The history of research ethics

Throughout the ages – and especially after the scientific revolution in the 17th century – the behaviour of researchers has been subject to some form of regulations that have reflected the normative system prevailing within the research community. In addition, researchers have also sought to show respect for general ethical rules and social norms. These are integral to research ethics.

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Introduction

In the modern age – i.e. since the Enlightenment Era – these internal scientific norms have been accompanied by a positive view of science. Research, in the natural sciences in particular, has been regarded as an expression of liberation and progress. Many good and insightful analyses have been written on this subject (e.g. Hovedkomiteen for norsk forskning 1981; Kaiser 2000).

Clearly, this normative system is active and necessary today as well. Research is encompassed and motivated by a positive assurance that its results will be applied for the benefit of humankind, as we can often read in political documents. This introductory article will not discuss such matters. It will rather address some of the reasons why distrust in research could develop in parallel to this optimistic belief in future progress. Such distrust arose in the wake of abuse directed at individuals and a fear of destructive consequences for society and life. In these conflicts, a recognition arose of how these internal scientific norms (as well as the professional ethics of the researchers) were insufficient to protect individuals against abuse and prevent destructive consequences. On this basis, a research ethics code that to some extent was developed outside and independently of the research community itself gradually came into being – and appears to be required in order to provide individuals and societies with adequate protection against strong scientific, social and economic interests.

Weighty dissertations have been written to offer explanations as to why these conflicts arose, referring to issues such as structural changes in the way in which research is undertaken, close associations with military purposes, political ideologies, the critique of rationality etc. This type of documentation will not be given any particular emphasis here. I am more concerned with providing an overview of the landmarks in the development of modern research ethics as they have emerged through history.

The Second World War – a watershed in research ethics

Many consider the Second World War as the most important landmark. This is mainly due to the reckoning with the scientific, medical experiments conducted on prisoners of war in the concentration camps. This research provided important results, but was based on causing injury or death to the people who participated in it. Other key events during the Second World War also helped raise awareness of the consequences of participation in research. One prime example is the Manhattan project, a large-scale research project to produce atomic bombs. The research succeeded, and the destructive consequences were made abundantly obvious in Hiroshima and Nagasaki.

It is interesting to note some of the differences between these two research areas. In the medical area there was hardly any willingness among the researchers to undertake self-criticism or reckoning. In the natural sciences, the researchers themselves alerted the world to the possibilities for mass destruction resulting from the use of nuclear weapons.

Altogether 23 doctors were brought to justice in Nuremberg in 1947 for having conducted medical research on people in the concentration camps. As a direct response to the terminal experiments that had been undertaken, the verdict defined an ethical code (see The Nuremberg Code) consisting of ten rules intended to prevent the same abuse from happening again:

No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects (Article 5).
The voluntary consent of the human subject is absolutely essential (Article 1).

[...] the scientist in charge must be prepared to terminate the experiment at any stage, if [...] a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject (Article 10).

It was only in the wake of the Nuremberg trials that the World Medical Association started to prepare guidelines for biomedical research on humans: The Geneva Declaration (1947) and the Helsinki Declaration (1964). However, neither trials nor guidelines could prevent the abuse of people in medical research in the post-war years (see Ruyter 2003: 315–346 for examples). As a result, the World Medical Association in 1975 recommended the establishment of independent committees of research ethics to assess all medical research involving people. In my opinion, this measure has had the greatest effect on reducing the abuse of participants in medical research, and it has also helped promote good scientific practice. This establishment represents a new landmark in the form of an organised code of research ethics, which has enlisted a number of supporters.

