty of Science comprises of 12 departments (see introduction). Because the BETHCIE consists of only 7 members, not all the departments are represented. Therefore, the BETHCIE can always ask for advice from researchers, who are not represented in the BETHCIE.
The Faculty Board appoints and approves new members, the BETHCIE may suggest and nominate new members to the Board. New members are appointed by the Board for a period of three years. This period may be extended for another three years.
Formally, the BETHCIE advises the Faculty Board. However, to optimize the work flow, the Faculty has chosen to grant the BETHCIE the mandate to advise researchers directly, without the intervention of the Faculty Board.

3.2 Legal and ethical advice
The board aims to always have at least one member with a philosophy/ethics background as a member of an Ethical Review Committee. Furthermore, Henk Sportel, h.sportel@vu.nl has been assigned as the legal counsel for all ethical committees at the VU (FSW, FGB, FGW and SBE).

4. The Faculty Board will appoint one of the members as committee chair, the BETHCIE may suggest members as committee chair to the Board. 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.

6. The Board 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.

7. The chair, vice chair (if appointed) and executive secretary constitute the executive board of the Ethics Review Committee.

8. The expertise of the committee members must cover the major disciplines of the Institute and the typical ethical issues involved.

9. The ethics review committee is responsible for acquiring and maintaining relevant knowledge and skills with regard to recurring ethical issues, as well as evaluating new developments and perspectives.

10. The ethics review committee strives towards raising ethical awareness among applicant researchers through clear and timely information, as well as through constructive dialogue.

11. The ethics review committee must be able to invoke independent external expertise from someone who is not affiliated with the institute where the research is being assessed. Ethics Review Committees from sister organizations at other institutes may be invoked for this purpose.

12. The ethics review committee must have structural (i.e. organized) access to both ethical and legal expertise.

13. The ethics review committee may be extended (temporarily or permanently) by non-voting advisors.

13.1 Ad hoc reviewers
During busy times, the BETHCIE may make use of ad hoc reviewers, who are not members of the committee, but who are knowledgeable researchers within the faculty.

14. The Ethics Review Committee's working method and related procedures must be specified in a set of regulations available to all stakeholders.

14.1 General
The Board shall determine its own review procedure, which shall be laid down in a document to be submitted to the 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 BETHCIE website as well as from the chair and executive secretary.

14.2 Submission
The researcher starts the ethical review procedure, by submitting the online 'Self-Check' at the VU BETHCIE webpage. In case of ethical issues, the researchers must fill in the online application form and upload the requested documents (art. 14.3.).
Students (BSc/MSc) and PhD students are not allowed to submit applications themselves. However, the supervisor may request the BETHCIE for ethical review of research conducted by (PhD) students.
Proposals will not be reviewed when the research has already commenced or been completed.

14.3 Submission documents
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 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 also be uploaded together with the online form:
- 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 participants: the consent form signed by parents, guardians or other legal representatives is uploaded.
- Statement issued by the METC that research is not subject to the provisions of the 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).

14.4 Review Procedure
The researcher starts the review procedure, by completing the online 'Self-Check'. The 'Self-Check' concludes whether the research requires ethical review by the BETHCIE
If the 'Self-Check' concludes that the research does not require further ethical review, the researcher must submit the research proposal. After submitting the research proposal, the researcher shall receive an email containing the 'Self-Check' and a statement by the BETHCIE that the research complies with the Code of Ethics of the VU Faculty of Science. The researcher shall archive the 'Self-Check' and the positive statement from the BETHCIE. The BETHCIE may always request the researcher to provide the committee with the 'Self-Check'.

If the online 'Self-Check' concludes that the research does require an ethics review, the researcher must apply for ethical review by the BETHCIE. The researcher must upload the application form and the required documents as specified under 14.3.

The executive secretary receives the submitted documents and checks whether the answers to the control questions in the online questionnaire give reason to believe that comprehensive review is required ('pre-check'). If not, a light review procedure is started. Otherwise, a comprehensive review procedure is started.
If the ethical issues are considered small, the research proposal will be submitted for a light review by the BETHCIE. The executive secretary will send the research proposal to one BETHCIE member. The member will give an advice and discuss this with the chairman. The chairman will directly present the advice to the researcher.

