



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

Austria

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

No single legislation covers all biomedical research. Several different laws cover various different matters although some matters are not covered by special regulation, for which generally accepted legal principles apply. The following are relevant:

Drug Act

The Medicines Act (*Arzneimittelgesetz*) 1983, which has been amended on several occasions, most recently in 2008 (BGBl. I Nr. 115/2008), implementing the Directive 2001/20/EC.

Medical Devices Act

The Medical Devices Act (*Medizinproduktegesetz*) 1996, modified in 2008 (BGBl. I Nr. 77/2008).

Hospital Act

The Hospitals Act (*Krankenanstaltengesetz*) 1957, under which ethics committees were first established, modified in 2008 (BGBl. I Nr. 49/2008).

The Genetic Act (*Gentechnikgesetz*) 1994

The University Act (*Universitätsgesetz*) 2002

Data Protection Act

Bundesgesetz über den Schutz personenbezogener Daten (Datenschutzgesetz 2000 - DSG 2000), zuletzt geändert durch BGBl. I Nr. 2/2008.

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?

For the ethical review process of projects within the three Medical Universities, the Federal Act on University Organization stipulates that ethics committees have to be established to review 'applied medical research on humans'. Ethical review of medical research on humans that does not involve drugs, medical devices, or the application of a new medical method is mandatory only in university settings.

For the ethical review process outside Universities, the ethics committees in the nine Austrian provinces are established under the Hospital Act, which also covers the law of hospitals, drugs and medical devices. The supervising authority for these is the Austrian Drug Regulatory Authority (Bundesamt für Sicherheit im Gesundheitswesen). However the nine provinces are obliged to cover the regulations concerning these matters individually for their province. Austria therefore has general federal laws about the establishment of ethics committees but these laws can be interpreted locally.

The competent ethics committee is the committee established by the institution or the hospital, etc, where the patients are recruited locally, additionally the law requires the establishment of Ethics Committees for Drug trials and clinical trials with medical devices which are conducted outside of institutions (e.g. private practices etc.).

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

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

NB: For Austria Questions 3 and 4 are most appropriately answered together.

The sponsor of the Clinical Trial submits the application to the competent ethics committee (EC) and the competent authority (CA).

The CA reviews only the justification for and the relevance of the Clinical Trial

The EC acts as the “expert reviewer” for the CA and decides within 35 days, with only one “clockstop” possible to obtain supplementary information

If the EC vote is negative, the CA issues a legal document (*Bescheid*) prohibiting the clinical trial.

The website of the CA is <http://www.ages.at>

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?

There is no single website that provides this information.

The website of the Austrian Ministry for Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend) is <http://www.bmgfj.gv.at>, the website of the Austrian Drug Regulatory Authority (Bundesamt für Sicherheit im Gesundheitswesen) is <http://www.ages.at>

A website that provides information including forms, dates, contacts etc. for all Austrian ECs is <http://ethikkommissionen.at>

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

The Ethics Committee review is an integral part of the CA authorization, as the CA reviews only justification and relevance of the trial. The Ethics Committee has to inform the CA about a “clockstop”, so that the time line is interrupted. All other votes and decisions have to be forwarded to the CA.

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, or first to the Ethics Committee, as per the answer to Question 7.

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

There are about 26 (research) ethics committees in Austria.

According to the law (Hospital Act) every hospital needs to have a (research) ethics committee that has to review applications for clinical trials. Additionally the province authorities have to establish (research) ethics committees for clinical trials in institutions outside of hospitals (outpatients). This applies to clinical trials with drugs as well as to clinical trials with medical devices and methods. However, it is possible that one Ethics Committee is the competent committee for several hospitals.

Concerning the number of committees that are authorised to consider multi-site studies, see answer to Question 12 below.

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

They are permitted by law to charge fees. Usually fees are waived for applications academic research.

