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EFGCP Multi-Stakeholder Workshop & Discussion

## How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation?

11 September 2014

Square Congress Centre, Brussels, Belgium



UNIVERSITÀ  
CATTOLICA  
del Sacro Cuore

SESSION 2: WHAT WILL MAKE THE REGULATION A SUCCESS ON NATIONAL LEVEL?

Panel Discussion

The Future Approach to Ethical Review of Clinical Trials  
What Should We Do Differently on National Level?

Reorganization of ECs in Italy:  
are we facilitating the New CTs Regulation?

*Antonio G. Spagnolo, M.D*

Institute of Bioethics, Faculty of Medicine and surgery, Rome

## Research Ethics Committees and clinical research in Italy: where are we going?

R. MINACORI, P. REFOLO, D. SACCHINI, A.G. SPAGNOLO

Institute of Bioethics, Faculty of Medicine and Surgery "Agostino Gemelli", Catholic University of the Sacred Heart, Rome, Italy.

**Abstract.** Italian Ethics Committees (ECs) have entered a new phase because of the recent Law no. 189 of 8 November 2012 and the Ministry of Health Decree of 8 February 2013. The new norms have introduced important changes. In fact, ECs are now established not to serve a single hospital or research institution but to serve Regions. Moreover, they are established on the base of the number of inhabitants, research sites and expected amount of clinical trials.

The implementation of the new norms into practice have produced a drastic reduction in the number of ECs. This fact could raise some issues but it could obtain some benefits.

The paper explains the main steps of ECs and clinical research development in Italy. Special attention will be paid to recent trends. Moreover, the new norms will be illustrated, showing possible issues and benefits connected to their implementation.

ical centers. The fundamental reason for setting up them was to apply and to promote ethical principles into medical practice and research. In other words, ECs were particularly intended to make more clear the mission of the hospital/research center, even though it is doubtful if every Italian EC had developed own statutes referred to ethical principles and values.

This issue is relevant: in fact, at that time in Italy no specific law on ECs was in force and the only reference was the World Medical Association "Declaration of Helsinki". Instead, a great contribution was soon given by the simultaneous increasing spread of bioethics, beyond academics.

Afterwards, ECs were established in hospitals, local health units, research institutes, assuming importance and credibility above all for the evaluation of clinical trials rather than representing a place for a wider ethical reflection. This aspect

# Regionalization of Italian ECs



Figure 1. RECs number established by Italian Regions.

Table I. REC composition according the Ministry of Health Decree of 8 February 2013.

- a) Three medical doctors;
- b) A general practitioner;
- c) A pediatrician;
- d) A biostatistician;
- e) A pharmacologist;
- f) A pharmacist of the regional health service;
- g) The medical director or his/her deputy and – in the case of IRCCS - the scientific director;
- h) An expert in law and insurance, or a forensic doctor;
- i) An expert in bioethics;
- l) A representative of the health professions involved in the trial;
- m) A representative of the voluntary associations or the association for patients' rights;
- n) An expert in medical devices;
- o) In the case of medical device, a clinical engineer or other qualified professional;
- p) In the case of food studies, a nutrition expert;
- q) In the case of new technical procedures, an expert in the field;
- r) An expert in genetics in the case of genetic studies.

# Where are we going with the reorganization of ECs in Italy?



The regionalization of Ecs:

- they review not just clinical trials related to a single site but many sites: this could cause a challenging workload.
- as they review clinical trials carried out in other search sites, they could not know all the elements needed for evaluating the local feasibility.
- "overloaded" Committees are pressed to give opinions quickly and could have difficulties to monitor a great amount of studies.
- - ECs risk to become simple "technical" bodies, losing their original ethical mission. The discussion on the relevant ethical aspects risks to be reduced or shifted in favor of reviewing technical-procedural aspects.

