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Research Conduct: Ethical Codes

This article will focus on the use of ethical codes in dealing with moral problems concerning research involving humans, nonhuman animals and the environment, that is, moral problems that arise mainly in the experimentally working sciences, especially biomedicine. More general issues such as truth telling, or usage of best scientific methods that if neglected may cause moral problems, will not be considered here.

1. History of Ethical Codes of Research Conduct

The (ab-)use of humans for research purposes has a long tradition reaching back far beyond the beginnings of modern experimental science in the Renaissance to ancient Egypt and Persia. Unfortunately, morally questionable experiments were also performed in the recent past. Well known are the atrocities perpetrated by physicians during the Nazi regime in Germany during the 1930s and 1940s. But even later, contemptible experiments were uncovered elsewhere (Beecher 1966): an inglorious example is the US Public Health Service Syphilis Study (better known as Tuskegee Syphilis Study) in the course of which a large number of black men diagnosed with syphilis had been left untreated in order to observe the 'natural' course of the disease.

Although the abuse of human experimental subjects is by no means the only moral issue in research conduct (see Sect. 3), it gave rise to the first international moral framework regulating research conduct—the Nuremberg Code of 1947. It was followed by the World Medical Association's (WMA) *Declaration of Helsinki* in 1964 (with several revised versions), and in 1993 by the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, which was drafted in cooperation by the Council of Medical Organizations of Medical Science (CIOMS) and the World Health Organization (WHO). Besides these widely adopted international guidelines there is a large number of further international and national guidelines. Although regulating research conduct was for a long time equivalent to regulating research on human subjects (for an overview see Veatch 1995), the debate on animal rights as well as on the protection of the environment has also stimulated the issuing of many guidelines covering these areas. (A large selection of relevant texts, including those named above, are reprinted in Spicer 1995.)

2. Ethical Codes—Philosophical Remarks

A moral, or an ethos, is understood as a set of rules of action (norms). Ethics, a scientific subdiscipline of philosophy, is the critical assessment of different morals. There are many morals (e.g., the ethos of physicians, the ethos of lawyers, etc.) but only one ethics; the latter should not, however, hide the fact that there is no agreement between ethicists as to what the correct criteria for this assessment are (see *Bioethics: Examples from the Life Sciences*).

A moral or ethos can exist in unwritten or (partly) written form. An ethical code is a written, i.e., codified, moral or ethos; an ethical code is, therefore, a moral and not, as its name might suggest, a part of ethics. Insofar as oaths (such as the Hippocratic oath), prayers, and creeds present a certain moral, they are open to an ethical assessment too.

An ethical code is an instrument of self-regulation established by a certain profession (e.g., physicians' organizations) or those groups directly involved in the actions of that profession (e.g., patients or funding bodies). In contrast, national laws and international conventions (e.g., the Convention on Human Rights and Biomedicine adopted by the European Council in 1996) are issued by government bodies. Using the principle of subsidiarity, i.e., the principle that what can be regulated on a lower level should not be regulated on a higher level, ethical codes allow an increased flexibility in view of new moral challenges when compared to statutory regulations.

An ethical code of research conduct is a codified set of rules of action (norms) that should be adopted by every researcher to whom the code is addressed. If a researcher obeys an ethical code he or she is said to

perform her research in a morally acceptable way. 'Performing morally acceptable research' is relative to the justified ethical code applied in testing a certain piece of research. It might be the case, however, that the evaluation of a certain act of research is morally acceptable relative to one ethical code but not to another. For example, a medical experimenter by performing a certain act of research (e.g., on human embryos) might obey the ethical code to which he is subject in his country, but by the very same act might disobey the ethical code obligatory in another country. In those cases where the differing evaluations of acts of research is deemed unacceptable, the philosophical evaluation of ethical codes has its place. The main areas of interest in this context are the application of results from research, the generation of knowledge through research, and the credibility of researchers. Conflicts may arise due to the incompatibility between—as already noted—different ethical codes, certain parts of a certain ethical code, or an ethical code and what might be called public morals.

