



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

Cyprus

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

The following laws/legislations should be known:

- (i) The law for Good Clinical Practice involving drugs for human use (Laws for 2001 until 2004).
- (ii) The law establishing the National Bioethics Committee, which was enacted in December 2001. The Ethics Committee was initiated in 2002.
- (iii) The operational guidelines for the establishment of ethics committees in reviewing biomedical research involving human subjects

All biomedical research projects involving human subjects are covered by a single legislation (for Good Clinical Practice). However, there is no legislation that pertains to non-interventional clinical studies.

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 National Bioethics Committee in Cyprus was established by the Parliament and the members are chosen by the Ministry of Health.

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

4. What is the process for obtaining ethical review of a clinical trial protocol by a competent authority in Cyprus?

(NB: For Cyprus these two questions are most appropriately answered together.)

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All clinical trials are authorized to begin only upon approval by the National Bioethics Committee and the National Health Authority (Medicines Council – a.k.a. Pharmaceutical services).

The website of the Cyprus Medicines Authority (pharmaceutical services) is:
<http://www.moh.gov.cy>

The website of the Cyprus Bioethics Committee is: <http://www.biethics.gov.cy>

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?

Yes. Trials with single or multiple sites are submitted to the National Bioethics Committee.

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 the Cyprus Bioethics Committee <http://www.biethics.gov.cy>

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

There is no procedural interaction between the National Health Authority (Medicines Council) and the National Bioethics Committee during the approval process in Cyprus.

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

Either in parallel, or sequentially, either way.
However, most sponsors opt for parallel submission.

9. How many (research) ethics committees are there in Cyprus that are recognized for the review of clinical trials with IMPs for multi-site and single-site trials?

One. Recently this committee was divided into 2 sub-groups, one of which reviews biomedical research projects and the other clinical research projects.

10. How is the EC funded in Cyprus? Does it charge fees? If yes what is its scale of fees?

The National Bioethics Committee in Cyprus is funded by a budget appointed by the Ministry of Health. The Committee does not charge fees.

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 or the investigator is responsible for submitting the request for ethical review.

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

The National Bioethics Committee makes a decision for the study as one multi-site study taking place in the republic, and not for each site independently.

13. How many members serve on the EC?

13 members serve on the National Bioethics Committee.

14. How many members constitute a quorum?

9 members, including the president (or if the president is absent, the vice-president) constitute a quorum.

15. How are EC members appointed?

The National Bioethics Committee is established by Parliament, but the members are appointed by the Council of the Ministry of Health.

16. How is the independence of members ensured?

The law that established the National Bioethics Committee states that the committee is independent and multidisciplinary. The Committee is not under the administrative control of any ministry or other body.

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

Prior to the beginning of every meeting, each member is obliged to declare any personal direct or indirect interest that he/she may have with the proposed project that will be under review during that meeting.

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

The National Bioethics Committee – if possible - is composed of 4 members from the sociology or anthropology disciplines, 4 members from the medical or biological disciplines and 4 members from any discipline, who have been acknowledged in the country for their acclaimed work.

Members are selected from citizens with distinguished morality, and knowledge in their relevant discipline.

19. How does the EC obtain specialist expertise?

If members of the committee feel they need specialist expertise in order to reach a conclusion, they have the right to ask for the opinion of an expert who is not a member of the committee.

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

Members of the committee are supposed (based on the Ethics Committee Operational Guidelines in Cyprus) to receive introductory training in the work of an Ethics Committee, as well as continuing opportunities to improve and increase their abilities for ethical review. The training of the members is solely the responsibility of the institution that established the Ethics Committee.

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

Ethics Committee Members in Cyprus have access to various specific training programmes; however, more information is not available.

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

Time assessments are the same for both single- and multi-site studies. The National Bioethics Committee has 60 days from the day it receives the application, to review the application and come back with an answer whether the study is approved or not, or to come back with questions regarding points in the application that require clarification or further information. For studies using gene or somatic cell therapy, the 60 day deadline can be extended for 30 more days.

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

If the amendments are important for the safety of the subjects or would lead to altered scientific deduction, the sponsor informs the National Bioethics Committee about the importance of the amendments, and submits the amendments to the Committee as well as the Health Authorities. The National Bioethics Committee then has 35 days from the day the amendments were submitted to make a decision.

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

By asking for the investigator's CV (which includes the investigator's past clinical research experience) in the application form. No requirements for site-assessment exist in the application form for EC approval.

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?

A copy of the financial agreement is required to be submitted to the Cyprus Ethics Committee.

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

Not known.

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

Yes, the Committee had to establish SOPs and abide by them. The Ministry Council has the right to dismiss any member of the Bioethics Committee who has been sick for an extended period of time, has missed a lot of the meetings, or for misconduct.

28. Is there an appeal mechanism?

Yes, the Principal Investigator has the right to appeal the decision of the Bioethics Committee. The Bioethics Committee reviews the appeal as soon as possible and issues its decision which is final and binding to all parties.

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

In all SUSARs reports, the program/study is re-evaluated by the Ethics Committee, which will communicate its opinion to the applicant. The Committee has the right to approve changes in the protocol of the study, to postpone or terminate the study.

30. How are 'substantial amendments' defined?

For the Ethics Committee in Cyprus, any protocol amendment (minor or major) is considered important and has to be submitted to the Committee for review and approval. This is the standard procedure.

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

The sponsor is required to provide indemnity insurance for research projects. Specific requirements are unknown.

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

Not known.

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

In the case of a vulnerable subject, his/her guardian or representative must have a chance to discuss with the investigator or member of the investigating team and understand the purpose of the study, the dangers and disadvantages. The participant in the study must be notified of his right to remove himself from the study at any point during the study. The legal guardian or representative of a vulnerable subject can give his/her informed consent in order for the subject to take part in the study.

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

The EC has the right to perform follow-up evaluations of the research if deemed necessary. If complaints are voiced by participants, then the committee can re-assess the ethical validity of the project.

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

Submission of an annual safety report or a summary of the final report is not compulsory, however, the EC may ask for it at one of the follow-up evaluations. If, however, a request for a final report or an annual safety report submission is made by the EC upon the initial approval of the research project, then the documents must be submitted to the EC for evaluation at the appropriate time.

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

No, only on children having a medical condition relevant to the study or of such nature that it is applied only to children. Strict regulations apply on research on children.

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

No, it is not allowed.

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