A proposal is submitted to comprehensive review, if the answers to the online questionnaire give reason for this. The proposal is then reviewed by two members of the BETHCIE and discussed in the BETHCIE meeting. If, based on a light review, the BETHCIE member and the chair decide that the research proposal must be submitted for comprehensive review, the research proposal will be sent to a second BETHCIE member and the proposal will be discussed during the BETHCIE meeting.
If the committee member or the chair are of the opinion that there are substantial ethical issues that need broader discussion, the review of an extra committee member or an external expert will be invoked, and the research proposal will be discussed in the BETHCIE meeting (comprehensive review).

14.5 BETHCIE meeting
The BETHCIE meets monthly, except July, August and January (unless necessary). 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.

14.6 Duration of the review procedure
The BETHCIE aims for a turnaround time (i.e. time until first assessment) of two full weeks, with a maximum of four weeks. **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.

14.7 Decision: advice
The applicant may receive a standard statement, stating that the research proposal complies with the ethical guidelines of the Faculty of Science. The applicant may also receive an advice, a positive advice provided some minor adjustments (no need to re-submit), a request for major changes (resubmit) or an outright rejection (this research should not be done).

14.8 Defer to METC
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.

14.9 Validity duration of advice
A positive advice is valid for 5 years. The researcher is expected to start the proposed research within 1 year of obtaining approval. As regulations (concerning e.g. privacy) change quite rapidly, researchers who did not start their research within 1 year after approval, are advised to resubmit their proposal for a quick re-evaluation.

14.10 *Unexpected checks*
The BETHCIE will carry out unexpected checks by every 1 out of 5 research proposals for which a positive statement has been issued by the BETHCIE as a result of the online 'Self-Check'. The BETHCIE shall verify the answers given at the questions from the online 'Self-Check' and check if the research proposal complies with the ethical guidelines.
If the BETHCIE considers that the researcher did not answer the questions correctly and the research proposal therefore does not comply with the ethical guidelines, the BETHCIE shall give a negative advice. The BETHCIE shall motivate which questions were answered incorrectly. The BETHCIE shall also fully substantiate why the research proposal does not comply with the ethical guidelines. The secretary will communicate the negative advice to the researcher. The researcher will be requested to resubmit the 'Self-Check', with the given advice taken into consideration.

I. COMPLAINTS PROCEDURE

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 university's regulations.

2. The ethics review committee has adopted a publicly available complaints procedure for participants who have complaints about 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 BETHCIE, bethcie.beta@vu.nl. The (vice)-chair will conduct a conversation with the person against whom the complaint is made, in order to give the researcher the opportunity to respond. The BETHCIE will publish 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 BETHCIE 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 BETHCIE 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 Ethics Review Committees at the VU will take seat to independently monitor the decision process.
If the researcher or the research project concerns the BETHCIE 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 BETHCIE 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 BETHCIE itself
In case the complaint concerns the decisions or functioning of the BETHCIE itself, the first step is to explain the problem to the BETHCIE chair, through bethcie.beta@vu.nl. If this is for some reason not preferred, or turned out unsatisfactory, a complaint can be filed with the Faculty Board.

J. GENERALIZED VALIDITY, MULTI-CENTER RESEARCH, AND RESEARCH AT EXTERNAL INSTITUTIONS OR LOCATIONS

1. If an ethics review committee of an Institute of Social and Behavioural Sciences reaches a decision, this decision is deemed valid for all other Dutch Institutes of Social and Behavioural Sciences. Thus, if a researcher moves from one institute to another and the research program moves with her/him, no additional review is necessary. Nevertheless, it is due diligence to report the continuation of the study and its ethics approval at the new workplace.

2. Whether single- or multi-center research, the responsibility for ethical review lies primarily with the principal investigator or penholder and the Institution he or she is affiliated with. In case of research projects executed in multiple Institutes of Social and Behavioural Sciences, it is deemed sufficient to perform the ethical review at a single Institute only.

Here the BETHCIE deviates: If the multicenter study concerns only Dutch centers, then ethical review at a single Dutch institute is considered sufficient. However, if the principal investigator of the multicenter study did not obtain his/her approval from a Dutch ethical board, then the participant employed by the VU Faculty of Science may seek local ethical approval from the BETHCIE.