Natural-science research on nuclear weapons was not brought to trial, but it ushered in a broad political and general debate on how the use of nuclear weapons best could be prevented. It is important to note that in this discussion, physicists and engineers in particular have assumed a significant role in influencing the public and the politicians, for example through the so-called Pugwash movement that was founded in 1957 and along with its founder Joseph Rotblat was awarded the Nobel Peace Prize in 1995. Dorothy Hodgkin, Nobel Prize Laureate in chemistry and president of Pugwash in 1976–1988, urged all Nobel Prize Laureates to sign the Pugwash declaration against nuclear weapons, and 111 of them did so. However, even the Pugwash movement appears to have realised that declarations and awards are insufficient instruments to prevent undesirable consequences of natural-science research. In 1997, Joseph Rotblat called on scientists to convene to establish an international ethics committee to monitor natural-science research "regardless of how unpleasant it will be for scientists to be monitored". No such committee has been established. There is no regulation of research in this area comparable to the one that is in effect in the field of medicine.

Pollution of the environment as a result of industrial development was the second major area of the natural sciences that gave rise to a focus on the consequences of research. Rachel Carson's

Silent spring (Carson 1962) was probably the first book to articulate the widespread concerns about air pollution, by asking why the birds are disappearing. Over the years, the environmental problems have grown in scale, and they are characterised as being "anthropogenic and thus a result of human action" (Ariansen 1992:11) and often based on research. This was naturally followed by questions about how these problems could be rectified. The first major environmental conference was held in Stockholm in 1974, a precursor of the principles that have been enshrined in legislation from the 1970s onwards as well as in international conventions.

The social sciences have not seen the same dramatic abuse of research participants, nor have they been confronted with the same potential social consequences. This has not prevented powerful reactions to the publication of certain types of research projects. This has been a particular result of the use of sensitive personal information. On the basis of research projects, objections have been especially raised against the use of personally identifiable information without the persons involved (or their guardians) knowing that such information had been used for research purposes. It has also been claimed that this type of study violates privacy and that it is impossible to prevent such information from being abused in the future. One such project was the so-called Metropolitan study, which was conducted in Norway and Sweden in the 1960s (Johansen, Kaspersen and Skullerud 2001:35–37). The part of the study that attracted most attention involved schoolchildren. In 1964, the Oslo school board supplied information on boys born in 1954 to the project. The study was to follow the boys from age 11 until they had become well-established adults (at the age of approximately 30 years) with the purpose of providing better vocational guidance and social assistance to young people in the future. The information supplied by the school board included names, age, housing conditions, the guardian's profession, school grades and IQ. The project attracted harsh public criticism (including by law professor Knut S. Selmer), and demands for prior consent by parents and sufficient protection of the data were put forward. The researchers appeared reluctant to introduce amendments to a project that could plead such laudable aims, but they were willing to withdraw pupils from the study if protests were received. The consequence of this vehement public criticism was a potential weakening of trust in social research. As a result, the social researchers themselves took the initiative to establish a data protection secretariat under the Norwegian Research Council for Science and the Humanities. With the development of computers – and the question of protection

of individuals – the Metropolitan study can be regarded as an essential reason behind the proposals for political measures to prevent abuse after 1967–68. This led to the Act relating to Personal Data Filing Systems in 1978 and the establishment of the Norwegian Data Protection Authority in 1980. Ten years later, the National Committee for Research Ethics in the Social Sciences and the Humanities was established, following a proposal in Report no. 28 (1988–89) to the Storting (White Paper), On research.

(See also the introductory articles on research ethics in Medical and health sciences, Natural sciences and technology and Humanities and social sciences.)

Landmarks before the Second World War: the early days

As noted above, forms of self-regulation have always existed in professions that conduct research. Most often this has been implicit, although occasionally also defined in writing. The early days of research ethics are almost exclusively associated with the field of medicine.

In the context of the development of modern medical science and experimental methods, some interesting reflections were made regarding how one should proceed when the research process involves people or animals. Some reflections of this kind were provided by Claude Bernard (1813–1878), an influential French physiologist. Many consider him to be the founder of experimental medicine, since he established the principles for conducting experiments (Bernard 1965). In contrast to the long-standing tradition in research of using vulnerable people in experiments, Bernard proposed that the researcher should begin by using himself and continue by including family members and colleagues, before starting to use patients, for example, in experiments. This may seem like a reasonable principle in research ethics: if you do not want to expose yourself to something, you should not expose anybody else to it either. Or in other words: researchers, who are best qualified to understand any risks involved, should start by exposing themselves to the risks before proceeding with other research participants who are less well equipped to understand them. Self-experiments have been practised both before and after Bernard, and they are also specifically referred to in the Nuremberg Code, but they have never been used on a large scale. More commonly, there seems to have been little debate among researchers on moral problems associated with the use of vulnerable research participants. These

were often exposed to a considerable risk, which was tolerated in consideration of the benefits to be gained from potential progress (cf. Elkeles 1996).

