



# The EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe (Update: March 2008)

## Poland

1. What laws or regulations apply to an application for conducting a clinical trial in Poland?

The Pharmaceutical Act of 2004 includes, under Chapter 2a, legislation on Clinical Investigations of Therapeutic Products. The detailed legislation is set out in Articles 37a to z and aa to al, and adopts the principles of the clinical trials Directive 2001/20/EC. It also covers veterinary products. This Act was amended a few times since 2004. The very last amendment was in *Legislation Journal of the Republic of Poland (2007) 75: Pos.492*.

The Act about Medical Devices of 2004, April 20th, which covers regulations about medical devices. *Legislation Journal of the Republic of Poland (2005), 64: Pos 565 (date of last amendment)*.

The Polish Medical Act of 1996, under Articles 21 to 29, provides legislation regarding medical experiments on humans and, for example, specifies that only a physician (or a dentist) can conduct such experiments, including clinical trials.

- Additional Regulations of the Minister of Health (May 11, 1999 Order of the Minister of Health and Social Welfare in the matter how to establish, create finance for and the mode of action of Bioethics Committees. *Legislation Journal of the Republic of Poland (1999) 47: Pos. 480*) set out how to create finance for, and the mode of action of, Bioethics Committees in Poland; and Regulations of the Minister of Finance cover insurance arrangements for clinical trials

The other important national regulations are:

- November 29, 2002 Order of the Minister of Health in the matter of Central Register of Clinical Trials (2004) *Legislation Journal of the Republic of Poland (2002) 209: Pos. 1783*
- December 10, 2002 Order of the Minister of Health concerning detailed requirements of Good Clinical Practice *Legislation Journal of the Republic of Poland (2002) 221: Pos. 1864*
- April 30, 2004 Order of the Minister of Health on Clinical Trials on Minors (2004) *Legislation Journal of the Republic of Poland (2002) 104: Pos. 1108*

- April 30, 2004 Order of the Minister of Finance concerning the mandatory civil liability insurance of researchers and sponsors. *Legislation Journal of the Republic of Poland* (2004) **101**: Pos. 1034
- April 30, 2004 Order of the Minister of Health concerning classification of the medical products of different use. *Legislation Journal of the Republic of Poland* (2004) **100**: pos. 1027
- March 11, 2005 Order of the Minister of Health concerning detailed requirements of Good Clinical Practice *Legislation Journal of the Republic of Poland* (2005) **57**: pos. 500
- May 18, 2005 Order of the Minister of Finance amending the regulation concerning the mandatory civil liability insurance of researchers and sponsors. *Legislation Journal of the Republic of Poland* (2005) **101**: Pos. 845
- April 7, 2005 Order of the Minister of Health concerning the nature and extent of inspection of clinical trials. *Legislation Journal of the Republic of Poland* (2005) **69**: pos. 623.
- January 3, 2007 Order of the Minister of Health concerning the application form for authorization of clinical trial of medicinal product and to obtain an opinion about clinical trial of medicinal product from bioethical committee *Legislation Journal of the Republic of Poland* (2007) **6**: pos. 46.

A very important document which should be recognized as a national medical guideline is the Code of Medical Ethics (2003) prepared and published by National Chamber of Physicians and Dentists (<http://www.nil.org.pl>). In this document in Chapter II on Scientific Research and Biomedical Experiments detailed guidelines are set out in Articles 41a to 51 ([http://www.nil.org.pl/xml/nil/wladze/str\\_zl/zjazd7/kel](http://www.nil.org.pl/xml/nil/wladze/str_zl/zjazd7/kel)).

There is no legislation about the use of human tissue in research, but there is legislation about tissue transplantation – July 1, 2005 Act about sampling, storage and transplanting of cells, tissues and organs. *Legislation Journal of the Republic of Poland* (2005) **169**: pos. 1411.

2. Which government, legal or authoritative body or bodies is or are responsible for the establishment and/or accreditation of (research) ethics committees for reviewing clinical trials for investigational medicinal products, their supervision and quality? Are there different (research) ethics committees reviewing other projects?

There are three groups of Bioethics Committees in Poland, all covered by the 1999 Regulations (see 1 above)

- The Bioethics Committees of the Medical Universities
- The Bioethics Committees of the (non-university) Medical or Scientific Institutes
- The Bioethics Committees of the Regional Chambers of Physicians and Dentists. (NB The Regional Chambers are the regulatory bodies for doctors and dentists in Poland)

They all consider all types of research involving human subjects, depending on the location of the Chief Investigator, or, for multi-centre studies, the Co-ordinating Investigator.

There is no accreditation system for supervision or quality of the research ethics committees.

3. What is the process for achieving clinical trial authorisation from the competent authority in Poland?

The sponsor must apply for an authorisation to conduct a clinical trial on an IMP to the competent authority in Poland, which is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, one department of which is responsible for GCP assessment and maintains the Central Register of Clinical Trials (<http://www.urpl.gov.pl>).

4. What is the process for obtaining ethical review of a clinical trial protocol by a competent (research) ethics committee in Poland?