## Criticism about the variability of the composition and functioning of ECs in the Italian regions

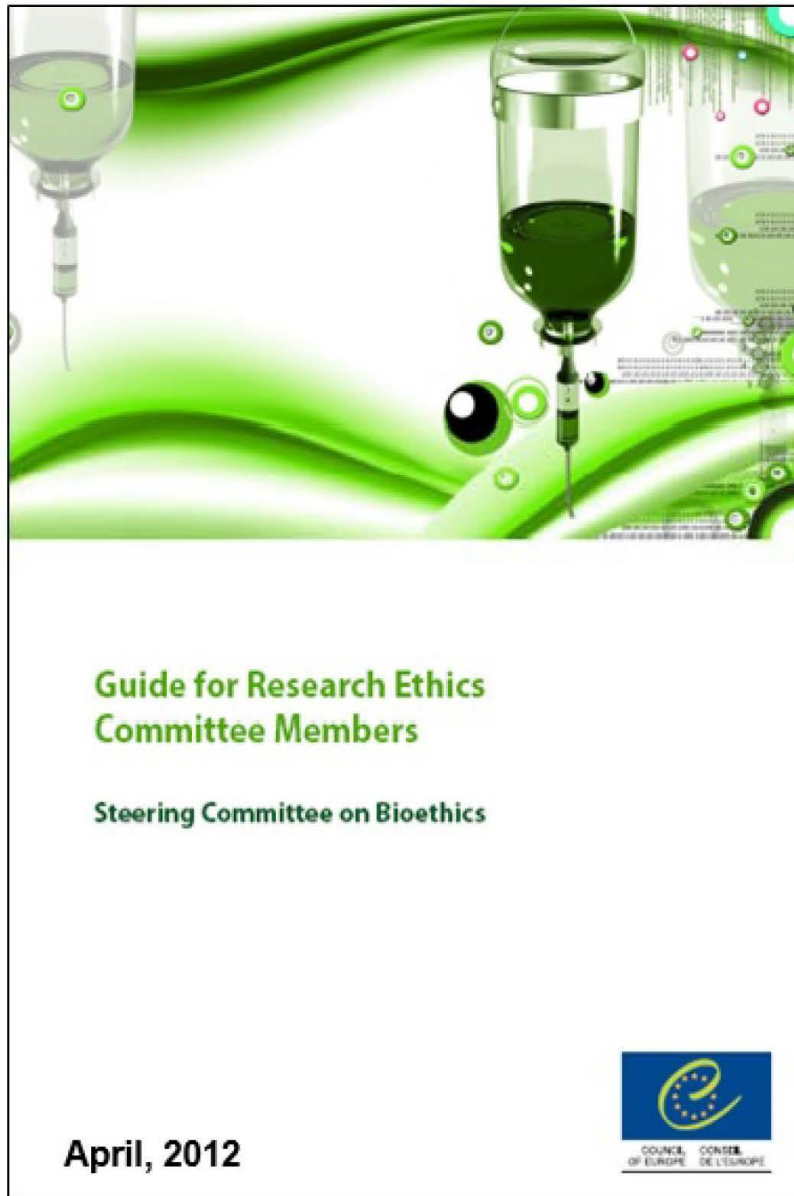
<i>Expert of medical devices</i>	In some regions is mandatory a nurse
<i>Expert in bioethics, representative of patients</i>	In some regions is mandatory NOT a physician
<i>Representative of healthcare workers</i>	In some regions only a nurse
<i>Expert in genetics or nutraceutics</i>	In some regions are permanent members, in other are members ad hoc
<i>Access to documentation of the study for members</i>	In some regions all members can access to documentation, in other only specific members
<i>Components for the purposes of a quorum</i>	In some regions only permanent members in other also members ad hoc
<i>The appointment of members</i>	In some regions direct appointment, in other through a competition
[...]	

## In view of the harmonization of the ethical review system in Europe

Some proposal:

- An official national network of the Italian (in charge of the NCB?) in connection with an European network (Eurec?) that provides for regular periodic meetings on various aspects of ethical review.
- Encourage (require mandatory?) periodic training of the members of ECs and the use of an operational manual of reference for the ethical evaluation (the Guide for research ethics committees member issued by the Council of Europe?)
- Give emphasis on the role of monitoring of approved trials as a tool to improve next approvals
- Introduce a system of quality certification for assessing the ethical review through a mechanism of both internal audit and an independent external evaluation.

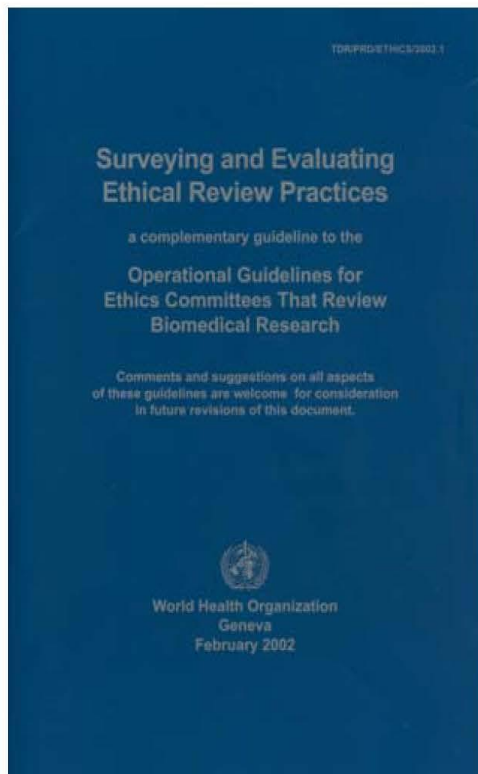




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# Surveying and Evaluating Ethical Review Practices



- ✓ Increased national and international interest in ensuring that ethical review reaches the highest standards
- ✓ As expression of good practice, there should be a system of quality certification for assessing the results of the system of ethical review:
  - *Mechanism of internal audit*
  - *Independent external evaluation*

HEC Forum

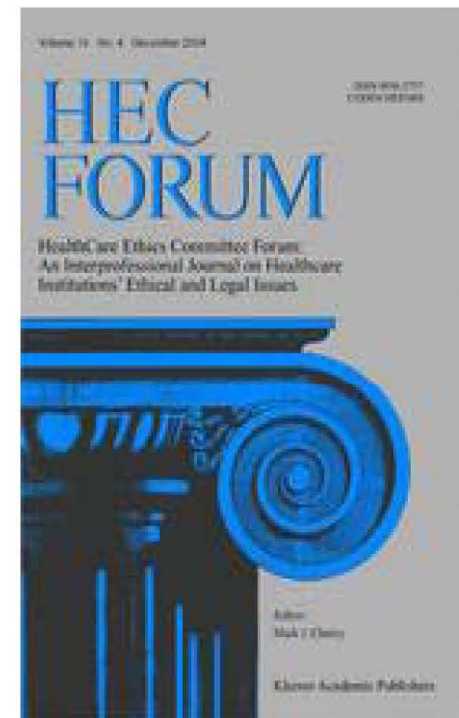
DOI 10.1007/s10730-013-9210-8

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## Research Ethics Committee Auditing: The Experience of a University Hospital

Daniela Marchetti • Angelico Spagnolo •  
Marina Cicerone • Fidelia Cascini •  
Giuseppe La Monaca • Antonio G. Spagnolo

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