

DEVELOPMENT OF RESEARCH ETHICS IN SERBIA

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RESEARCH ETHICS REGULATED BY LAW ON HEALTH CARE

- ◆ The law on health care provided regulation of research on human beings.
- ◆ The main objectives of the regulation are to establish a **central ethics committee** (at the Serbian Medical Association) and **local ethics committees** (at the Clinical Centers and Hospitals).

RESEARCH ETHICS IN MEDICAL CURRICULUM

There are lectures on clinical ethics in the medical curriculum, and it is also proposed that ethics committees play a central educational role by helping physicians to be aware of moral problems and by contributing to the training of research teams.

RESEARCH ETHICAL COMMITTEES

- ◆ Ethical review committees should be so composed as to be able to provide complete and adequate review of the research proposals submitted to them.
- ◆ It is generally presumed that their membership should include **physicians, scientists** and other professionals such as **nurses, lawyers, ethicists and clergy**, as well as **lay persons** qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected.
- ◆ They should include both **men and women**.
- ◆ Not all ethical committees in Serbia have attained this goal.

TRAINING OF THE MEMBERS OF RESEARCH ETHICAL COMMITTEES

- ◆ Members of the research ethics committees, especially chairmen, receive appropriate **training**, in the country and abroad, necessary to the fulfillment of their duties.
- ◆ Besides the **national recommendations**, a new **Declaration of Helsinki**, written up by the World Medical Association in 2000 is a basis for regulations concerning biomedical research. It stipulates that all participants, including those in control groups, are to receive the best prophylactic, diagnostic and therapeutic methods.

TRAINING OF THE MEMBERS OF RESEARCH ETHICAL COMMITTEES

- ◆ The latest version of **International Ethics Guidelines for Biomedical Research Involving Human Subjects**, written by the Council for International Organizations of Medical Sciences, does not exclude placebo trials when an effective treatment exists, as does the Declaration of Helsinki. It does stipulate that the investigator must justify the research in relation to the expected benefits to society while minimizing any risk to the individuals involved.
- ◆ Recommendations of the Declaration of Helsinki prevail in Serbia.

FOLLOW-UP AND MONITORING OF THE TRIAL

- ◆ The main role of research ethics committees is to assess both the scientific and ethical aspects of submitted protocols.
- ◆ Ethical committees are responsible not only for approval of the protocol and its amendments but also for **follow-up and monitoring of the trial after its closure**. This last commitment is rarely fulfilled because of lack of time and resources assigned to the ethics committee.

RESEARCH ETHICAL COMMITTEES IN SERBIA

An analysis of the work of research ethical committee at the University Clinical Center in Nis (Serbia) reveals that major time was devoted to the:

- ◆ **clinical investigation of drugs,**
- ◆ **treatment procedures**
(e.g. hemofiltration, automated peritoneal dialysis, basal/bolus therapy by an insulin preparation),
- ◆ **new diagnostic methods, etc.**

CLINICAL INVESTIGATION OF DRUGS IN SERBIA

- ◆ Clinical investigation of drugs was requested by **foreign pharmaceutical companies**, as a part of international collaborative studies or, more common, as a part of drug registration procedure in Serbia.
- ◆ The benefits of such studies are small for the patients involved, with drug supplied only in the trial period. With a relatively good health care system and inexpensive investigation Serbia could attract major pharmaceutical companies to seek research collaboration.
- ◆ Registration of the drug means that it could enter the pharmacies in Serbia, and that patients could buy it. Social security has accepted for free only a few drugs registered in the last three years.

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