There were, however, reactions to the use of people in research that caused authorities other than the profession itself to attempt to set a standard. One example from Norway is the trial of Gerhard Armauer Hansen (1841–1912) in Bergen. He was deprived of his licence as a doctor at the Leprosy Foundation in Bergen. Hansen, who is one of Norway's most recognised researchers, is known for his discovery of the leprosy bacillus. In his investigation of the causes of leprosy he wanted to try to demonstrate that the disease is infectious by using a cataract needle to graft material from a sufferer into the eye of a patient who suffered from another type of leprosy. For this purpose he invited a 33 year-old woman to his surgery. She was reluctantly stung in the eye with the needle, and protested at this treatment. With the assistance of a clergyman, she and some other local residents lodged a complaint in Bergen city court. In his own explanation, Hansen reproaches himself for "not having communicated my intentions to the patient in advance", but was quick to excuse himself: " [...] since I could not assume that the patient would regard the experiment from the same point of view as myself, and being convinced that I had total command over the potentially occurring affliction, I refrained from doing so" (quoted in Patrix 1997:190). The court found him guilty of having caused her "bodily harm" that he could not assume "that she would have consented to submit to, if in advance he had made her aware thereof" (quoted in Aasen 2000:102)

The verdict by Bergen city court is one of the earliest signs of requirements for consent when there is a risk of causing injury (bodily harm) without this being in the best interests of the person, with the intention of gaining new knowledge in experimental research. It appears, though, that the verdict had little effect on prevailing practices. Hansen enjoyed widespread support among his colleagues. Still, this does not change the fact that a requirement for consent is included in the verdict.

This is well worth noting, since many theoreticians share the perception that the requirement for informed consent is a post-war phenomenon (for example Faden, Beauchamp and King 1986). It should also be noted that in many types of research, the researchers themselves enforced the requirement that only volunteers could be included after having consented without having been

required to do so. One example is Walter Reed's research on yellow fever in the 1920s. In other contexts, the authorities imposed a requirement for consent, for example for research on soldiers in the US Navy from 1932 onwards (President's Advisory Committee 1996:499).

Only a few years after the Hansen verdict, the German professor Albert Neisser (1841–1912) was criticised for experiments he had undertaken to develop a serum therapy for syphilis, wishing to show that it would lead to immunity. One of his experiments came under public scrutiny (see Ruyter 2003:315–346 for a description) and an indictment was filed against him. Neisser was found guilty, but only received a fine. The court's emphasis on his failure to obtain consent from the participants before starting the experiment was decisive.

An interesting point in this connection is that the authorities in Prussia issued a directive in 1900 to regulate medical research (Ruyter, Føre and Solbakk 2000:250). The directive contains two material guidelines that can be found in all subsequent research ethics. The first is known from the Hansen case, here expressed as a requirement for "unambiguous consent". The second is the personal responsibility of the head of the clinic to ensure compliance with the directive. This directive appears to be the first document in which medical research is regulated by authorities other than the researchers themselves. The document places responsibility with the management, and its purpose is to protect patients in the clinics against being used in experiments that are harmful to them and undertaken without their permission.

As can be seen from these examples, there was a great interest in diseases that were assumed to be communicable. This gave rise to a large number of experimental trials, especially with children (Grodin and Glantz 1994:7–10), in which the participants were exposed to substantial risks. Some of the experiments proved to be highly useful in the development of effective vaccines and therapies, such as the vaccine against rabies (1885) and the antitoxic treatment of diphtheria (1893–94). Criticism was raised against this type of research, but this criticism failed to bring about any change in practices. Resistance was often voiced by groups that were opposed to animal experiments as such. Those who established societies for protection of animals would also promote organisations for prevention of abuse of children (Schultz 1968). Because of their ideological basis, they were often regarded as marginal and their impact was therefore limited.

