

## EDITORIAL

## The “Code of Ethics of the Italian National Institute of Health”

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On 13<sup>th</sup> January 2015 the Ethics Committee of the Istituto Superiore di Sanità (ISS, Italian National Institute of Health) adopted the “Code of Ethics of the Italian National Institute of Health” [1], which was implemented by means of an *ad hoc* Order [2].

The ethical principles, values and criteria affirmed in the Code reflect the multitude and broad range of activities and functions performed by the Institute. As stated in its statute, the Institute “pursues the protection of public health, especially through the exercise of research, control, consultancy, regulatory and training activities” [3]. The Institute’s research studies range from basic research to clinical and diagnostic applications in a translational perspective, while its institutional responsibilities cover the whole range of public health interventions.

It follows from this that the activities of the Institute’s Ethics Committee also range over the numerous fields of research in which the ISS is engaged. In accordance with article 12 (paragraph 10) of Law 189 of 8<sup>th</sup> November 2012 [4] and the Decree of 8th February 2013 [5], its key function is the evaluation and authorization of clinical trials, but it is also involved in the whole range of activities pursued by and through the Institute, a peculiarity that is reflected in the fact that the Ethics Committee of the ISS is designated as being of “national importance” [6] and is not subject to local planning procedures for Ethics Committee laid down in current regulations [5].

The document is defined as a “Code” in the broadest sense of the word’s meaning. According to *The new dictionary of medical ethics codes* are texts that “serve principally to lay down the rights and duties which should underpin professional practice” [7]. Codes may come in different forms and be variously grouped, but the “main difference in classification is not in the content but in who the reader of the code is” [8]. The “Code of Ethics of the Italian National Institute of Health” [1] (hereafter referred to as the “Code”) can be included among those that Harris defines as a “code of conduct” and which he describes “as a document prepared for the benefit and regulation of the group” [9].

**THE CONTENTS OF THE CODE**

The Code comprises five chapters preceded by a brief

foreword explaining its origins and structure. The five chapters concern: integrity in research, conflicts of interest, trials with human subjects, public health, experiments involving animals.

In the first chapter the Committee decided to adopt the “Executive summary” of the “European Code of conduct for research integrity” [10] drawn up by the European Science Foundation (ESF) and the federation of All European Academies (ALLEA), which brings together 53 national academies from 43 states. The “European Code of conduct for research integrity” is considered one of the most authoritative codes on the subject currently circulating in the European Union and has been adopted by several institutions. The principle of integrity in research applies in particular to: honesty in presenting goals and intentions; reliability of research; fairness in communication; objectivity; independent and impartial communication with other researchers and with the public; duty of care for humans, animals, the environment; fairness in providing references and giving credit for the work of others; responsibility for future generations in the supervision of young scientists and scholars.

Unlike the first chapter, the ensuing chapters do not adhere strictly to documents already adopted by other institutions. They nonetheless refer to values and principles that are widely shared and affirmed in the major ethical codes concerning biomedicine in general and research with human subjects, including: the World Medical Association’s “Declaration of Helsinki” [11], the “Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine” published by the Council of Europe [12], and the “International Ethical Guidelines for Biomedical Research Involving Human Subjects” published by the Council for International Organizations of Medical Sciences [13].

The second chapter introduces general criteria for the management of possible conflicts of interest that might compromise the independence of researchers or the impartiality of their professional activities. As the Institute is part of a vast network of national and international contacts, it is to be expected that situations may arise in which conflicts of interest, whether of an economic or non-economic nature, are a possibility. The Code proposes a “Declaration of Interests” (DoI) form on which

researchers and all the Institute's personnel detail the circumstances in which such conflicts may emerge. The implementation of practical rules and supervision are not the responsibility of the Ethics Committee but of the Central Administration.

The third chapter addresses issues concerning trials with human subjects. Although the Institute is not a centre for the direct treatment of patients, it both coordinates and participates in multicentre trials. In ethical terms the issue is of major importance: clinical trials call for very careful evaluation, primarily on account of the possible risks they may involve and their possible direct effects on the health of individuals. This is why the evaluations expressed by the Ethics Committee on other types of research are in the form of opinions, whereas those regarding clinical trials are either a legally valid authorisation or a legally binding ban. The Code provides guidance regarding: the value and validity of research projects, the fair selection of subjects, risk-benefit ratios, independent review, informed consent, respect for potential and enrolled subjects. While the Code does not aim to offer either an interpretation of current legislation or guidelines for its interpretation, the third chapter mentions both the difficulties involved when patients are unable to express consent and the Italian regulations concerning legal representation when their participation in clinical trials is envisaged.

The fourth chapter moves to the broader sphere of public health research and interventions, in other words from a primarily individual dimension to one embracing the public at large. The competition – at times a clash –

between the two dimensions gives rise to one of the key problems for public health ethics. The maximisation of the community good must not be allowed to compromise the good of individual subjects. The Code therefore recalls the ethical principle that the collective good is achieved by protecting and promoting the good of each and every individual.

The final chapter introduces the basic ethical criteria for trials involving animals. Experiments with animal models must be scientifically valid, methodologically appropriate, statistically reasonable, and original. While the Code is not a practical guide to the application of regulations, the text takes into account the situation in Italy following the entry into force of the Legislative Decree of 4<sup>th</sup> March 2014 [14] which transposed the EU Directive (2010/63/EU) on the protection of animals used for scientific purposes [15].

The Code thus affirms the basic ethical criteria that should underpin the Institute's numerous activities in the broad fields of biomedicine and public health, with particular emphasis on research. These criteria reiterate principles regarding such questions as basic research, trials with human subjects and public health that are widely shared, albeit generally treated separately in texts on more specific issues.

Although the Institute has always pursued principles and values that are unanimously held to be inalienable, the Code is the first such document to be adopted.

For the Institute's numerous activities the Code is a fixed point of reference, but nonetheless not a definitive one: it will be updated as and when circumstances require.

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