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Does Germany need a (new) research ethics for the social sciences?

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Claudia Oellers, Eva Wegner

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Does Germany Need a (New) Research Ethics for the Social Sciences?

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Abstract

This paper evaluates the German, UK, and US approaches to dealing with research

ethics in the social sciences. It focuses 1) on the extent to which these research

ethic frameworks protect the key rights of research subjects and 2) the extent to to

which they take into account the methodology and approaches used in social

science and do not simply emulate those of the natural sciences.

The U.S. approach stands for a highly regulated, and partly bureaucratic, approach

where the ethics review is modeled on the methodology of natural sciences. In the

UK, in contrast, a social science research ethics framework has been developed that

remedies some of these shortcomings. It is implemented through pressure from

funding institutions and aims to respond to the needs of social science research.

The German social science ethics framework consists of non-binding codes of

conduct, guidelines about good scientific practice, and ethic codes of the German

professional associations and funding institutions. We find that ethical behavior in

Germany is most typically understood as ethical behavior towards the peers. We

recommend the establishment of a new research ethics framework for the social

sciences in Germany modeled on the UK's.

Keywords: research ethics, good scientific practice, institutional review boards

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1. Introduction

Several recent papers address the need for a rethinking of research ethics in social sciences (see, for instance, Lane 2009, Weber 2009). Typically, two reasons are especially emphasized. First, new forms of collaboration of social scientists with researchers in other fields, judged ethically more sensitive, especially biomedical research. Research that looks, for instance, at the behavioral consequences of genetic configurations can easily confront social scientists with new ethical problems. Secondly, because of technological progress that allows for a large amounts of data to be exchanged through or to be freely accessible in the internet. Data that are either available from agencies or that citizens expose themselves, for instance, on their websites or in forums, would create new possibilities of data matching. This would produce new challenges for an obvious key principle of research ethics, the anonymity of research subjects. Indeed, these two developments are among the key motivations that gave rise to a new research ethic framework of the UK Economic and Social Research Council (see ESRC 2005).

These developments are certainly important and invite to rethink and revise research ethics in the social sciences. At the same time, an exclusive focus on new developments may bury the fact that existing social science research ethics framework may already be inadequate for "standard" empirical work in the social sciences. Our paper thus evaluates different ways of dealing with research ethics, focusing on two questions that must be at the core of any discussion and revision of social science research ethics. First, to what extent does a research ethic framework protect the key rights of research subjects, such as information and anonymity? Second, to what extent is that framework appropriate for social science research? That is, is it simply modeled on the natural sciences or does is respond to the different methodology/approaches used in social science?

We look first at the German social science ethics framework, essentially one of non-binding codes of conduct, guidelines about good scientific practice, and ethic codes of the German professional associations and funding institutions. We find that ethical behavior is most typically understood as ethical behavior towards the peers. Second, we discuss the U.S.-American and British approaches to research ethics in the social sciences.

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It is also contested whether these new trends do indeed constitute new challenges for social science. Greely (2008) for instance, argues that although many feel differently about it, the data commonly used in the social sciences is not less sensitive than information about health issues.

The U.S. approach stands for a highly regulated, and partly bureaucratic, approach where the ethics review is modeled on the methodology of natural sciences. The mentioned new framework used in the UK, in contrast, stands for a reformist approach that is implemented through pressure from funding institutions and aims to respond to the needs of social science research. Finally, we address the question whether any of these could serve as a role model for German social science.

2. Research Ethics' Infrastructure in Germany

In Germany, ethical requirements for research vary strongly across research fields. Requirements are high and legally binding in medical/ biomedical research and low in the social sciences where the only legal standard to comply with is the Data Protection Act (see Schaar 2009).