Once again, a research project in Germany caused prevailing practices to be challenged. In 1930, fourteen infants died as a result of a BCG vaccine. The case led to a widespread public debate with demands for control and follow-up. In 1931, the Ministry of the Interior issued new guidelines for therapies and scientific experiments involving people (Ruyter, Førde and Solbakk 2000:251–253). The guidelines reaffirmed the responsibility and requirement for unambiguous consent. In addition, they state that researchers shall not exploit "social emergencies" (Section 7), as a response to the idea that orphans in children's homes, among others, were regarded as "ideal" candidates for experiments "under controlled conditions" (Grodin and Glantz 1994:13). This concern points towards a principle that was later incorporated into the Helsinki Declaration, stating that healthy adults should be selected first, before more vulnerable groups are included. In Norwegian this is referred to as the "descending order of permissibility". Moreover, the guidelines stipulate that the experiments must be "relatively harmless" (Section 8) and that any potential harm must be "reasonably proportionate" to the expected benefit (Section 4).

It is striking to note that this emphasis on responsibility and the enforcement of guidelines did not lead to a more effective protection of research participants. It was only in 1975 that the World Medical Association came down in favour of requiring advance approval by an independent committee before a project can be initiated. With regard to this decision as well, we can find historical examples of the need for this approval to be pointed out.

The earliest example that I am aware of from Norway dates from 1969. (The journalist Kjell Pedersen drew my attention to this reference). In the minutes from a meeting of the Norwegian Council for Radiation Protection there is a call for "ethical/radiological committees" in the context of the need for advance approval of controversial research projects; the case in question involved "plans for a Nordic study of circulatory factors in the facial skin of Sámi people etc., with the aid of a method that includes exposing the research participants to radiation". In the investigation of radiation experiments in the USA, it was discovered that some rudimentary mechanisms for assessment of research projects, such as internal control, had existed since 1946 (President's Advisory Committee 1996:500). After various forms of internal control had been attempted in the USA, it was decided that all institutions must establish local committees of research ethics for peer review in order to provide sufficient protection to all research

participants. In 1971, this was introduced as a condition for undertaking research that involved human subjects. As a result of this development, Sweden established local committees of research ethics in all university hospitals in the late 1960s. The new element in the revised Helsinki Declaration was its requirement for independent ethical review. From this requirement we can find a direct link to the way in which the regional committees of medical and health research ethics were established in Denmark and Norway after 1985. The committees were not established locally, but regionally, with broad interdisciplinary representation, including laypeople. A precursor to the regional committees was the ethics commission that had been established by the Norwegian Research Council for Science and the Humanities in 1978 to assess ethical aspects of applications within this field, as well as the so-called Andenæs committee that deliberated guidelines and councils for professional ethics (1977).

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Literature

CHAPTER 1: REFER TO

Aasen, H. Sinding (2000). *Pasientens rett til selvbestemmelse ved medisinsk behandling.*Bergen: Kunnskapsforlaget

Ariansen, P. (1992). *Miljøfilosofi. En innføring*. Oslo: Universitetsforlaget

Bernard, C. (1865). *Introduction à l'étude de la mèdecine expèrimentale.* Paris: Bailliere. Translated to English in 1927, republished in 1957 with the title *An introduction to the study of experimental medicine.* New York: Dover

Carson, R. (1962). *Silent spring*. New York: Houghton Lifflin. Published in 2000 with a new introduction by P. Matthiessen. London: Folio Society

Elkeles, B. (1996). *Der moralische Diskurs über das medizinische Menschenexperiment im 19. Jahrhundert.* Stuttgart: Gustav Fischer

Faden, R.R., T.L. Beuchamp & N.M.P. King (1986). *A history and theory of informed consent.*New York: Oxford University Press

