

Memo¹

**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

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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.