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Aan de besturen van de Sociaalwetenschappelijke
faculteiten



Ons kenmerk	Uw kenmerk	Telefoon	Datum
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Betreft		E-mail	
landelijke Code ethische toetsing onderzoek		bureau@socsci.ru.nl	

Geacht bestuur,

Op instigatie van het Discipline overleg Sociale Wetenschappen, DSW, heeft een werkgroep van deskundigen zich bezig gehouden met de landelijke harmonisatie van de regelingen betreffende ethische toetsing van sociaalwetenschappelijk onderzoek. De werkgroep heeft een Code opgesteld die recent door het DSW is vastgesteld.

De Code is geen strak keurslijf maar geeft een richting aan en moet beschouwd worden als work in progress. In dat licht zal de werkgroep gevraagd worden om in het vervoltraject aandacht te schenken aan een nadere regeling van de ethische toetsing van maatschappijwetenschappelijk onderzoek.

Bijgaand treft u achtergrondinformatie aan over nut en noodzaak van de ethische toetsing en vervolgens de Code zelf.

Namens het Disciplineoverleg Sociale Wetenschappen

Met vriendelijke groet,

prof. dr. D.H.J. Wigboldus
voorzitter

mr. A.I.M. van Berkum
secretaris

bijlage: twee

Memo'

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

General

In two meetings of chairs/members and secretaries of the Ethical Review Committees of the Social and Behavioural Sciences of the Netherlands universities, held in 2013 and 2014, and initiated by DSW (*"Disciplineorgaan Sociale Wetenschappen"*) a strong urge was expressed to draw up specific guidelines for the review of human related research in the Social and Behavioural Sciences. These guidelines should be in accordance with national, European and international rules, with the aim of attaining/in order to attain a clearer demarcation of the competences required for reviewing the ethical aspects of research in the social and behavioural sciences involving human participants. Basic principles of ethical review, as mentioned in a report of a dedicated working group of the EU, will form the backbone of a Code of Ethical Review of Research of the Social and Behavioural Sciences involving human participants.

In its third meeting of 22 May 2015 the national working group has adopted the attached draft Code. DSW is now asked to agree on the current version. Upon acceptance of the Code as leading for the ethical review procedures of their respective faculties, DSW is requested to send it to all relevant parties, e.g. VSNU, OC&W, VWS and professional organisations such as NIP. CCMO and NVMETC (*Nederlandse Vereniging van METC's*) should be informed, too.

The working group also became aware of a recent article in 'De Psycholoog' (Cecile Brekelmans et al. May 2015) in which it has been suggested to extend the current WMO for medical-scientific research to all research involving human participants. This should lead to the establishment of separate review committees for behavioural and social research apart from the METC's: the GETC's (*Gedragwetenschappelijke ethische toetsingscommissies*). Thereupon, GETC's should receive a formal judicial status, with equivalent procedures for acknowledgment, reviewing and control. The working group concluded in its meeting of 22nd of May to proceed with the current route, i.e. the creation of a specific code for the social & behavioural sciences (and humanities, where relevant), eventually to be followed by inclusion in the legal system.

Why is independent ethics review necessary?

Studies involving human participants are customary in the Social and Behavioural Sciences, but until now the ethical review of research is not regulated for all disciplines and if it is, not above institutional level. The participation of human participants by itself justifies ethical review. Also, peer

¹ Main authors: Marcel Schrijnemaekers L.L.M and Rense Hoekstra MSc; Faculty of Psychology & Neuroscience, Maastricht University.

reviewed and other research publications as well as funding organizations such as the European Union require an ethical review before publication and funding are granted.

Until now, the review of research in the social and behavioural sciences involving human participants has been viewed mainly in terms of the Medical Research Involving Human Participants Act ("*Wet medisch-wetenschappelijk onderzoek met mensen*", WMO act). This holds (true) in particular for research in the behavioural sciences that shows an overlap with bio-medical research, in which case it is sometimes necessary to determine for each specific study whether the WMO act is applicable. Yet the WMO is often used, too, as a reference point for the ethical review of research in the social sciences that clearly does not come under the WMO act. Evidently, the WMO act provides far-reaching protection for research participants. In this memo the view is held that, in the ethical review of social science research, the WMO act is a legal requirement to be met where applicable. However, the act and its resulting requirements do not form guidelines to be followed in a blanket manner for the review of non- WMO-liable research. In other words, research involving human participants that does not evidently come under the WMO act can be reviewed independently in terms of its ethical aspects by the various disciplines in the social and behavioural sciences, without there being any existing legal frameworks (as yet) for this review.

WMO act - article 1, paragraph 1(b): scientific research: medical science research that involves subjecting people to certain acts or compels them to show certain behaviours.

It follows from the above that the distinguishing element in the review of WMO-liable research is whether or not the research can be defined as *medical* research.

