

History and definitions

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The history of human rights and ethics relating to research on human beings is fairly long, but limited in scope, if we take into account only research based on evidence and not prejudices and religious beliefs.

Well-known figures such as Ambroise Paré (1510-90), who ended the treatment of gunshot wounds with boiling oil, replacing it with the use of ointment, James Lind (1716-94), who described the effect of lemon juice in the prevention of scurvy, Johannes Fibiger (1867-1928), who made a systematic comparison of serum treatment of diphtheria and treatment without serum, and Austin Bradford Hill (1898-1991), who was in charge of the controlled trial demonstrating the effect of streptomycin on pulmonary tuberculosis, to mention just a few forerunners of modern scientific methodology, were primarily inspired by the need to discover the truth about the potential effects of known or new biomedical practices, an additional motivation being to help the soldiers, sailors, children and tuberculosis patients concerned.

However, despite any optimism that may prevail concerning human and societal developments, it is the transgression of ethical boundaries that has been the key incentive for devising and applying ethical concepts and standards relating to biomedical research, codes of good practice in this field and control systems based on the establishment of research ethics committees.

In other words, the development of high ethical standards has historically been less a progression phenomenon, bound up with greater prosperity and general political progress, but more a transgression phenomenon, as a reaction to severe disregard for fundamental human rights. As a consequence of the shift from transgression to progression, the primary focus today is the key figure of biomedical research ethics, the patient or the healthy volunteer, whose safety and right to respect and autonomy must be guaranteed.

The need for definitions

Ethics as a term in itself – that is, unrelated to research – has a much longer history than research ethics. “Biomedical research ethics” is accordingly a new expression, which has been part of scientific terminology for only the last four to five decades. As a recent addition to scientific language, this expression has caused much conceptual confusion and a correspondingly strong need to define the term or, at least for its users, to clarify the meaning they attach to it. In order to reduce the scope for confusion, the key terms of research ethics are defined below.

To leave etymology behind and focus instead on semantics, ethics – in the sense I accept for it – can be defined as follows:

An overall term for the immaterial values, norms and attitudes prevalent in a country or culture, which underlie that country's or culture's concept of humankind and the laws and codes based thereon and shape citizens' personal existence and relations with each other and with the legal and private institutions of society. From a global perspective, ethics also includes responsibility for the ecological balance of planet Earth, its soil, water and air and its biological diversity.

After the Second World War and the large-scale serious violations of human rights, even in research, perpetrated in the concentration camps, prisons and ghettos, the main focus of ethical codes and supervisory measures was the human being as an individual, with strong emphasis on rights. I call this part of ethics “individuality ethics”. It is still a fundamental, inescapable part of ethics.

However, it often overshadows our important responsibility for our fellow human beings, sometimes known as distributional ethics, but which I call “collectivity ethics”, to use a less technical term. Even if the starting point for codes and for research ethics committees is the safety of and respect for individual trial participants, they also need to consider the societal aspects of solidarity and altruism, where these are based on genuine informed consent. There could be no scientific progress if the population of Europe did not have a latent sense of collectivity ethics, not only among healthy volunteers but

also among participants in randomised drug trials,* in phase-one and phase-two drug trials, in epidemiological projects, in genetic family studies and in many other research areas.

The ethics of research, as an overall term for all ethical aspects of biomedical science, has until recently been taken to mean research ethics concerned with the safety of and respect for research subjects. Research ethics is, however, a *toto pro parte* term (an overall term applied to a part), which from a linguistic standpoint excludes another important branch of the ethics of research: researchers' ethics, that is, good-practice standards concerning the reliability of harvested variables, interpretation of data, trustworthiness of publications and respect for other scientists' intellectual property.

This second part of the ethics of research will not be discussed at length here, although ethical good conduct and reliability are conditions for obtaining genuine informed consent. In Europe, experience has shown that codes and supervisory agencies with fraud-prevention aims are best established independently of those dealing with research ethics, yet with some sort of co-ordinating link between the two, and this argues against discussing that branch of ethics here.

Biomedicine comprises all the disciplines related to the health services and their educational institutions. As we will see later, the ethics of biomedicine also covers projects carried out by non-health professionals, if they obtain access to patients and make their diagnoses via the health system, its case records and other data.

The term "intervention" is used here to mean any planned measurable influence on a person's mind or body. It comprises interviews, cognitive tests, diagnostic tests, surgery, drug therapy, preventive arrangements, information about serious life conditions and events, and so on. Use of the term "intervention" makes it possible to avoid the usual excessive reliance on the narrower term "therapy".

Research subjects can be healthy volunteers, participating patients or, in some countries, fertilised human eggs, foetuses and even deceased persons.

Randomised drug trials:

these consist of a study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are used.

Pathogenesis:
the manner of development of a disease.

The term “human rights” in a contemporary context, as used here, refers to the international (including European) declarations, directives, conventions and similar codes.

Ethical codes, apart from those mentioned above, include a large number of United Nations declarations and professional bodies’ declarations, guidelines and the like, in addition to national law on research ethics. There are now a very large number of codes worldwide, which can sometimes be confusing for biomedical scientists, as some of these codes even contradict each other. The final section of this chapter suggests a hierarchical order for these many codes.

Ethical committees, in the accepted sense used here, mean ethical research committees dealing with biomedical research involving human beings, excluding such committees’ advisory functions not related to research, for instance giving advice on therapeutic dilemmas.