CODE OF ETHICS FOR RESEARCH
IN THE SOCIAL AND BEHAVIOURAL SCIENCES
INvolving human participants

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

Preamble

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

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

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

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

- Avoidance of exploitation;
- Just distribution of benefits and burden;
- Respect for persons:
  1. Participants are treated as autonomous agents;
  2. Participants with diminished autonomy are entitled to protection;
- Respect for human dignity;
- Scientific validity;
- Scientific, social and/or educational relevance;
- Respect for rights and specific interests of (specific groups of) research participants, and/or the community/society

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1 In its broadest sense, this also includes the humanities.
2 Some types of behavioural interventions and treatment programs are examples of research that could be considered to fall under the regimen of the WMO, and thus should be evaluated by an METC. According to the CCMO, it is to the local METC and the Ethics Review Committee to decide who is reviewing what.
These ethical principles may be operationalised by translating them into tools and procedures that can vary, depending on the field and context of the research.

For the researcher this means:

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

A. GENERAL.

1. All Institutes of Social and Behavioural Sciences at Dutch Universities should in principle comply with the guidelines below. If an Institute decides to divert from these guidelines, the Institute must be able to explain why this has been decided.

2. Research in the social and behavioural sciences involving human participants must be carried out in accordance with a tailored protocol.

3. Approval of the research protocol must be obtained from an ethics review committee established for that purpose either by the Institute where the research is conducted, or the body that carries the main responsibility for the research.

4. The review on ethical aspects shall be conducted with due regard to relevant international, European and national laws, rules (including grant or editorial rules) and guidelines, including local habits and customs in both the country of the researcher/applicant and the country where the research is to be conducted.

5. A positive review of the research protocol shall be obtained only if:
   a. It is reasonably plausible that the scientific research will lead to relevant insights in the field of the social and behavioural sciences.

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

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

5 Including research that is executed within the context of education with students as participants.
b. It is reasonably plausible that the insights, mentioned under a. cannot be gained by means or methods of scientific research other than research involving human participants, or by alternative means of research of a less intrusive nature.

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

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

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

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

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

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

i. The processing and storage of data is safe-guarded in accordance with the applicable laws and regulations.

j. The research meets any other requirements that can reasonably be set.

6. An ethical review committee may suspend or revoke a positive review of a research protocol if there are reasonable grounds to assume that continuation of the research would lead to the imposition of unacceptable difficulties or risks on the human participants involved.

**B. INFORMED CONSENT PROCESS**

1. During the process of obtaining informed consent from participants, the researcher(s) must provide information that is comprehensible for the target population, and made available beforehand as much as possible (so the subject can make a well thought decision) regarding the:
   a. voluntariness of participation;
   b. nature, purpose and duration of the research;
   c. procedures, including the expected duration and the extend of strain for participants;
   d. reasonably foreseeable factors that may be expected to influence participants’ willingness to participate, such as potential risks, discomfort, adverse effects and benefits;
   e. right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation;
   f. recording of voices and images, where applicable (see also H);
   g. confidentiality protection and limitations;
   h. procedures for incidental findings;
   i. applicable insurance guarantees (see also I);
   j. period of time to which the consent applies;
   k. re-use of specified data in the current, future or other research, where applicable;
   l. incentives for participation;
   m. names and details of the responsible researcher and contact person(s) for questions about the research and rights of research participants;
   n. participants should be informed on the fact that/told that data will be stored and encrypted for a certain period of time.
2. Participants, particularly children and vulnerable adults, including their legal representatives, must be given ample opportunity to understand the nature, purpose and anticipated consequences of research participation, so they are able to give informed consent to the extent to which they are capable to do so.

3. Researchers must keep adequate records of when, how and from whom informed consent was obtained, unless this could or proves to be detrimental to participants (see also C.) and/or where the formal registration of the informed consent has a negative effect on the execution of the study.

4. Supplemental informed consent (as circumstances indicate) must be obtained when research is conducted over an extended period of time, or when there is a significant change in the nature or focus of the research activities.

C. DATA PROTECTION AND PRIVACY

There are major risks relating to the disclosure of a person’s identity and insufficient protection of private information in social and behavioural sciences research. This, in turn, may lead to discrimination, stigmatisation or psychological discomfort or harm. Thus, considerable effort should be devoted to safeguarding participants’ privacy and the confidentiality of data processed in social sciences research. Furthermore, certain groups may be more vulnerable to harm from having information they provide linked to them (e.g. illegal immigrants, victims of home violence, prostitutes, people engaged in criminal activities and HIV-positive employees). In these cases, standard procedures for obtaining written informed consent may be more harmful to the participants than offering them protection and may, therefore, need to be replaced by other measures of protection including verbal informed consent.