The fee agreed to by the Forum of Austrian Ethics Committees, an association of Austrian Ethics Committees founded on a voluntary basis in 1997 on the initiative of the Ethics Committee of the Vienna Medical University is currently (June 2007):

- a) for single site clinical trials, as well as for multi-site clinical trials with only one centre in Austria: €1,500.00
- b) for multi-site clinical trials submitted to an Ethics Committee authorized to review multi-site trials (“one single national opinion”): €1,000.00
- c) for the administration of a multi-site clinical trial at each “local” Ethics Committee: €500.00

For academic applications (without industrial sponsor) the fees may be waived. Fees include the assessment and evaluation of any follow-up documents (amendments, reports, etc.).

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 sponsor, a person authorized by the sponsor, the coordinating investigator or the principal investigator may submit the request.

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

The new Austrian drug law has changed the situation. Since the implementation of the EU Directive a single opinion procedure is possible, but is only required for clinical trials with drugs. Currently there are 7 Ethics Committees (*Leitethikkommissionen*) entitled to achieve “one single opinion”, nominated by the Health Authorities. They are the three Ethics Committees of the Medical Universities (Vienna, Graz and Innsbruck), the Ethics Committee of the City of Vienna (which is serving the Vienna public hospitals), the Ethics Committee of Lower Austria, the Ethics Committee of Upper Austria and the Ethics Committee of Salzburg.

The procedure for “one single opinion” is as follows:

The sponsor chooses the multi-site Ethics Committee, which has to be competent for one of the sites undertaking the multi-site study; if there is no such committee at any of the sites where the study is to be conducted, the sponsor chooses freely from one of the seven recognised *Leitethikkommissionen*. The sponsor submits the same application documents to local Ethics Committee as to multi-site Ethics Committees but local Ethics Committees are not included in the review procedure. The local Ethics

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

Committees may provide an opinion regarding the suitability of the site and the qualification of the investigators to the multi-site Ethics Committee.

The *Leitethikkommissionen* can refuse submission if its current workload is too big.

The multi-site Ethics Committee decides within 35 days, with only one “clockstop” permitted. If the vote is negative, the competent authority issues a legal document prohibiting the clinical trial.

13. How many members serve on an EC?

The number of members differs. There is a minimum number of 10 members, although the figure itself is not mentioned.

14. How many members constitute a quorum?

A majority of appointed members (i.e. 50% + 1).

15. How are EC members appointed?

EC members are appointed by the authority responsible for establishing the EC. This may be the university or the hospital or the institution outside the universities (see Question 2 above).

16. How is the independence of members ensured?

The independence of members is stated by law.

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

The law requires that the statutes of Ethics Committees set up regulations for cases of conflict of interests.

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

Members need to have specific qualifications.

The EC has to be constituted under consideration of a balance between male and female members.

For each application a physician (or dentist) in the specific medical field (*Medizinisches Sonderfach*) has to be involved, in addition to a physician who is not associated in any way with the trial and is not the medical director of the institution where the trial is to take place.

The constitution of the EC must include a member of the nursing staff, a member of the pharmacy, a member who has ethical expertise (eg member of the clergy), a lawyer, a

member of an instituted patients representation, a member of an organised group of handicapped representatives and a statistician.

For multi-site clinical trials on IMPs, the EC expressing the “single opinion” has to include a pharmacologist.

For clinical trials of medical devices there has to be a member with technical expertise.

The composition is regulated in the Hospital Act, the Medicines Act, the Medical Devices Act and the University Act.

19. How do ECs obtain specialist expertise?

There are two ways of obtaining specialist expertise:

1. The ethics committee is required to have one member present who specialises in the medical area (*Medizinisches Sonderfach*) of the clinical trial which the committee is assessing.
2. The second way is to get the specific expertise by asking for an expert review. The law specifies that in cases the expertise of the members is not sufficient, the Ethics Committee has to have procedures for obtaining an expert review. Additionally for paediatric clinical trials it is stated by law that there must be an expert present who has paediatric expertise. The same is required for clinical trials in psychiatry and also in emergency medicine.

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

There are generally no specific education or training requirements. The Statutes of the Medical University of Vienna and the Statutes of the Medical University of Graz however, require the chair to provide initial and ongoing training for members on a yearly basis.