The Chief Investigator, or the Co-ordinating Investigator, must apply for a Bioethics Committee opinion to the appropriate committee depending on his or her place of work and the site at which the trial is to be conducted.

5. Is there a single organisation to which to apply for ethical review of a clinical trial for an investigational medicinal product, regardless of whether this is for a single site or multiple sites?

No.

6. What is the website for the organisation that issues guidelines on the ethical review of a clinical trial for an investigational medicinal product?

<http://www.mz.gov.pl/wwwmzold/index?ml=en>

7. Is there a procedural interaction between the national or local competent authority and the (research) ethics committee during the approval process?

No. However, the Bioethics Committee is required to provide the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products with a copy of its opinion following the ethical review, and this Office will not issue an authorisation for the trial unless the Bioethics Committee opinion is favourable.

8. Does the application to the EC and to the competent authority have to be submitted in parallel, or, if not, in which order?

The applications can be considered in parallel, but the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products has the final say, as it will not issue an authorisation for the trial without a favourable opinion from the Bioethics Committee.

9. How many (research) ethics committees are there in Poland?

There are 54 Regional Bioethics Committees and one Appeal Bioethics Committee in the Ministry of Health.

The 54 Regional Committees comprise

13 appointed by the Medical Universities

18 appointed by the Medical or Scientific Institutes

23 appointed by the Regional Chambers of Physicians and Dentists

They are all recognised for the review of all clinical trials with IMPs.

10. How are ECs funded in Poland? Do they charge fees? If yes what is their scale of fees?

There is no central funding for Bioethics Committees in Poland. The committees established by the universities and the medical/scientific institutes are funded by their parent bodies, but they rely on fees from sponsors for the assessment of sponsored studies-. Un-sponsored studies are assessed free of charge. The committees established by the Regional Chambers of Physicians and Dentists also rely on fees from sponsored studies for their funding, but whereas they will also assess un-sponsored studies free of charge, they will not give a decision on such studies, as their opinion has to be referred back to the Regional Council of Physicians for a final decision. In these cases the Regional Chamber of Physicians and Dentists must cover all expenses connected with the evaluation of un-sponsored studies.

The level of fees charged depends on a number of factors, including the location of the clinical trial; some committees charge a single fee for the complete assessment of a study, whilst some charge a lower fee for the initial assessment followed by additional fees for any subsequent assessment. There is no fixed tariff, each regional committee setting its own level of fees and each university or institute committee having its fees determined by the parent body. Thus in Warsaw, for example, the Regional Chamber of Physicians and Dentists charges 7,000 zlotys (= 1,800 euros) for the total ethical review process of a clinical trial submission.

11. Who is responsible for submitting the request for ethical review to the competent ethics committee for single-site and for multi-site clinical trials?

The 1999 Regulations allow either the sponsor or the investigator to submit an application. However, the investigator is preferred.

12. How is a "single opinion" achieved for multi-site studies?

The Co-ordinating Investigator is identified and the appropriate Bioethics Committee for that investigator provides the "single opinion". The study sponsor (i.e. the pharmaceutical company) selects a national coordinator for a multicenter clinical trial. Bioethics committee to which national coordinator is subordinated will review the multi-site clinical trial's protocol – Art.37s of the Polish Pharmaceutical Act. (According to Polish law, the study sponsor is responsible for selecting a national coordinator for a multi-site clinical trial).

A site specific assessment is sought from the relevant Bioethics Committees for any other investigators in Poland and is required within 14 days of the request for information. However, a passive approval process is in operation and no response is regarded as a favourable response.

13. How many members serve on an EC?

Between 11 and 15.

14. How many members constitute a quorum?

50% + 1 including at least two lay persons (a priest, a nurse, a pharmacist, a philosopher or a lawyer). Any bioethics committee session is not valid if chairman or vice-chairman is not present at the session.

15. How are EC members appointed?

Those for Medical Universities are appointed by the Rector, and those for Medical and Scientific Institutes are appointed by the Director, in both cases with advice. Candidates for those for the Regional Chambers of Physicians and Dentists are nominated and then voted in by the representative Regional Council of Physicians at a secret ballot or public voting.

16. How is the independence of members ensured?

The 1999 Regulations require that the background details of all Bioethics Committee members be published. Members of the bioethics committees in Poland cannot be dismissed. There are two exceptions - when the member does not participate in bioethics committee sessions, or when the member asks for dismissal.

17. How are conflicts of interest of EC members avoided?

Members of a Bioethics Committee are expected to declare any conflicts of interest and should there be any significant conflict of interest, such as participation in the trial under review, the member must leave the meeting and take no part in that review process. But these regulations are not specified in governmental legislation. Some RECs have these obligations in their internal statute.

18. What backgrounds and/or qualifications of members are actively sought?

The 1999 Regulations specify that each Bioethics Committee shall include a priest, a nurse, a pharmacist, a philosopher and a lawyer, the remainder being physicians. There is no requirement for a paediatrician, a psychiatrist or a statistician to be appointed. All candidates to the Bioethics Committee must have the highest professional qualifications and at least 10 years history of professional practice.