Ferry, G. (1998). *Dorothy Hodgkin: a life*. London: Granta

Grodin, M.A. & L.H.Glantz (1994). *Children as research subjects. Science, ethics and law.*Oxford: Oxford University Press

Hovedkomiteen for norsk forskning (1981). *Forskning og etisk ansvar*. Oslo: Hovedkomiteene for norsk forskning

Johansen, M.W., K.-B- Kaspersen & Å.M.B. Skullerud (2001). *Personopplysningsloven. Kommentarutgave.* Oslo: Universitetsforlaget

Kaiser, M. (2000). *Hva er vitenskap?* Oslo: Universitetsforlaget

Patrix, J.-M. (1997). *Gerhard Armauer Hansen. Leprabasillens oppdager*. Bergen: Eide

President's advisory committee (1996). Final report: *Ethics of human subjects' research: a historical perspective. Human radiation research.* Oxford: Oxford University Press

Ruyter, Knut (red.): *Forskningsetikk. Beskyttelse av enkeltpersoner og samfunn*. Oslo: Gyldendal Norsk Forlag 2003

Ruyter, KW, Reidun Førde & Jan Helge Solbakk (2000) *Medisinsk etikk - en problembasert tilnærming*. Gyldendal Norsk Forlag AS, Oslo

Schultz, W.J. (1968). *The humane movement in the United States, 1910-1922*. New York: AMS Press

CHAPTER 2: FURTHER READING

Bert, P. (1878). *La pression barométriquet: recherches de physiologie expérimentale*. Paris: Masson

Bynum, W. (1878). Reflections on the history of human experimentation. I: Spicker, S.F. et al (red) . *The use of human beings in research.* Dordrecht: Klüver

Deutsche Forschungsgemeinschaft (1998). Empfehlungen der Kommission "Selbstkontrolle in der Wissenschaft". Vorschläge zur Sicherung guter wissenschatlicher Praxis. Tilgjengelig på www.dfg.de/aktuell/download/empf_selbskontr.html

Deutsche Forschungsgemeinschaft (2000). Abschlusserbericht. Unstimmigkeiten auch im Umfeld von Friedhelm Herrmann. http://www.dfg.de/aktuell/pressemitteilungen/Archiv/presse_2000_26.html

European Environment Agency (2002). *Late report from early warnings: the precautionary principle 1896.2000).* Environmental issue report no.22

Forskingsetiske komiteer (2002a). *Oppdragsforskning: kvalitet, etterrettelighet og åpenhet*. Foreløpig rapport (For english version, see: Contract Research: Openness, Quality, Accountability)

Forsman, B. (2002). *Vetenskap och moral*. Nora: Nya Doxa

Fukuyama, F. (2002). *Our posthuman future: consequences of the biotechnology revolution.*New York: Farrar, Straus, Giroux

Müller-Hill, B (1984). *Tödliche Wissenschaft: die Aussonderund von Juden, Zigeunern und Geisteskranken, 1933.1945.* Reinbek: Rowohlt

Nathan, D.G. & D.J. Weatherall (1999). Academica and industry: lessons from the unfortunate events in Toronto. *Lancet* 353;9155:771

Nylenna M, Andersen D, Dahlquist G et al. Handling of scientific dishonesty in the Nordic countries. *Lancet* 1999; 354:57-61

Rothman, D.J. (2000). The shame of medical research. *The New York Review of Books*. November 30

Ruyter, Knut W. (2014): "Forskningsetikk". In: Ruyter KW, Førde R, Solbakk JH. *Medisinsk og helsefaglig etikk*. Gyldendal Akademisk

Schomberg, R. von (2002). Agricultural biotechnology in the trade-environment interface: counterbalancing adverse effects of globalization. I: D. Barben et al (red), *Biotechnologie – Globalisierung – Demokratie.* Berlin: Stigma

Utbildningsdepartementet (2001). *Etikprövning av forskning som avser människor*.Departementsserien 2001:62

Weber, W. (2000). European clinical research scandals: investigators question self-regualtion. *Lancet* 356: 9223:52