3. For multi-center research, depending on the nature and context of the collaboration, ethical review for different parts of the research may be obtained separately from different Institutes (e.g. behavioural studies in one institute, and physiological studies in another).

4. If the research is primarily performed at an institution or location (including abroad) which is not an Institute of Social and Behavioural Sciences (henceforth "external organization"), the researcher should:

a. Demonstrate that the research is carried out with the demonstrable permission of the responsible authorities of the external organization in question, or explain why such permission is not possible or not desired.
b. Check the local ethical guidelines and procedures valid at that organization, and compare these against the National Code as specified here, and its implementation as specified by the home institute. In case of conflicting values, principles or procedures, the researcher should check with the Ethics Review Committee of the home institute.

5. In case a local scientific and ethics infrastructure is absent or deemed inadequate for evaluating the planned research, the researcher provides an assessment on how the research plan fits with or otherwise relates to the local values, customs and traditions of the participants, community or society concerned.

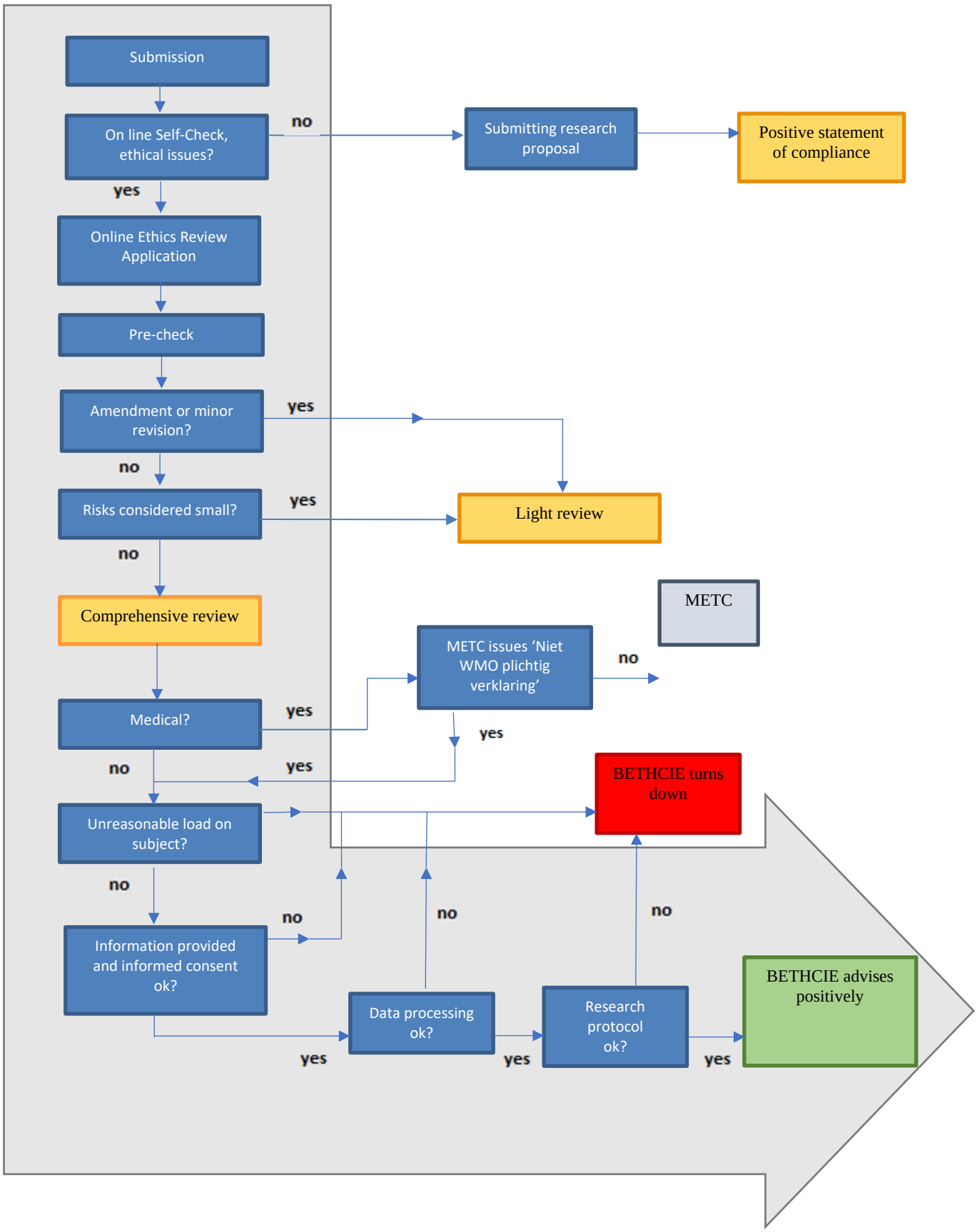
K. CONDUCT OF RESEARCHERS

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 analyze 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.

L. ASSESSMENT PROCEDURE AND CRITERIA



Step 1: Submission
The executive secretary will receive the submitted research plan by uploading the questionnaire at the VU webpage.

Step 2.1: On line 'Self-Check'
The online 'Self-Check' tells the researcher whether the research requires ethics review. If the 'Self-Check' concludes that the research does not require an ethics review, the researcher must submit the research proposal to the BETHCIE. After submitting the research proposal, the researcher will receive an email containing the Self-Check, together with a statement by the BETCHIE that the research complies with the guidelines of the VU Faculty of Science. The researcher can start with the research project.

Step 2.2: Online Ethical Review application form
If the 'Self-Check concludes ethical review is required, the researcher must apply for ethical review by the BETHCIE. Therefore, the researcher must submit the application form and upload the required documents: the information letter, the consent form and a data management plan.

Step 3: Pre-check and questionnaire
The secretary checks whether the answers to the control questions in the online questionnaire give reason to believe that comprehensive review is required. If not, a light review procedure is started. Otherwise, a comprehensive review procedure is started.

Step 4: Is this an amendment or minor revision?
