

**ETHICAL ISSUES
IN CLINICAL RESEARCH
AND PROTECTING HUMAN
RESEARCH SUBJECTS**

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Informed consent

- ◆ A cornerstone in health care is the duty to inform patients not only of their right to partake in decisions about their care but also of the various options for treatment. This applies particularly in clinical research, for which the Helsinki Declaration has defined patients' rights.
- ◆ **Informed consent** is of great importance both in routine care and in clinical research.
- ◆ Directives defining informed consent in relation to clinical trials have not been issued in Serbia. Even if information is given to the patient it is not always comprehended. In some studies in Serbia about one half of the patients had misunderstood the information in certain respects.

Healthy volunteers

Clinical research involving healthy volunteers is important for advancing medical knowledge but raises a variety of ethical issues, many of which stem from the fact that such studies pose risks to research participants without the prospect of medical benefits to them.

Since regulation is not strict in Serbia, ethical issues in research with healthy volunteers should be reconsidered and the ethical requirements should include:

1. scientific or social value;
2. scientific validity;
3. fair subject selection;
4. favorable risk-to-benefit ratio;
5. independent review;
6. informed consent;
7. respect for enrolled subjects.

Donor organs

- ◆ A worldwide shortage of donor organs has led to the development of **national and international systems for organ procurement** and allocation. Such systems promote organ donation and ensure fair distribution of available donor organs through a combination of legislation, organ exchange organizations, transplant coordinators, publicity campaigns, donor cards, and professional training programs.
- ◆ Serbia also employ **transplant coordinators** whose role involves promoting links between transplant centers and intensive care units, establishing protocols for organ donation, and helping hospital staff deal with the sensitive issues involved in organ donation.
- ◆ National system in Serbia is moderately developed.
- ◆ Organ trafficking and paid organs do not exist in Serbia.

Research involving persons unable to give consent

Research involving persons in particular children or persons unable to give consent, pregnant women or healthy volunteers for clinical trials is very sensitive. According to EU regulation the applicant should:

30 "rtqxkfg" lwuvkhkecvkqp "hqt" uwej "tgugcte j" kp "vgtou" qh
" " "v jg" rqvvgpvkcn "dgpghkvu" qh "v jg" tgugcte j" kp "tgncv kqp
" " "vq" v jg" rquukdng "tkumu" vq "rgtuqpu="

40 "kpfkecvg" v jg" pwodgt "qh" rgtuqpu "kpxqnxgf" cpf "fguetkdg
" " "v jg" ugngev kqp "etkvgtkc="

50 "rtqxkfg" fgvcknu "qh" v jg" cttcpigogpvu "ocfg" hqt
" " "rtqxkfkpi" kphqtocv kqp "vq" rgtuqpu "cpf" hqt "qdvckpkpi
" " "kphqtogf" eqpugpv="

60 "urgekh { "cp { "rc {ogpvu. "kpfwegogpvu" qt "qv jgt" dgpghkvu
" " "vq" dg" ikxgp "vq" v jg" rgtuqpu "eqpegtpgf="

70 "fguetkdg" v jg" eqorgpucv kqp "cpf" vtgcvogpv "cxckncdng
" " "vq" uwdlgevu "hqt" vtken/tgncv gf "kplwtkgu0

Research involving persons unable to give consent

For persons unable to give a valid consent applicants should, in addition to the previous:

1. indicate the degree of risk and burden involved for the subject;
2. whether and how the persons might benefit from the procedures envisaged;
3. indicate why it is necessary to involve persons unable to give a valid consent;
4. describe what arrangements are made to seek the agreement of the person's parent, guardian or other representative.

Developing countries

When research is to be performed in developing countries and/or by partners from developing countries or when the results can be potentially applied in these countries, the applicants should also describe the arrangements for: (1) sharing of benefits and allocation of intellectual property rights; (2) contribution to capacity building in developing countries (i.e. capacity to assess and use modern technologies while respecting their own choices, needs and local conditions).

- ◆ The supply of new drugs must be guaranteed after a trial has ended, even for patients' lifetime if necessary.
- ◆ Those who carry the burdens of the research should also have access to the resultant benefits.
- ◆ EC funded protocols must specify "who will benefit, how, and for how long".

Refugees and internally displaced peoples

- ◆ A debate is now underway about the proper ethical guidelines to apply when doing research in refugee populations and among internally displaced peoples.
- ◆ The debate pivots on the tension between the need to develop evidence based emergency health measures and the need to protect vulnerable populations from possible exploitation or harm.
- ◆ A 750,000 population of these lives now in Serbia.

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