



**The EFGCP Report on
The Procedure for the Ethical Review of Protocols
for Clinical Research Projects in Europe**
(Update: April 2009)

Czech Republic

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

For health care including biomedical research in general, the Act No. 20/1966 on the care for the health of people (many times amended, last amendment 2008) applies. Biomedical research is mentioned in § 27b.

Directive 2001/20/EC was implemented in the Czech legislation in 2003 when the Act No. 79/1997 was substituted by Act. Nr. 378 / 2007. This act also implemented Directive 2005/28/EC; Act No. 123/2000 provided the legislation on health care devices. The regulation to the Act 378/ 2007 is pending.

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

The responsible body is the State Institute for Control of Drugs (SÚKL) which is authorised for these activities concerning drugs by Ministry of Health. According to the Act nr. 378/2007 on pharmaceuticals, there are two types of ethics committees in the Czech Republic:

- a) Local ethics committees established by the director of the relevant health care institution or research institution. They review all research projects.
- b) Ethics committees for multi-centre (MEC) studies are also established by the director of the relevant health care institution or research institution, but recommended by SÚKL and approved by the Ministry of Health. They play the role of a Central EC. Each MEC is inspected annually by SÚKL.

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

Authorisation from SUKL (<http://www.sukl.cz>) is requested only for study drugs that are prepared by biotechnology (GMOs) and/or containing human or animal tissues. Clinical trials with other drugs (registered /non registered) are notified using the EU Clinical Trial Application form.

4. What is the process for obtaining ethical review of a clinical trial protocol by a competent (research) Ethics Committee in the Czech Republic?

The opinion of an ethics committee (EC) should be sought for any CT or biomedical research project to be conducted in the Czech Republic.

Single-site trial ethical review is done by the relevant Local ethics committee; multi-site clinical trial ethical review is done by an ethics committee for multi-site studies (MEC) (and also by each of the Local ECs).

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?

The website of SÚKL, which is currently the only competent authority that issues some guidelines on the ethical review of clinical trial projects, is <http://www.sukl.cz>

The Czech Forum of Ethics Committees, which is a new organisation gradually taking the initiative in this field is <http://www.forumek.cz>

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

No.

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

In parallel, but independently.

9. How many (research) ethics committees are there in the Czech Republic?

There are 9 Multicentre ECs and around 100 Local ECs.

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

Fees are paid to the institution where the EC is located, and are not paid directly to the EC. The MEC fee is charged in the range of 40,000.00 – 100,000.00 CZK (1,600.00 – 4,000.00 EUR) depending on the number of sites. Local ECs usually charge between 5,000.00 and 10,000.00 CZK. The fee for Amendment negotiation is usually 5,000.00 CZK.

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?

Requests to Local ECs may be submitted by the sponsor or the investigator. Requests to MECs should be submitted by the sponsor or the sponsor's authorised person.

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

A single opinion for the Czech Republic is made by an MEC and SUKL provides EMEA this information. In the case of a negative Local EC opinion, that is valid only for the relevant site.

Currently the sponsor can choose which MEC for multi-site studies, but mechanisms for random assignment are pending.

13. How many members serve on an EC?

Between 6 and 25.

14. How many members constitute a quorum?

Usually a majority of members, but with a minimum of 5, one not affiliated to the institution and one lay person.

15. How are EC members appointed?

They are usually named by the head of the relevant health care or research institution.

16. How is the independence of members ensured?

Mainly by an appeal to their conscience. There is obligatory membership of an EC of one lay person and one person not affiliated to the institution.

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

No member of an EC involved in a research project is allowed to be present when that project is being considered.

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

No special qualifications are sought. One lay person and one person not affiliated to the institution are demanded.

19. How do ECs obtain specialist expertise?

They can ask for expertise. This is recommended in law and by the competent authority. In research involving children, a paediatrician must be involved.

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

Currently there are no requirements. Recently, however, (at the end of 2005) the Forum of Ethics Committees was established, which will take responsibility for the education of members of EC.

21. What training programmes are available for EC members in the Czech Republic?

Currently no regular training is available. The Forum of Ethics Committees organises meetings twice a year and there is a 4 day Summer School of Medical Ethics.

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

60 days for both.

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

They are considered by the EC within 35 days, a fee having been paid (see 10).

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

There is currently no guidance on how this is done, but in practice this is the responsibility of the Local EC.

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?

Although this is a legal duty of an EC, it is not considered consequently.

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

ECs review compensation arrangements for study subjects.

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

Quality assurance process is beginning. Currently it is organised by the competent authority (SÚKL) once a year.

28. Is there an appeal mechanism?

No.

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

With many difficulties because of too much irrelevant information which the EC has no opportunity to solve. More reliance is placed on the Annual Safety Report.

30. How are 'substantial amendments' defined?

Such amendments are not defined, but it is understood as changes of design, purpose, risk/benefit or comfort for study subject, they represent a big burden.

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

Insurance is legally obligatory.

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

Members of ECs are not considered to be responsible for any risk connected with clinical trials.

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

Members of ECs know the problem and they consider carefully any research with potential involvement of vulnerable subjects. There are no special regulations.

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

Follow up of approved projects differs between ECs. There are problems of time shortage, and a low sense of competence.

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?

They acknowledge receipt of these documents to sponsor.

36. Do national regulations in the Czech Republic allow research on healthy volunteer children (subjects under 16)?

No.

37. Do national regulations in the Czech Republic allow payment, (other than expenses), to children taking part in research?

No.

Validated April 2009

© 2009 EFGCP aisbl – all rights reserved