The ethics of science deals with the reconstruction (and thereby critical assessment) of rules of action, whether codified or not. This reconstruction displays presuppositions concerning the scope of the research in question, the criteria for the 'scientific' generation of knowledge, and the acceptable application of this knowledge. (Motivation of research, be it longing for social acceptance or money, does not play any role in the ethics of science; only prescriptive claims of validity related to certain acts of research are at issue here.) Ethical codes of research conduct can be subjected to such a reconstructive process. The task of ethics is to make distinguishable by way of reconstructing those moral norms that can be universalized, in other words, that are valid for everybody. This assessment should be done by using a method that is, in principle, accessible to everyone. Those moral norms that have proven to be valid can then justifiably be used to test an act of research with regard to its moral acceptability.

The application of moral rules of action in research contexts—the testing of certain acts of research concerning their norm-conforming character—is easily established in small social groups only. For example, working together in a laboratory on a daily basis, the members of the peer group develop a strong intuition of whether certain acts of research do obey the relevant rules of action or not. Acts that do not conform to the rules of action are, therefore, easily identified and the committing actor is kept from doing those acts again. This habitualization of rules of action seems to be, therefore, an appropriate measure of enforcing rules of action in small social groups (Gethmann 1989).

In complex scientific communities with a highly differentiated division of labor the habitualization of moral norms does not work satisfactorily, because the peer review between researchers cannot be sufficiently secured. In this situation it is necessary to design procedures that achieve the control of obedience to moral norms and their enforcement (institutionalization): though not everyone can evaluate whether a certain experiment is morally acceptable (according to certain standards), because not everyone has the expert knowledge necessary for that evaluation, everyone—at least in principle—should be able to assess whether the procedure used by an institutional review board for evaluating this research (e.g., by a peer-reviewed journal, where the review is done by making use of certain rules of action) is correct. Or to give another example: not everyone can assess whether a certain clinical study obeys the relevant rules of action, but everyone should be able—at least in principle—to assess whether the procedure by which the responsible ethics committee evaluates this study is correct (see also *Ethical Practices, Institutional Oversight, and Enforcement: United States Perspectives*; *Ethics Committees in Science: European Perspectives*).

The codification of moral norms, that is the generation of ethical codes, runs largely in parallel with the institutionalization of these norms. Codifying norms enhances their ability to be put into operation: codified norms are less open to inter-individual interpretability of their meaning than norms that are subject to an oral tradition. This stability of meaning supports the efficiency of institutionalized procedures of control of obedience to and enforcement of those norms (cf. the legal requirement of writing for certain documents).

Connected to this is the issue of the status of obligation of ethical codes: statutory regulations must be obeyed (with the problematic exception of toleration of illegal acts or illegal acts that are exempt from punishment). In contrast to that, ethical codes can have a status of obligation varying between a mere declaration of intent and binding professional law. Depending on the act at issue, the consequences of non-obedience of an ethical code may vary from a mere moral reproof to a prohibition from practicing a profession. In addition, the status of obligation of ethical codes may vary over time. This can be illustrated by the *Declaration of Helsinki*: issued by a professional organization, the World Medical Association, it was originally seen as an ethical code binding only for the members of the WMA. Today, however, the Declaration has gained a status comparable to the United Nations' Universal Declaration of Human Rights, to the extent that even non-members of the World Medical Association cannot simply depart from the rules of action it lays down. There is a case, therefore, for transferring the ethical code into an international convention or even law issued by the United Nations.

Finally the question arises, by what procedures should ethical codes be developed and changed. Since the development of ethical codes starts from consensus statements, many codes have been blamed for being developed without a wide enough consultation of the relevant stakeholders. It is claimed, for example, that

codes with an allegedly international validity are negotiated mainly by representatives from Western countries.