In case of a small amendment to a previously approved research plan, or a minor revision, a light review by one member of the Board, often the chair, is sufficient. In case of a major revision, the revision is reviewed by the original BETHCIE reviewer(s) and the chair. A comprehensive amendment is at least reviewed by the chair and one member of the BETHCIE, unless comprehensive review is deemed necessary, in which case two members of the BETHCIE will review the amendment and the amendment will be discussed in the BETHCIE meeting.

Step 5: Small Risks
If the ethical issues are considered small, the research proposal will be submitted for a light review by the BETHCIE. The executive secretary will send the research proposal to one BETHCIE member. The member will give an advice and discuss this with the chairman. The chairman will directly present the advice to the researcher.

Step 6: Comprehensive review
A proposal is submitted to comprehensive review, if the answers to the online questionnaire give reason for this. The proposal is then reviewed by two members of the BETHCIE and discussed in the BETHCIE meeting. If, based on a light review, the BETHCIE member and the chair decide that the research proposal must be submitted for comprehensive review, the research proposal will be sent to a second BETHCIE member and the proposal will be discussed during the BETHCIE meeting.

Step 7: Is the research proposal medical in nature?
Researchers must submit their research plan to the METC when the research is subject to the provisions of the WMO. According to the CCMO (ccmo.nl), a study falls under the scope of the WMO if both the following conditions are met:
I. It concerns medical-clinical 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 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 ethics review committees about which types of research require review by the appropriate METC and which do not. In the meantime, the BETHCIE 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 or clinical in nature**. The study makes use of participants 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*[4]) *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 by a METC. fMRI measurements do currently require ethical review by a METC if they are carried out at VU University Amsterdam Medical Center (VUmc); the Spinoza Centre for Neuroimaging has its own review procedures.

Step 8. 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 9. 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 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.

[4] http://wetten.overheid.nl/BWBR0006251/HoofdstukIV/Article36/geldigheidsdatum_06-06-2014)

Step 10. 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 11. 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? The data management plan can be very complex and is thus not considered to be the responsibility of the BETHCIE. The BETHCIE may refer the researcher to the University Library to check the proposal on data-management issues.

Step 12. 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?