

Research Ethics Committees in Slovenia

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Establishment of Research Ethics Committees (RECs)

Since the 1960s there has been a formal system for ethical review of medical research in Slovenia. Although there is no specific law regulating biomedical research on humans the Oviedo Convention¹ has been in force since 1 December 1999. This important legally binding international instrument contains rather detailed provisions on biomedical research. There is also a long-standing practice, of over 40 years, of ethical review of medical research. There are currently several binding internal regulations that are observed:

- All research on human subjects funded by public money must be reviewed for ethical acceptability and approved by the National Medical Ethics Committee (NMEC), by regulation of Ministry of Education, Science and Sports.
- All biomedical research in the framework of theses for M.Sc. or D.Sc. degrees, as well as students' scientific research, must gain previous approval by the NMEC (by regulation of the Medical School).
- Ethical approval is required by the Slovene Directive on Clinical Drug Trials² for all clinical trials of pharmaceutical products. Slovenia has also started to implement the provisions of the European Directive 2001/20/EC on the application of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use.
- Any scientific paper reporting on biomedical research submitted for publication in a Slovene medical journal, must be accompanied by the documented approval of an REC.
- Slovenia has signed and is expected to ratify the Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research.³

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¹ Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine (1997, Council of Europe ETS No. 164), 1–12.

² Pravilnik o kliničnem preskušanju zdravil (Directive on Clinical Drug Trials), UL RS 28. 7. 2000, No. 67: 8372–8385.

³ Additional Protocol to the Convention of Human Rights and Biomedicine concerning Biomedical Research (30 June 2004) Council of Europe, CETS No. 195.

This should provide a basis for the new law on biomedical research, regulating among other things, ethical *review* of research in great detail.

The NMEC takes care of the large majority of all ethical review of research. The ethical committees within the regional hospitals are authorized to review local studies not presenting any serious risk or burden, for example, non-invasive and observational research. An ethics committee of the institute of oncology advises on oncological research, however, an approval still has to be obtained from the NMEC.

Ethical review is required for all research involving intervention on, or interaction with human beings. Additionally, it is required for all research on personal medical data, and biological material of human origin are also covered.

The Health Minister appoints members to the NMEC from a selection of reputed experts nominated by the Medical School, the National Health Council, and the Slovene Medical Chamber.

The NMEC, as an independent body, is not formally accountable to any supervising authority. According to Article 8 of the Act on the NMEC,⁴ its decisions cannot be appealed. If a different view is adopted by the CDBI of the Council of Europe or the World Health Organization, the NMEC is obliged to reconsider its decision. Regional RECs are responsible to the NMEC.

General Powers of RECs

In general an approval by an REC is sufficient, and necessary, for the research to go ahead. However in clinical drug studies (phase I–III), an approval of the Agency for Medicinal Products (of the Ministry of Health) is also required.

Occasionally researchers have failed to submit research for which they wrongly assumed that review is not required, often because in their opinion it did not present any ethical problem. When such cases come to light, a careful retrograde review is obtained; so far the evaluation has never been negative. Cases of intentional non-compliance have so far not been recorded. If they were, disciplinary action would follow with potentially serious consequences for the researcher, for example, revocation of the licence.

There are no circumstances under which RECs will approve activities, rendering them lawful, that would otherwise be unlawful.

General Legal Responsibility of RECs

RECs may reject or advise against activities that are lawful. This is because not everything that is ethically unacceptable is prohibited by the law. In principle

⁴ Ministerial Decree on the Constitution, Terms of Reference and Procedures of the National Medical Ethics Committee (in Slovene) *Uradni list Republike Slovenije (Official Gazette of the Republic of Slovenia)* No. 30, 2 June 1995, 2149–2150.

RECs cannot approve activities that are unlawful. However, legislation in certain areas lags behind the developments in science as well as medical practice. Therefore the NMEC, as an exception, may authorize research on corpses or materials removed from them in certain cases where this could be a punishable offence according to the existing law (for example where there is intervention without explicit consent of the person before their death).

Formal *legal* guidance at the national level does not exist. However, the NMEC in its deliberation relies on the provisions of the Oviedo Convention⁵ and its Additional protocol on Biomedical Research,⁶ as well as on established international guidelines such as the Helsinki Declaration. The NMEC has also adopted and published a guideline for researchers developing a research project involving human beings. This has been largely based on the Protocol, supplementing the Convention on Human Rights and Biomedicine, on Biomedical Research.

The Impact of Directive 2001/20/EC on Good Clinical Practice

Most provisions of Directive 2001/20/EC on Good Clinical Practice have already been incorporated into the Slovenian regulation of clinical studies. The Slovenian Directive on Clinical Drug Testing,⁷ regulating good clinical practice in the field of pharmaceutical research and research on medical appliances, is based on this Directive. In addition, the rather detailed provisions of the Protocol on Biomedical Research have been observed by both the RECs and the scientific community since these guidelines have been in use.

The Law in Practice

The law sets out minimum requirements; in sensitive cases, therefore, the NMEC enforces higher standards of protection where rights of the human subjects are concerned. The NMEC takes great care to ensure that privacy of sensitive personal data is properly observed. In case of the NMEC, its decisions are final according to the law. However the NMEC is obliged to reconsider its decisions if the appropriate forum of the Council of Europe adopts a different stance on the subject. On the other hand, civil legal actions against an REC that approved a research project in which subjects have suffered undue damage are conceivable, however such cases have so far not occurred.

Specific Data Protection Matters

When consent has not been obtained from the data subject, RECs do have power to make decisions about when research is justified in the public interest. Where

⁵ See n. 1 above.

⁶ See n. 3 above.

⁷ See n. 2 above.

unreasonable effort would be necessary to contact the data subjects, the potential risk of damage to the data subject appear remote, and the study is expected to provide important new scientific information, the NMEC may exempt the research proposer from the duty to seek consent.

Other exemptions from the data protection rights of the data subject are also allowed. For example, where research on data or biological samples identifies potentially serious, and preventable, risks to health of the data subject; the individual's identity may be uncoded and appropriate action taken to initiate the necessary preventive measures or treatment.

Coded data are only considered to be rendered anonymous when the data controller's code, which can be used to discover the identity of the data subject, is irreversibly erased. The NMEC insists on information as to anticipated or intended processing of personal data to be given to data subjects, whether or not the data are rendered anonymous. RECs do not consider data as being anonymous for the purposes of processing when it still exists in personal form in the hands of those who obtained the data from the data subject. In fact in cases of particularly sensitive information, the NMEC requires both assurance from the researchers that links to an identifiable data subject be irreversibly destroyed and for details of the actual procedure to be used to be provided.

The collecting and analysing of genetic information is considered to be a situation where data protection rights may easily be violated. The NMEC's practice is to inform the proposers of molecular genetic studies that an approval is only granted for the *particular* study submitted, and that any new study on the same material is subject to a new review. The donors of the material must also be so informed. They must have a choice to give their consent only to the present study (as opposed to all future studies), and in case of any new study to be asked for a new consent. A request for blank advance consent for any future studies is in principle only acceptable for irreversibly anonymized material.