HELLENIC NATIONAL

BIOETHICS COMMISSION

OPINION ON

CONFLICT OF INTEREST IN BIOMEDICAL RESEARCH

HELLENIC NATIONAL BIOETHICS COMMISSION
Evelpidon 47, PC 113 62 Athens
Tel.: 0030 210- 88.47.700, Fax: 0030 210- 88.47.701
E-mail: secretariat@bioethics.gr, url: www.bioethics.gr

The Hellenic National Bioethics Commission met repeatedly upon invitation by the President in order to consider the ethical and social issues within its jurisdiction with regard to conflict of interest in clinical research, especially in clinical trials of pharmaceutical agents. Dealing with this issue is a continuance of the already issued expert opinions on clinical trials on human subjects (2004), the establishment of ethics committees that review biomedical research (2005) and research ethics in the biological sciences (2008). The timeliness of the matter is due to the usual criticism on the accountability of clinical trials of pharmaceutical agents or biomedical technology appliances that are funded by the pharmaceutical industry. The accountability of clinical studies is crucial for public health, as it remains the single guarantee for drug efficiency and non-hazardous research products directed to the public.

1. *General Principle*

The Commission believes that the collaboration between the private sector and hospitals or research institutes is desirable because it ensures innovation, but under the strict condition that the ethical integrity of research is protected.

In this context, "conflict of interest" may emerge between pursuing the truth, which is the aim of scientific research, and the financial profit anticipated by the research sponsors.

a) The relationship between researcher/sponsor: the duty to reveal the truth

In clinical studies, the person that primarily encounters conflict of interest is the researcher who realizes that the research results may not be of financial benefit to the sponsor, and faces the dilemma of revealing the truth or defending the financial interest.

The Commission believes that the researcher has always the moral duty to search for and reveal the truth, even when this is unfavorable to the sponsor. Serving health via the accuracy of the results of clinical studies is absolutely preceding, even in the case that this is discouraging for funding research in the future. The Commission feels that

the risk of such discouragement should be undertaken by the scientific community, due to the significance of protecting public health.

b) Revealing the truth and the right to information

The Commission stresses that providing the public with products resulting from deficient or inaccurate biomedical research offends the personal right to appropriate information. This right is a fundamental requirement for self-determination of a person in health matters (informed consent).

2. Special Issues

a) Promoting collaborative clinical studies

The Commission believes that an efficient way to eliminate conflict of interest phenomena is to conduct collaborative clinical studies, i.e. studies in which several companies take part. As a result, it is possible to directly compare more products under trial, based on a common protocol. Thus, on one hand, funding from many sponsors diminishes data counterfeiting aiming at their own profit, and on the other hand, research is driven towards more reliable results.

b) *Publication of negative results*

In view of the verified practice followed by specific pharmaceutical companies, which attempt to obstruct publication of negative results concerning the product under trial, even by taking legal action[1], the Commission believes that since a clinical study shows negative results, either for the efficiency or the safety of the product which is under trial, the results must be published. In addition, it is essential to take concern in treating equally any possible overlapping findings for similar products. This way, both the scientific community and the sponsors are informed early enough as to decide on the rational direction of their future interest.

[1] Von Elm E., Röllin Al., Blümle An, Huwiler K., Witschi M., Egger M. Publication and non-publication of clinical trials. Swiss Med. Weekly, 138:197, 2008.

c) Freedom of research group members

The Commission believes that the independency of the scientific opinion of each research group member must be absolutely consolidated. Complaints concerning plagiarism, falsification or conscious concealment of results must be immediately investigated, ensuring that this will not prove detrimental to the complainants.

3. Control mechanisms

The Commission reminds that the legislation in force, which is in harmony with the Directive 2001/20, already provides control levels in conflict of interest in clinical studies, both during the approval process of the relevant protocol and the course of the study. Moreover, the Commission notes that, according to the Medical Ethics Act (v. 3418/2005), the disciplinary bodies of Medical Associations are also responsible to prevent conflict of interest in doctors/researchers. The same applies to scientists of other disciplines who participate in the research group according to the relevant provisions of the legislation.

Above and beyond, the Commission believes that in order to address the problem it is necessary to adopt additional procedures and measures, such as:

- The establishment of Special Ethics Committees in hospitals and research institutes that conduct clinical studies, with the responsibility to control the implementation of research protocols. Intervention of such committees to the researcher/sponsor relationship may possibly prevent unethical dependencies in time.

- Since conflict of interest may well extend in the relationships between research institutes or universities and the commercial companies that are active in biomedical research, establishment of a distinct control procedure for clinical research in the central level of the University (Central Research Committee, with members independent of the institute's administration), additionally to the procedure followed by the National Ethics Committee for Clinical Studies in the Ministry of Health (which involves university and non-university research groups). Founding the relevant control mechanism is appropriate, because of the potential direct relationships between companies and universities or even members of the above

mentioned committee. This novel procedure will emphasize the additional academic responsibility of university researchers to safeguard the accountability of the clinical studies they participate. Nevertheless, control does not involve a) the cost of laboratory consumables, laboratory equipment and salaries of external associates, b) charity donations to the research group or individual researchers and c) legal income by previous work (e.g. patents). It is important to emphasize that, the decisions reached by the control committees (Special Ethics Committees and Central Research Committees) must be entirely justified.

- The initiative to promote internal procedures of research ethics in industries that sponsor clinical studies, via their communal representatives (e.g. Panhellenic Association of Pharmaceutical Industry, Hellenic Federation of Enterprises).

- Submission to the responsible hospital authorities where the clinical studies is conducted, of a disclosure by each researcher stating any possible working relationship with the company/sponsor or any possible income or other kind or association, such as receiving company's products, gifts, travel expenditure coverage etc. This disclosure should also be submitted to the responsible authorities of the State which are authorized to control the research, prior to the start of the clinical research, but also to every participating patient. In addition, publication of the relevant research results must be accompanied by a notification to the editorial boards of national scientific journals, and submitted conference abstracts must be accompanied by a notification to the conference organizing committees. Members of the control bodies also ought to submit a similar disclosure, as well as the research institutes on the assumption that there is any financial relationship (sponsorships, dividend payments of commercial products in the research etc.), including the company/sponsor.

- The establishment of a regular education to raise the researchers' awareness of potential conflict of interest, and inform about the means of control (e.g. in the context of introductory information provide to a

research group by their head or the ethics committee of the research institute, as well as by organizing special seminars).

Finally, the Committee supports the right to access control mechanisms by whoever participates in a certain clinical study and invokes evidence of misconduct.

Athens, 5 July 2011