Taking into account the respective opinions of the relevant stakeholders is an important step in the preparation of an ethical code. But, as said before, the task of a critical assessment of an ethical code or its draft versions is to single out those moral rules of action that can be universalized, i.e., are valid for everybody. This means, however, that the assessment and its results should be independent of the person, and their background, who is actually performing the assessment. Therefore, procedures for developing ethical codes do not make it necessary to involve all stakeholders; even involving only a very few experts can lead to an ethically justified result. But reflecting on the preconditions of a procedural development of justified norms should not lead to a neglect of the difficulties in the practical implementation of these procedures: the debate on changes to international ethical codes like the *Declaration of Helsinki* involves highly political issues such as conflicts of interest, where the involved parties persist in their claims, be they justified or not. Deciding the question of who should participate in the negotiation of ethical codes is, therefore, an important task in addition to the purely ethical assessment of the rules of action laid down in these codes (Schüklenk and Ashcroft 2000).

3. *Major Issues of Ethical Codes of Research Conduct*

Research bears chances and risks for, among others, patients, society, future generations, nonhuman animals, and the environment (for an introduction see Brody 1998). An important issue of ethical codes is to state criteria relative to which the weighing of these chances and risks can be achieved. An extensively discussed example is the concept of informed consent, which features prominently in many medical codes of research conduct. The lesson drawn from the history of medical research during the twentieth century led to a broad consensus that research without informed consent of the research subject—roughly, a decision made understandingly, intentionally, and without controlling influences—is highly problematic from the moral perspective. Taking this into account the Nuremberg Code demands that in research on humans 'the voluntary consent of the human subject is absolutely essential,' virtually making impossible research on those with diminished decision-making capacities. In contrast to that, the *Declaration of Helsinki* decreased the importance of informed consent and introduced 'best interest' criteria that are supposed to regulate research on incompetent research subjects (e.g., demented or comatose patients). Though vastly treated in the literature, the issue of whether informed consent is a necessary precondition of any research—and if yes, what informed consent actually means—is not satisfactorily solved. Especially in the context of international ethical codes that are designed to supersede national codes, codes that often rest on diverging traditions, this issue remains a controversial subject of debate (see *Research Subjects, Informed and Implied Consent of*).

Another criterion used in ethical codes for the sake of weighing chances and risks is that of benefit. But benefit for whom? Basically the question is whether those affected by research may be burdened with the risks connected to research without benefiting from this research. For example, the debate on the acceptability of nontherapeutic research focuses on this problem: the research subjects in nontherapeutic research are burdened with the risks of this research (like drug side-effects) without benefiting from it (see *Medical Experiments: Ethical Aspects*).

Delivering criteria for weighing the risks and chances of research conduct is not the only topic usually covered by ethical codes. Other topics include fraud and misconduct in research, conflicts of interest, and ownership of results of research (see *Intellectual Property Rights: Ethical Aspects*; *Research Funding: Ethical Aspects*).

An issue of increasing importance for ethical codes is posed by moral problems connected to research involving nonhuman animals and the environment. The former brings up the question as to whether the burden of such research can legitimately be left to those animals. In particular, the so called animal rights movement has done much to raise the level of attention to these problems (see *Animal Rights in Research and Research Application*).

Although the effects of research on the environment have so far not been the main threat that pushed environmental protection forward, research nonetheless can have morally questionable effects on the environment. The release of genetically modified organisms (GMOs), for example, may endanger biodiversity, in that the number of wild-type plants and animals may be reduced by suppression. Although a large number of living species is by itself not necessarily morally preferable, a reduced biodiversity may have (probably only in the future) adverse effects on the ecosystem and thereby on mankind. This would mean, however, that the potential benefits of GMOs are allocated to the living, while the potential burdens due to a damaged environment are left to future generations. Besides postulating rules for actions that demand consideration in dealing with the environment insofar as it is the 'subject' of research, ethical codes may also contain the demand that research actively seeks to improve environmental protection.

See also: Litigation: Effects on Medical Research