19. How do ECs obtain specialist expertise?

Every project is evaluated by an appropriate specialist, if not represented on the Bioethics Committee already (including, for example, a paediatrician or a psychiatrist). Additionally, every project is evaluated by an insurance broker who is an expert on insurance law. No statistical advice is sought.

20. What are the training requirements for members of ECs?

There are no mandatory requirements for the training of members of Bioethics Committees. However, participation in conferences and other training schedules is encouraged. Expenses connected with the training of members of Bioethics Committees must be covered from Bioethics Committees' resources.

21. What training programmes are available for EC members in Poland?

There is no formal training programme specified in the Regulations, but courses are organised by the GCP Society and by the Bioethics Committees themselves.

22. What are the timelines for the assessment of single- and multi-site studies?

The ethical review of any study, whether single- or multi-site, must be completed within 60 days. The clock may stop to request further information or clarification from the applicant.

In the case of multi-site studies, site-specific assessments (SSA) may take place in parallel with the main application so that the main REC has information about all the other sites within the 60 days. The timeline for SSAs is 14 days, but no response is deemed to be a positive response.

23. How are substantial amendments submitted during the review process dealt with?

These are dealt with within the periods allowed for the clock to stop.

24. How does an EC assess the suitability of investigators and of sites?

A CV must be submitted with each application to a Bioethics Committee and main investigators must attend the meeting of the committee that considers the application. Permission is needed from the authorities responsible for the hospital, university or institute where the study is to be conducted, and this must be submitted to the Bioethics Committee. The 1999 Regulations specify that the decision of the Bioethics Committee must be conveyed not only to the investigator and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, but also to the authorities of the hospital, university or institute.

25. How are the requirements for (research) ethics committees to review the contractual or financial arrangements in clinical trials for both investigators and hospitals handled?

In the Order of the Minister of Health concerning the application form for authorization of clinical trial of medicinal product and to obtain an opinion about clinical trial of medicinal product from bioethical committee appeared the requirement for RECs and governmental bodies to review the contractual and financial arrangements between sponsor and investigator, sponsor and center (for example hospital) and center and investigator.

26. How are the requirements for ethics committees to review the compensation arrangements for study subjects handled?

The law forbids payment to patients for taking part in a clinical trial, other than their travelling expenses. Loss of earnings is not covered. Payment may be made to healthy volunteers taking part in bioavailability studies, or Phase I studies conducted in Poland. Payment for "sick" volunteers is forbidden.

27. Is there an ongoing quality assurance process (e.g. audits, inspections, internal SOP) for (research) ethics committees in Poland?

Not yet.

28. Is there an appeal mechanism?

Yes. An appeal against any negative decision made by a Bioethics Committee can be made within 14 days to the Appeal Bioethics Committee of the Minister of Health. (*N B The hearing of appeals is the only function of this committee.*)

29. How do ECs deal with SUSAR reports and Annual Safety Reports?

Individual SUSAR reports are received and evaluated by the expert who evaluated the original protocol and then presented during sessions of Bioethics Committees. In questionable or doubtful cases Bioethics Committee asks for further clarifications. Any expert's opinion and SUSAR reports are included within the project archives.

Annual Safety Reports are evaluated by the member of the Bioethics Committee, or expert, who evaluated the original protocol.

30. How are 'substantial amendments' defined?

These are clearly defined in the 2004 Act and in the Order of the Minister of Health concerning detailed requirements of Good Clinical Practice.

31. What are the indemnity insurance requirements for research projects?

Prior to 2004, information regarding indemnity insurance had to be specified in the application to the Bioethics Committee. Under the 2004 Act, however, every clinical trial must have liability insurance that identifies who would be responsible for any 'harm' arising from the conduct of the trial. Detailed legislation is specified in two Orders of the Minister of Finance – the latest amended document is listed above. This has given an important role for the insurance broker on the committee (see 17 above).

32. What are the indemnity insurance requirements for ethics committee members themselves?

This is not covered, though it is largely recognised as being a hypothetical liability. Nevertheless, some lawyers consider it important that such liability *is* covered, and some Bioethics Committees do therefore have indemnity insurance.

33. How is informed consent obtained from vulnerable subjects who are potentially to be involved in a clinical trial?

Various safeguards exist and are precisely described in the Regulations. Clinical trials involving children are covered by Minister of Health Regulations of April 2004, mentally ill patients unable to give consent may be legally represented, and research on the unconscious patient is covered by submitting a protocol for such a study in advance to the Local Guardianship Court: this Court can then give permission for such a study to take place on condition that it is notified when an unconscious patient is actually recruited.

34. How do ECs assess the progress and outcome of research projects that they have approved?

The Order of the Minister of Health concerning detailed requirements of Good Clinical Practice and last amendments of the Pharmaceutical Act regulates these requirements.

35. How does the EC ensure reception of the Annual Safety Report and the Summary of the Final Report of a research project that it has approved?

The Order of the Minister of Health concerning detailed requirements of Good Clinical Practice and last amendments of the Pharmaceutical Act regulates these requirements.

*Validated February 2008*

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