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

There are some institutions such as the Vienna School of Clinical Research, an international Vienna based institution where a special international 4 days course in English language for “Ethics in Medical Research” has been held regularly twice a year since 2004. There are also other institutions which provide specific courses and seminars on this subject, eg. the yearly course “*Ethik in der Medizin*” of the Academy of the Province Lower Austria (*Niederösterreichische Landesakademie*) is a special 2 days educational course for members of Austrian Ethics Committees.

The Ethics Committee of the Medical University of Vienna offers an electronic training program for members.

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

The timelines for all applications for clinical trials with drugs which are submitted to the announced deadline are 35 days with one “clock stop” possible to ask for further information.

Clinical trials regarding gene therapy, somatic cell therapy including xenogene cell therapy as well as including all drugs with genetically altered organisms have a timeline of 90 days.

The timelines for clinical trials including medical devices are 60 days. All other trials have no regulation.

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

The process depends on the time of receipt of the amendment. If received in time, the amendment will be dealt with in the respective convened meeting of the EC and will be considered during the decision making. In case of receipt after the respective meeting the decision will be made based on the documents available at the meeting and the amendment will be dealt with separately.

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

The investigator has to provide a CV. The authorities have established minimum requirements regarding the necessary qualifications of investigators.

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?

The law requires that the Ethics Committee should evaluate the basic aspects of the financial arrangements and contracts.

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

The compensation for subjects is evaluated in the review procedure.

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

Ethics Committees do have to apply for the status of multicentre Ethics Committees providing their statutes, their SOPs, statistics, list of members etc. But there is no specific generalized accreditation procedure.

The Drug Act and the Medical Devices Act states that the authorities are entitled to carry out inspections in these fields.

28. Is there an appeal mechanism?

A limited appeal mechanism to the Competent Authority has been introduced since the implementation of the European GCP Directive.

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

Ethics Committees review the submitted documents.

30. How are 'substantial amendments' defined?

In accordance with the regulations.

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

The indemnity insurance arrangements for research projects are regulated by law in the Drug Act and as well in the Medical Devices Act.

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

There are no specific requirements for insurance of ECs.

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

If a compromised patient is a patient who is not able to consent due to an emergency situation (sepsis, accident, organ failure, etc) the Drug Act and since January 2006 also the Medical Devices Act allow for a waiver of consent if the following requirements are fulfilled:

- It is not possible to appoint a legal representative
- No information is available that the patient would refuse participation
- Research is important for the validation of data
- The drug (or medical device) is meant for emergency situations
- The trial is for the benefit for the patient (or there is no risk at all)
- The trial has the approval of a competent EC
- The EC has expertise in emergency medicine
- The interests of patient are deemed more important than public interest
- The public has to be informed (eg a poster with the information about the clinical trial at the department where the study is conducted and/or information on the website of the hospital)
- The patient has to be asked immediately after regaining consciousness for further participation otherwise his participation in the trial has to be stopped.

For all other patients who are not able to consent such as children or mentally compromised patients, respectively the parents or a legal representative has to give assent. The child and the patient have to be informed according to their ability to understand, and asked for consent.

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

If Ethics Committees operate according to international guidelines, they review on a yearly basis all approved protocols.

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?

No processes yet in place.

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

The law allows research on healthy volunteer children (the legal age in Austria is 18) if the clinical research project provides a direct benefit for the "group of children". Many other requirements have to be fulfilled. An EC with paediatric expertise has to approve the research project; clinical research on adults has to be carried out previously, the research is essential to validate data obtained in clinical trials on adults; parents/legal representatives have given written informed consent, the minor has given his assent after having been informed by a physician with experience in paediatric medicine.

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

No financial inducement for the participation is provided except compensation; the clinical trial is designed to minimise pain, discomfort, fear; the risk threshold has to be monitored continuously; the interest of the child has to prevail over the interest of science and society).

Validated April 2009

© 2009 EFGCP aisbl – all rights reserved