Similar to other countries, ethical questions have always been more prominent in natural sciences in Germany. In the early 1970s some universities already established research ethics committees (RECs). In 1979 the German Medical Association following an initiative of the German Research Foundation, recommended the introduction of RECs. For clinical trials, the approval by (RECs) became compulsory in 1994, following the Medicinal Product Act (MPG) and the 5th amendment to the Drugs Act (AMG). In 2004 a further amendment was enacted which implemented the good clinical practice directive of the EU (2001/20/EC). As a result, a majority of German medical faculties and medical research institutes do now possess RECs.²

For the social sciences there is no comparable legal regulation for approval of research through a research ethics committee. No important funding institution or state agency has made it its mission or a priority to further, or address systematically such standards in the social sciences. The only legal requirement to take into account in social sciences is the federal data protection. This law addresses issues of consent, data gathering, storage and processing for all kinds of research. It elaborates some general standards for data related issues in scientific research, such as the duty to anonymize information.³

Its rather within a framework of professional self-regulation by professional associations of sociologists or psychologists that ethic questions are addressed in the social science. These

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² The tendency to consider ethical issues more important in biomedical research than in social sciences is also shown in the work of the National Ethics Council, established by the Federal Government in 2001(since 2007 German Ethics Council). The council has published reports and recommendations on several topics, but most of them concern the field of biomedical research.

For more details on legal requirements regarding data protection, see Schaar 2009.

professional associations have created ethic committees and established ethic codes. For example, the joint ethic code of the two professional associations of sociologists, *Deutsche Gesellschaft für Soziologie* and *Berufsverband Deutscher Soziologen* dates back to 1992. It addresses ethical standards in research – integrity and objectivity as well as the protection of the research subjects – and in the relationship among academics, such as for instance, the duty of referees to state conflicts of interest. These two professional associations have Law on Statistics for Federal Purposes established a join ethics committee to which complaints on misconduct in all the areas covered by the ethics code can be brought. This ethics committee is supposed to help finding consensual solutions but it also has the prerogative to suggest sanctions, such as the temporary exclusion of a member or her full expulsion.

While this ethics committee may advice the professional associations on ethical questions, it is in no way involved with approving research projects from an ethical point of view. Such ethical evaluations are done, for instance, by the professional association of the German psychologists, the Deutsche Gesellschaft für Psychologie (DGPs). Its ethic committee evaluates applications for which a funding institution has required a review. In this case, and for a fee, the ethic committee evaluates whether the goals and procedures of the project comply with ethical standards. A few social science departments in Germany, for example, of the universities of Mannheim and Jena have also established local ethic committees on their own initiative that review research projects of faculty members.

More general standards are defined by the guidelines about good scientific practice, established by the Deutsche Forschungsgemeinschaft (DFG), after a series of misconduct in research in 1997 (see DFG 1997). These guidelines encompass all fields of scientific research and focus strongly on questions of ethical behaviour among researchers. The DFG recommended that universities establish their own guidelines on the basis of the DFG guidelines, and, in 1998, it decided that research institutions receiving funding from the DFG had to establish rules securing good scientific practice. In 1999, the DFG also created an institution – an ombudsmen-committee – to investigate cases of scientific misconduct and to monitor the implementation of the guidelines.

After more than ten years, it seems fair to say that the guidelines have remained relatively inconsequential for promoting good scientific practice in research and teaching. Indeed, the reports of the ombudsmen themselves lament that there is little awareness regarding good practice and misconduct.

Although German universities soon adopted either the DFG's rules or elaborated their own, they have made little effort to promote them. By and large researchers are unaware of the existence of these rules. This unawareness of researchers and the sorry efforts of universities to promote the rules was already pointed out by the DFG in 2001 and, according to the latest report in 2008, little progress has been made since. This report suggests that the awareness of good scientific practice could be increased via implementing another principle of the original guidelines (rule n°2), namely making these issues regarding good scientific conduct a standard item in teaching and training of junior researchers. Given that this suggestion has been largely ignored in the last ten years, it remains dubious, however, whether this suggestion will have much effect.

In the implementation of the guidelines, there has been an almost exclusive focus on conflicts in the scientific community. The statistics published by the ombudsmen show that the vast majority of cases concern conflicts between scientists concerning authorship or university appointments. Most cases concerned authorship and plagiarism (48/162 accepted cases), followed by those concerning ownership of research equipment and of data (35/162) and those concerning the hindering of research (27/162).⁵ The committee's dedication to conflicts among the scientific community and the absence of cases concerning the rights of research subjects follows logically from the structure and procedures of the committee. Because it does not initiate investigations, it is naturally left with those cases where colleagues accuse their peers and typically, this will concern issues where one's academic career is hindered by the other. Indeed, in Germany, good practice appears to cover almost exclusively the rights of researchers and how they are treated by their community. Good scientific conduct is one of scientific honesty towards one's colleagues, not towards the research subjects. In short, it is unlikely that such voluntary rules that give priority to "selfmonitoring" are sufficient to promote research ethics in social sciences empirical research and teaching.

