E54 Ethical Committee: A Southern Italian Experience

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Learning Overview: The goal of this presentation is to illustrate the results obtained by the Regional Unique Committee (CEUR) of Basilicata, a region of southern Italy, published in 2018 in response to the transposition of the European Directive on the evaluation of studies in the health sector.

Impact on the Forensic Science Community: This presentation will impact the forensic science community by demonstrating how the European Parliament directive for the protection of public health and the progression of medical and biological sciences have been implemented in Italy, particularly in Basilicata.

In Directive 2001/20/CE of the European Parliament, the Ethics Committee is defined as an independent body, made up of health and non-health personnel, responsible for guaranteeing the protection of the rights, safety, and well-being of trial subjects and providing public guarantees of this protection, issuing, for example, opinions on the testing protocols, the suitability of the investigator(s), the structures, and on the methods and documents used to inform the trial subjects before obtaining informed consent. In Italy, the establishment of Ethics Committees is provided by the law in public health facilities, private hospitals, and care institutions. The purpose is to guarantee the feasibility of a research project in terms of ethical and scientific correctness of the experimentation, the protection of the rights of those taking part in the clinical study, and the adequacy of the relationships between the center where the research is conducted and the sponsor of the study. The Ethics Committee may express a favorable or unfavorable opinion. The deadline for the expression of this opinion is 30 days from the presentation of the request of the research promoter. The Ethics Committee communicates its opinion to the Ministry of Health in this time frame. After having obtained a favorable opinion from the Ethics Committee (and if the competent authorities have not communicated motivated objections), the clinical trial can begin.

In Basilicata, a little region in South Italy, the CEUR was established by the Regional Law of 4 August 2011, n. 17 to make a single regional in-depth study on the bioethical aspects and all their ethical and legal implications connected with the health care and biomedical research and its environmental impact.

The provision of the Regional Council Resolution n. 930 of 10 July 2012 established that the function of the CEUR was to provide consultative activities in matters within its competence in favor of health care practice and biomedical research; to propose legislative and administrative solutions in the same subjects; to promote a bioethical culture in the regional territory and the development of bioethical sensitivity in health workers and the population; to increase the quality and safety levels of the health service; to guarantee the development of an organic and constant function of study and research, training, and education; scientific reference and advice in the field of bioethics; to take care of the relationships between local and national institutions interested in bioethical issues; and to provide advice for the Regional and National Council, if required.

In Basilicata, four hospitals ask CEUR for advice: a Scientific Research and Health Care Institute (called C.R.O.B.), a regional hospital (called "San Carlo" hospital), and two local health authorities (called ASP and ASM). In 2018 the approved studies were 92, among which 39 were proposed by the "San Carlo" Hospital, 35 by the C.R.O.B, 17 by the ASM, and 1 by the ASP. These 92 studies are divided into drug trials: 27 out of 92, of these, 10 were financed and 17 were non-profit, observational studies; 49 out of 92, of these five were financed and 44 were non-profit; compassionate use of drugs, 16 out of 92, not surprisingly all of them were non-profit.

The data concerning each hospital are summarized: "San Carlo" Hospital proposed 12 experiments with drugs (of which 4 were financed and 8 were non-profit); 24 observational studies (of which 3 were financed and 21 were non-profit), three therapeutic use of drugs; C.R.O.B. proposed 13 experiments with drugs, of which six were financed and seven were non-profit; 12 observational studies, of which 1 was financed and 11 were non-profit; 10 therapeutic use of drugs; ASM proposed 2 non-profit experiments with drugs, 12 non-profit observational studies, 3 therapeutic use of drugs; ASP proposed 1 financed observational study.

Ethics Committee, European Parliament Directive, Basilicata Data