Czech Republic

**Question 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 supreme act is the Convention on Human Rights and Biomedicine (Act No. 96/2001). An additional Protocol concerning Biomedical research is not yet ratified.


In the Act No 373/2011 on specific health services §33 - §40 regulates verification of new procedures by the use of methods which were not yet introduced in clinical practice.

**Question 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.

In March 2012 the subcommittee for clinical research was established at the Ethics Committee of Ministry of Health. According to Act No. 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
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

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.

**Question 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.

**Question 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).

**Question 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.

**Question 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.

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

No.
**Question 8:** Does the application to the REC and to the competent authority have to be submitted in parallel, or, if not, in which order?

In parallel, but independently.

**Question 9:** How many (research) ethics committees are there in the Czech Republic?

There are 11 Multicentre RECs and nearly 100 Local RECs.

**Question 10:** How are RECs 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 REC is located, and are not paid directly to the REC. The MREC fee is charged in the range of 40 000-100 000 - CZK (1600 – 4000 Euros) depending on the number of sites. Local RECs usually charge around 10 000 - CZK. The fee for Amendment negotiation is usually 5000 - CZK.

**Question 11:** Who is responsible for submitting the request for ethical review to the competent (research) ethics committee for single-site and for multi-site clinical trials?

Requests to Local RECs may be submitted by the sponsor or the investigator. Requests to MRECs should be submitted by the sponsor or the sponsor’s authorised (power of attorney) person.

**Question 12:** How is a “single opinion” achieved for multi-site studies?

A single opinion for the Czech Republic is made by an MREC and SUKL provides EMEA this information. In the case of a negative local REC opinion, that is valid only for the relevant site. Currently the sponsor can choose which MREC for multi-site studies.

**Question 13:** How many members serve on a REC?

Between 6 and 25.

**Question 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.

**Question 15:** How are REC members appointed?

They are usually named by the head of the relevant health care or research institution.
**Question 16: How is the independence of members ensured?**

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

**Question 17: How are conflicts of interest of REC members avoided?**

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

**Question 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.

**Question 19: How do RECs 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.

**Question 20: What are the training requirements for members of RECs?**

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

**Question 21: What training programmes are available for REC members in the Czech Republic?**

The Forum of Ethics Committees organises meetings twice a year and there is a 4 day Summer School of Medical Ethics. Competent authority (SÚKL) organises regular seminars for members of ethics committees.

**Question 22: What are the timelines for the assessment of single- and multi-site studies?**

60 days for both.

**Question 23: How are substantial amendments submitted during the review process dealt with?**

They are considered by the REC within 35 days, a fee having been paid (see 10).
Question 24: How does a REC 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 REC.

Question 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 REC, it is not considered consequently.

Question 26: How are the requirements for (research) ethics committees to review the compensation arrangements for study subjects handled?

RECs review compensation arrangements for study subjects.

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

A quality assurance process is continuing in MRECs. Currently it is organised by the competent authority (SÚKL) once a year.

Question 28: Is there an appeal mechanism?

No.

Question 29: How do RECs deal with SUSAR reports and Annual Safety Reports?

With considerable difficulty because of the provision of too much irrelevant information which the REC has no opportunity to solve. More reliance is placed on the Annual Safety Report and 6 Month listing. All RECs want to be provided by SUSAR reports from sites which they approved.

Question 30: How are ‘substantial amendments’ defined?

Such amendments are defined in the regulation 226 as substantial changes of documents e.g. changes of planned trial subjects, changes in dosage regime, changes of inclusion/exclusion criteria, measured parameters, or getting of evaluated samples. Also changes concerning quality of investigated products as a change of composition, production process, store conditions and expire period. They represent a big burden.
**Question 31:** What are the indemnity insurance requirements for research projects?

Insurance is legally obligatory for sponsor and investigator for a case of injury of trial subject.

**Question 32:** What are the indemnity insurance requirements for (research) ethics committee members themselves?

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

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

Members of RECs know the problem and they consider carefully any research with potential involvement of vulnerable subjects. It is obligatory to describe the process in a protocol and the REC is authorized to comment on it as well as to participate in the process of obtaining informed consent, for example: in unconscious patients.

**Question 34:** How do RECs assess the progress and outcome of research projects that they have approved?

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

**Question 35:** How does the REC ensure reception of the Annual Safety Report and the Summary of the Final Report of a research project that it has approved?

According to our law the sponsor has to send the ASR to the MREC and to the LREC if asked. Summary of Final Report is not yet asked for.

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

In particular cases, yes.

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

They do not mention this problem, but they recommend to be very careful in it.
Question 38: Do RECs invite or allow a) applicants or b) observers to attend committee meetings?

RECs sometimes invite applicants, but they are not open to any observers. They are not public meetings.

Question 39: Are the minutes of (research) ethics committee meetings made public?

No, there is no interest on any side.

Question 40: Is there any scope for Chairman’s actions in between meetings?

Only organisational, no decisional.

Question 41: Do (research) ethics committees ever appoint subcommittees for any specific purpose?

Yes, but rarely.

Question 42: Is there a national policy on the registration of clinical trials before they start?

A database of all clinical trials approved by state authority (SÚKL) exists, from the date of approval, regardless of its start.

Question 43: If the answer to Question 42 is ‘yes’, do (research) ethics committees have any role to play in reviewing such registration?

No.

Question 44: If the answer to Question 42 is ‘yes’, is this register of clinical trials made available to the public?

Yes.

Question 45: With regard to Clinical Trial Insurance, do research ethics committees in the Czech Republic work to a set template of requirements?

Not yet.

Question 46: If the answer to Q45 is ‘yes’, how are these requirements

a) Decided upon?

b) Cross referenced to statutory requirements?
c) Updated?

N/A

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