3. Social Science Research Ethics in the United States and Britain

3.1 US: the legal approach

In the U.S., federal regulations proscribe ethical standards for research involving human subjects since the early 1970s, if that research is conducted at federal institutions or is funded

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⁴ According to the second report of the ombudsmen-committee from June 2001, 58% of German universities had adopted such rules.

⁵ These statistics are from the first six years of the committee's work. They, as well as yearly reports can be found at http://www1.uni-hamburg.de/dfg_ombud/. Given that researchers seem to appeal to the DFG ombudsmen rather to those of their own institutions (seen as too partial), the statistics published by the DFG are of some generality.

by federal agencies (National Research Act 1974).

The National Research Act, on which current rules are built, was a reaction to abuses in human subjects' research.⁶ It led to the establishment of the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* which had two main tasks. First, to identify the basic ethical principles that should underlie the conduct of biomedical and behavioural research involving human subjects, and, second, to develop guidelines assuring that such research was conducted in accordance with those principles. In 1978, the Commission established the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" better known as the Belmont Report.

Important parts of the Belmont Report were included in the current legal framework for ethical research, the Code of Federal Regulations (CFR) Title 45 part 46 (Code of Federal Regulations Governing the Protection of Human Subjects in Research). This framework was enacted by the U.S. Department of Health and Human Services (HHS) -specifically its Office for Human Research Protections (OHRP) in 1991. It contains requirements for assuring compliance by research institutions,⁷ for researchers obtaining and documenting informed consent, and for ethics review committees' (Institutional Review Board (IRB)) membership, function, operations, review of research, and record keeping.

In 1991, 17 other Federal Agencies and Departments also adopted a uniform set of rules for the protection of human subjects, almost identical to 45 CFR part 46 (Subpart A).⁸ This joint agreement on the regulations is named the Federal Policy for Protection of Human Subjects, better known as the "Common Rule".

The Common Rule is based on three fundamental principles for ethical research:

- Respect for a persons' autonomy: the researcher has to give adequate and comprehensive information about the research project and on possible risks
- Beneficence: research has to maximise benefits for society and minimize risks for research subjects
- Justice: research must not exploit or ignore one group in order to benefit another group

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One of the most infamous cases of ethical misconduct of research is the Tuskegee Syphilis Study a longitudinal project conducted between 1932 and 1972 by the US Public Health Service on poor, illiterate black men in rural Alabama. During this study 28 participants died.

Institutions normally agree upon an assurance with the appropriate federal agency that funds their research. Most universities have an assurance with the HHS.

⁸ Further subparts of the CFR 45 part 46) are rules for research on foetuses, neonates, and pregnant women (Subpart B); rules for research with prisoners (Subpart C) and rules regarding research involving children (Subpart D).

Based on these principles, there are three core criteria for evaluating human subjects research: informed consent, risk-benefit assessment, and equitability of subject selection. Institutional Review Boards (IRBs) are the instrument approving whether research is following these criteria. Most large universities and hospitals conducting research have established their own IRBs.

There are three different types of IRBs (Parvizi et al 2007): (a) local IRBs that are affiliated with the institution or organization conducting research, (b) central IRBs that deal with large scale multi-site research, and (c) commercial IRBs paid to review research with human subjects. In the last decades the impact of IRBs on the research infrastructure has increased enormously. Indications of this development are the increasing number of IRBs and the increase in their power (see Bledsoe et al. 2007). Although universities in the US are generally confronted with numerous regulations and bureaucracies, the IRB system is the only one that has the direct power to stop, delay, or change the character of research (ibid).

At first glance it seems that the regulation of ethical research standards through the IRBs is an appropriate model not only to ensure the protection of the research subject but also to bring binding ethical standards to social sciences. The IRB's practice regarding the approval of research projects in the social sciences is, however, by no means undisputed. More precisely, IRBs have been criticized along three lines.

