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 mei 2018

Opmerkingen bij de herziene versie

In januari 2016 hebben de decanen verenigd in het Disciplineoverleg Sociale Wetenschappen (DSW) de Code of Ethics for Research in the Social and Behavioural Sciences Involving Human Participants vastgesteld. De Code is opgesteld door een landelijke werkgroep met als doel de ethische toetsing binnen de sociale en gedragswetenschappen te harmoniseren en versterken.

Zowel het opstellen als het implementeren van de Code kan als een succes beschouwd worden. Er wordt goed samengewerkt, informatie uitgewisseld, en hoewel er lokale verschillen zijn in de uitleg en implementatie van de Code, zijn deze verschillen doorgaans klein en is men het eens over onderliggende principes. Niettemin kwamen al snel geluiden dat de Code niet goed aansluit bij bepaalde onderzoeksvelden binnen de sociale wetenschappen, met name de sociologie en antropologie. Het initiatief voor de landelijke code kwam oorspronkelijk vanuit de hoek van de psychologie, een veld met een wat langere traditie van relatief expliciet en nauw omschreven toetsen, op basis van toetsingskaders die veelal geschoeid waren op biomedische leest. Zulke toetsingskaders gaan uit van duidelijk vooraf omschreven onderzoeksprotocollen, waarop individuele deelnemers geïnformeerde toestemming tot deelname geven. Dit is minder goed werkbaar gebleken voor onderzoeksvelden die te maken hebben met gemeenschappen in plaats van enkel individuen, met verschillende landen, autoriteiten en culturen, en methoden zoals participerende observatie. Deze nieuwe versie poogt beter aan te sluiten bij deze onderzoeksvelden, zonder doel en strekking van de oorspronkelijke code te verliezen.

Uitgangspunten:

- Er zijn gezamenlijke principes te formuleren over alle betrokken onderzoeksvelden. Bijvoorbeeld, waar de autonomie van het individu binnen de psychologie veelal buiten kijf staat, ziet men binnen de sociologie en culturele antropologie het individu als ingebed in een gemeenschap, hetgeen mede gevolgen heeft voor het begrip autonomie. Het oorspronkelijk geformuleerde principe om mensen louter als “autonomous agents” te beschouwen kan dan beter vervangen worden door het algemenere principe van respect voor het individu en de gemeenschap waarvan hij of zij deel uit maakt.
- Er is behoefte aan een duidelijk kader. In de sociologie en antropologie is men minder gewend aan expliciet geformuleerde toetsingskaders en -procedures. Veel is impliciet, of wordt middels participatie en onderlinge reflectie expliciet gemaakt. Dit is daarmee niet verkeerd en kan in veel gevallen zelfs de voorkeur hebben. Niettemin is er ook binnen deze velden een tendens om beter duidelijk te maken welke uitgangspunten gelden en hoe ethisch handelen bewaakt wordt – al dan niet gedwongen of aangespoord door externe partijen zoals wetenschappelijke tijdschriften, subsidievertrekkers, en beleidsmakers. Het helder formuleren van de uitgangspunten helpt hierbij. De implementatie van deze uitgangspunten kan per onderzoeksveld anders ingericht worden.
- Hiermee komen we op het laatste punt. We moeten waken voor de natuurlijke reflex om de Code te zien als nog meer regelgeving, als absolute regels waarvan niet afgeweken kan worden. Een van de principes van de Code is “pas toe of leg uit”. Dit betekent dat standaard uitgegaan wordt van de waarden, principes en procedures zoals die in de code geformuleerd worden – echter dat men in bepaalde gevallen kan afwijken als dit op ethische gronden beter te verdedigen is.

Tenslotte is van de gelegenheid gebruik gemaakt om bestaande punten te verhelderen, te hergroeperen en redundanties te verwijderen. Er is ook een werkversie beschikbaar waarin de oude en de nieuwe code naast elkaar staan met de belangrijkste wijzigingen toegelicht.

Preamble

The Code of Ethics for the Social and Behavioural Sciences provides guidelines for research in the social and behavioural sciences involving human participants. It intends to support researchers and ethical review boards in their ethical reflection. The Code of Ethics is subscribed to by all academic institutes that fall under the Deans of Social Sciences as united in the DSW (*Disciplineoverleg Sociale Wetenschappen*). Other institutes or research groups may also decide to comply with the code.

Research in the social and behavioural sciences is diverse in its nature and execution, and in many respects it differs greatly from biomedical research, leading to limited applicability of the Medical Research Involving Human Participants Act (*Wet medisch-wetenschappelijk onderzoek met mensen*, WMO). Thus an independent guideline for ethical review of research involving human participants is required, taking this diversity into account. The diversity not only concerns the broad spectrum that constitutes the social and behavioural sciences, but also the wide range of research methods applied, from surveys to participant observation, and from minimal physical interventions to ethnography.

Apply or Explain

The Code of Ethics for the Social and Behavioural Sciences does not intend to dictate the same specific measures and procedures for 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 not 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*.

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.
- 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 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

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.

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

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 organisation.

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

Board: The board of the Institute, typically the Dean plus the Directors of Research and Director of Education.

Research plan: A document addressing the rationale, background, objective(s), methodology, 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.

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.

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

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.

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

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. Positive review of a research plan 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.

5. 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.

6. 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.

7. 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. 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.

9. 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.

10. 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.

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.

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;
    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;

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 where 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 where 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 counts 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.

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.

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.

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.

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 stigmatised, discriminated against, prosecuted, or met with violence. For example, protecting someone's privacy may have implications for the way informed consent is being registered.

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. A social and behavioural sciences 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.

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 additional expertise.

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 organisations at other institutes may be invoked for this purpose.

12. The Ethics Review Committee must have structural (i.e. organised) access to both ethical and legal expertise.

13. The Ethics Review Committee may be extended (temporarily or permanently) by non-voting advisors.

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

I. COMPLAINTS PROCEDURE

1. Objections against an Ethics Review Committee's advice, or against an Institute Board's decision can be filed with the 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.

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.

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 organisation”), the researcher should:

    a. Demonstrate that the research is carried out with the demonstrable permission of the responsible authorities of the external organisation in question, or explain why such permission is not possible or not desired.

    b. Check the local ethical guidelines and procedures valid at that organisation, 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.