Definition of the Central Committee on Research Involving Human Participants: 'Medical research is research that aims to answer a question in the field of disease and health (aetiology, pathogenesis, indications/symptoms, diagnosis, prevention, outcome or treatment of disease), by means of the systematic acquisition of knowledge that is also valid for populations beyond the direct test population' (Central Committee on Research Involving Human Participants, Annual Report 2006).

This definition is elaborated in the recommendation entitled 'Psychological research and the WMO' given to the CCMO² on 6 March 2008, which runs as follows: "the WMO act applies if the research centres on a question about disease and/or health that relates to disease, or if it focuses on patients (i.e. people receiving medical treatment)." If, on these grounds, the research is not considered WMO-liable, the issue of whether certain acts or behaviours are imposed on the research participants is no longer relevant whether or not the WMO-act is applicable.

The committee for 'behavioural science research' concludes that research that comes under the WMO act is, in principle, limited to research that centres on medical research questions (directly related to medical treatment or therapy). Consequently, the nature of the research question is the main indicator of whether or not the research is WMO-liable.

The directive for answering the question of why independent ethics review of social science research is necessary can be found in the 'Guidance Note for Researchers and Evaluators of Social Sciences

² Advisory Committee established by the CCMO

and Humanities Research 2010' of the European Commission. In this document, the findings and advice collected during an expert meeting ordered by the European Commission are specified.³

The expert meeting was convened after a lack of awareness was found among researchers on how to deal with the ethical aspects of research in the Social Sciences and Humanities (SSH), and in view of the fact that the European Commission has made ethical review an integral component of the evaluation procedure for research proposals submitted for funding. In addition to addressing the importance of ethics review and its necessary components, this document also discusses the differences between SSH research and medical and biomedical research. The latter in particular is important for the method of review.

In the Guidance Note it is observed that the current and widely-used guidelines for ethics review of scientific research are focused mainly on medical and bio-medical research. Some have argued that adopting these guidelines in the same way could potentially harm rather than protect participants in SSH research; some even suggest that research of significant social relevance should be discontinued if it applies medical and/or bio-medical guidelines incorrectly.

Ethical aspects in SSH research

The ethical aspects concerning SSH research involving human participants are as diverse as the range of disciplines and fields it constitutes. The term SSH refers to the study of behavioural, cultural and social phenomena etc. (*condition humaine* in the humanities for pure analysis and in the social sciences with interventions).

The methodological approaches in these studies include questionnaires (i.e. surveys and interviews), focus groups, direct observation, physiological manipulations and recordings, standardised tests, descriptive methods, laboratory and field experiments, economic analyses, statistical modelling, ethnography and evaluation. In some SSH disciplines, in particular behavioural studies, minimal physical interventions are also used, such as taking (minor) blood samples. As contemporary research is becoming increasingly interdisciplinary, it is impossible to draw a strict line between SSH research and other types of research. This makes it difficult to devise clear ethical guidelines that can be applied to all forms of research. However, according to the Guidance Note⁴, the following basic principles and values invariably apply to all of the research disciplines,:

- avoidance of exploitation;
- just distribution of benefits and burden;
- respect for persons;
- respect for human dignity;
- scientific validity;
- scientific and social relevance;
- respect for the rights and interests of research participants.

³ http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf

⁴ NB: this also concerns communities and societies at risk.

These values may be operationalised by translating them into procedures and tools that may vary, depending on the field and (even the) context of the research.

These procedures and tools (e.g. informed consent, data protection and privacy, and the impact of research results) form the basis for the EU ethical review procedure for research proposals submitted for funding.

Legal status of the Code of Ethics

The Code as proposed here has as yet no formal legal status. Given the absence of adequate judicial coverage of ethical review for non-medical research, the fields of Social Sciences and Humanities are developing their own code, as a self-organising action. It is up to the field itself, as well as the relevant Ministries, to promote a legal funding of the current or adjusted Code.

Future Developments

Apart from acquiring a legal status, the Code will be developed and updated based on annual meetings of the Ethical Committees of all Dutch Social Sciences faculties. As an example, the Free University of Amsterdam's committee is currently developing additional guidelines for research projects including participants younger than 18 years. Discussing the results of those types of projects is expected to lead to a further refinement of the current Code in the forthcoming years.

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.¹ This requires an independent guideline for ethical review of research involving human participants, taking the existing diversity into account.

This diversity not only concerns the broad spectrum that constitutes the social and behavioural sciences, but also the research methods applied. Methods comprise surveys and interviews, focus groups, direct observation, physiological manipulation and recordings, standardised tests, descriptive methods, economic analyses, statistical modelling, ethnography and evaluation. In some disciplinary branches of the social sciences, in particular in psychology, minimal physical interventions are also used². 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

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 Institutes³ 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.⁴
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.⁵

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.

L. 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.