First, IRBs have especially become subject to criticism because of their inappropriateness for social science. Their composition and their requirements privilege research methods similar to the natural sciences. Indeed, the Common Rule regulations and the Belmont principles were elaborated with biomedical and laboratory science methods in mind. As Milne (2005) emphasizes, the type of research documentation to be brought to the IRB, such as, for instance the informed consent protocols, asks for objectivity, prediction, and control rather than description, interpretation, and discovery. In this approach, there seems to be little room for qualitative forms of data collection and research. This general critique holds in spite of some noteworthy exemptions from full IRB review for research that is particularly relevant to social science research. Such exemptions apply, for instance, to research about educational practices or research involving the collection or study of existing data if publicly available or unidentifiable.¹⁰

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⁹ Commercial IRBs have become more common in the last years. The responsibilities of these IRBs as profit-organizations are identical to those based at academic or medical institutions and they are governed by the same federal regulations.

¹⁰ For more detailed information, see NSF "What exemptions of the Common Rule are most appropriate to social science research?" (http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp)

Secondly, the research reviews have been criticized for their strong bent towards legal issues. As the process of research review focusses heavily on producing a legally valid written consent form, Bledsoe et al (2007: 631) argue that the main goals of reviews appears to be not so much to protect the research subjects but rather to deflect as much risk as possible from the institution. Being a legal contract between the investigator and the university, the IRB protocol is an instrument to place as much legal responsibility on the investigator by defining as many risks as possible that have to be considered prior to research. In other words universities turn to delegating legal risk to their faculty members.

Finally, ethic reviews have suffered an externalization and professionalization of ethical problems from the point of view of the researchers. Faced with extensive IRB protocols, researchers just tend to do their paperwork in the required manner, rather than thinking about the ethical issues related to their work.

3.2 United Kingdom: the reformist approach

Since 2006, explicit guidelines of the *Economic and Social Research Council* (ESRC), the main sponsor of social science research in the UK, force universities seeking funding from it to consider ethical issues in research and teaching alike. These guidelines seek to establish rules suitable for social sciences, stating that extant guidelines, such as for medical research, may not be appropriate for the social sciences with its diverse methodology. They also aim to respond to new challenges in social sciences research ethics arising, among others, from interdisciplinary research, globalization, and technological change (see ESRC 2005).

This *Research Ethics Framework* (REF) is the result of consultations with the UK social science community, including other funding institutions and professional associations. The resulting six key principles of ethical research require (1) that research should be designed, reviewed and undertaken to ensure integrity and quality, (2) that research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research and its risks, (3) confidentiality of information and anonymity of respondents, (4) voluntary participation, (5) avoiding harm to research participants, and (6) research independence and explicitness of conflicts of interest or partiality. It is noteworthy that four of these key principles deal with the protection of the research subjects (and not with misconduct amongst peers).

The implementation of ethical standards is delegated to universities or research institutes. Ensuring research ethics goes beyond a particular research project for which a research institution seeks funding. Indeed, only those institutions that have put in place mechanisms

and procedures to ensure minimal ethical standards can apply for funding at ESRC.

Although the ESRC does not impose a particular model to ensure ethical standards, it stipulates that minimal mechanisms include most importantly a Research Ethics Committee (REC)), which looks at ethical issues in research applications as well as it monitors the implementation of the project. Moreover, any application to the ESRC has to explain if and why it needs a review from the RECs. The reviewers from the ESRC, have to comment on these ethical self-assessment in the proposal and may reject a proposal or give a conditional award only. Additional "incentives" to ensure ethical standards in social science research are provided by the possible loss of funding by the ESRC, even if, other, non ESRC funded projects, breach ethical standards in a research institution.

Among the minimal standards are, however, not only research ethics in the actual research process but in training. At the very least, social science postgraduate training programs have incorporate the range of issues addressed in the REF. It also requires the development over time of minimum standards of training and competence in ethical issues. According to the REF, such minimum training requirements are likely to include: training for individual researcher, training for members of local and institution-wide RECs, training for postgraduate students in local ethics review requirements - in addition to more general ethics training-, as well as training for undergraduate students whose projects may require ethics review (see ESRC 2005, 16).