D. DECEPTION

1. 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 where there is no alternative procedure for effectively collecting the data wanted.

2. Prospective participants may not be deceived about research that is reasonably expected to cause physical pain or severe emotional distress. Special consideration must also be given towards additional safeguards required for the preservation of participants’ welfare.

3. Any deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than by the time of the conclusion of the study data collection. Participants must also be informed that they have the right to withdraw their data without any negative consequences.

E. WITHHOLDING INFORMATION
Information for participants may be withheld from participants only when it is necessary to preserve the integrity of the research, or if it is shown to be in the public interest. In case information for participants has been withheld, participants will be provided information following their participation in such a manner and to such an extent that, to their judgment, the informed consent remains intact.

**F. RESEARCH IN PUBLIC DOMAIN**

Unless informed consent has been obtained, research based on observations of public behaviour must be restricted to situations where people being studied would reasonably expect to be observed by strangers. Research in public places must also consider local cultural values and the privacy of persons who, even when in a public space, may consider themselves unobserved.

**G. DEBRIEFING**

1. Appropriate information regarding the nature and aims of the research, other than that provided when obtaining informed consent, must be provided to the participants. Reasonable steps must be taken to correct any misconceptions participants may have that the researcher is aware of.

2. Reasonable measures must be taken to reduce the risk of harm when scientific/human interests or values justify delaying or withholding such information.

3. Reasonable steps must be taken to minimize and repair any harm, should researchers become aware that research procedures have proven detrimental to a participant.

**H. RECORDING VOICES AND IMAGES IN RESEARCH**

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

**I. INSURANCE**

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.

**J. RESEARCH IN OTHER COUNTRIES**
1. The research must comply with all relevant European and national legislation, and with due regard of all relevant accepted international standards.

2. The research projects must benefit all stakeholders, with an emphasis on benefits for research participants and their communities. Special initiatives to support local communities (e.g. benefits generated by the research) can help to achieve this goal.

3. If local resources are used, adequate compensation must be provided.

4. Potentially vulnerable populations must be able to provide genuine informed consent. This requires taking into account any potential cultural differences, economic and linguistic barriers and levels of education and illiteracy.

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

K. ETHICS COMMITTEE

1. The social and behavioural sciences ethics committee must consist of at least five members, to be appointed by the board of the Institute where the research is conducted. The ethics review committee acts as an advisory body to the board of the Institute.

2. In order to guarantee the independence of the ethics review committee, the committee must have at least one member who is not on the scientific staff of the Institute where the research is conducted. All other committee members must be tenured staff of the Institute.

3. The committee should preferably consist of one member who is an expert in ethics/philosophy, and one an expert in judicial matters, having preferably at least a Master of Law degree. The expertise of the other members of the committee must cover the major research lines of the Institute. The board may appoint substitutes for the expert members.

4. The board will appoint one of the members as committee chair; the board may also appoint a vice chair.

5. The board appoints an executive secretary to the ethics review committee. The executive secretary is responsible for all procedural aspects with due regard to the committee and its mission. The executive secretary may be a member of either the Institute’s academic staff or support staff, and could also cover the legal expertise as mentioned in ad 3.

6. The chair, vice chair (if appointed) and executive secretary constitute the executive board of the ethics review committee.

7. The ethics review committee may be extended (temporarily or permanently) by non-voting advisors.
8. The board of the Institute is responsible for the adequate instrumentation, administrative and financial support of the ethics review committee. This also applies to the proper recording of all ethical reviews performed by the committee.

9. The committee's working method and related procedures must be specified in a set of regulations.

I. COMPLAINTS PROCEDURES

1. The ethics review committees of the Institutes are advisory bodies established by the boards of those Institutes. Any negative advice issued by an ethics committee may be accepted or disregarded by said board. When a board issues a negative decision, an objection can be filed with the same board. An appeal can be lodged against such a decision in accordance with the ’s university’s regulations.

2. Each ethics review committee has adopted a publicly available procedure regarding complaints from participants regarding/on all aspects of being included or excluded in a study that has been reviewed by the said committee.

M. GENERALIZED VALIDITY OF THE ETHICS ADVICE

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

2. In case of research projects executed in multiple Institutes of Social and Behavioural Sciences, it is deemed sufficient to perform the ethical review by a single ethics committee only.