As a – compared to the US – very recent framework, the REF is probably more suitable to serve as a model for research ethics in the social science for four main reasons. First, because securing research ethics is delegated to research institutions (although it is monitored by the ESRC). This decentralized approach could be suitable for Germany because it would respect the independence of universities. Second, because the REF seeks to decrease delays and unnecessary efforts: The evaluation and approval of the REC is not necessary for the actual application, but only at the beginning of the project. Third, because REF does not only create negative incentives and but introduces ethical issues into training. The purpose appears to be not to simply create a lengthy procedure to be complied with on one's way to obtaining funding but to contribute to a research culture where ethicals issues are viewed as an important part of research and training. Fourth, because the REF recognizes explicitly that qualitative methodology may require a different type of ethical review than quantitative methodology.¹²

¹¹ Members of the RECs need to be trained to deal with ethical issues and have to be compensated for their work. It is left open if social science sub-RECs are to be created or if ethical issues in social science research are to be treated by the general RECs.

¹² On the negative side are obviously the costs for research institutions as they need to create new bodies – the RECs – and compensate its

4. Discussion

The three discussed ethics frameworks for the social sciences vary strongly regarding both our two key criteria – protection of research subjects and appropriateness for the social sciences – and various important sub-issues, such as the degree of bindingness, the locus of implementation, and the weight they give to awareness raising in the training of researchers.

Obviously, the German approach is the most underdeveloped one. Ethic principles are strongly considered in (bio)medical research but this has not been extended to social sciences. Those guidelines that address the whole scientific community in Germany, such as the DFG guidelines on good scientific practice focus almost exclusively on ethical behavior among peers not on the protection of research subjects. Providing few constraints, they have moreover received little promotion inside the universities. Ethic codes of professional associations do include sections on the protection of research subjects. No ethic reviews of research projects protect, however, the rights of research subjects *ex ante* and their ethic committees as well as the DFG ombudsmen are, structurally, unlikely to be summoned by research subjects *ex post*.

The US approach, in contrast, with the requirement to have projects approved by IRBs, is highly protective of research subjects in the natural and social sciences alike. At the same time, the framework lacks consideration of methods specific to the social sciences which make especially informed consent more complicated to implement. As a result of the IRBs origin in and membership bent towards natural sciences, US social science research tends to lean towards "standard methods" in order to receive IRB approval. In this way, research ethics has a strong, and not only beneficial effect on the content of social science research. The high level of bureaucratic work involved to get IRB approval makes data gathering moreover cumbersome and is therefore only encouraged at the post-graduate level.

The UK approach seeks to strike a balance. Given that the largest social science funding institution makes ethic reviews and ethic committees a requirement, it given considerably more protection to the research subjects than the German system. Being designed for social science research, it is also much more open towards qualitative methodology than the US approach. Requiring ethic review only for approved research projects, it is also less a less lengthy procedure than the latter even if it requires researchers to think about ethical issues – i.e. the type of necessary review – when designing their project. Of the three approaches, it is also the one stressing most energetically the need to raise the awareness for ethical principles

during training.

5. Recommendations

Research ethics is about social responsibility and thus goes beyond legal regulations. An ethics framework should thus give priority to raising awareness for ethical principles in research. This means that research ethics, and, importantly, to learn to think about the ethical dimension of their work should be an integral part of the training of researchers. Germany would benefit from a new research ethics framework for the social sciences. This framework should focus on protecting the rights of the research subjects and encompass data access, data gathering, and data processing, but should make it a priority to accommodate social science methods. It could be enforced by being mandatory for funding – alike the UK approach. The US example shows that legal requirements may create to many bureaucratic hurdles for research as well as having an undesired streamlining effect on its content.

This ethics framework could be modeled on the UK's but should be elaborated in consultation with the relevant professional associations, the key funding institutions, and universities and independent research institutions in Germany. It should be reviewed upon request, following methodological innovations.

A German research ethics framework should give the responsibility for implementation to the universities. Independent research institutes should cooperate with the universities. To the present, social science departments have neglected these in training and research practice. "Local" ethics committees with alternating members would bring the discussion and consideration of ethical principles into the universities. Such a system would integrate researchers into the implementation process of ethical standards rather than suspecting them a priori of misconduct.

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