



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

**Greece**

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

The Greek legislation concerning interventional clinical trials on investigational medicinal products (CTIMPs) was published in the Greek Republic Gazette No 1973 of 31 December 2003. It refers to the Minister of Health's decision DYG 3/89292, which describes the law under which the Directive 2001/20/EC was adopted in Greece. The law has no title, as all laws in Greece are referred to by number.

Standard Operating Procedures for the National Ethics Committee were published in the Greek Republic Gazette No 1503 of 7 October 2004, referring to the Minister of Health's decision DYG 3(A) 69150.

*NB: The above legislation is published in Greek.*

The above legislation covers all interventional clinical trials including trials involving genetic and other biomedical research.

Medical Devices are covered by circular 33523/17-05-2007 describing the documentation and the application forms required. All non-interventional trials are still covered by the earlier legislation, A6/10983/1 of 1984, which covered all clinical research. Circular 55480/6-09-2006 describes the documentation and the application forms required.

Clinical studies involving the drawing of blood, etc (for other purposes) are not covered by legislation.

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 Ethics Committee (NEC) was established by a ministerial decision, the

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Chairman and Vice-Chairman of the NEC are determined by the Minister of Health. Ethics committees historically established by all the institutions in Greece still survive, but all clinical trials are now the responsibility of the NEC as established in the legislation published in December 2003 (see 1 above).

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

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

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

In order to conduct a clinical trial in Greece the application must be submitted to the EOF and a separate application must also be submitted to the National Ethics Committee (NEC). The EOF may only issue an authorisation once it has seen the approval of the NEC.

The website of the Greek Licensing Authority (EOF) is at <http://www.eof.gr>

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, the National Ethics Committee (NEC).

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

Not applicable. Relevant email address: [eed@eof.gr](mailto:eed@eof.gr)

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

The opinion of the National Ethics Committee (NEC) is communicated in written to EOF when issued.

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

No, it can be submitted in parallel or in the order preferred by the applicant.

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

One central (National Ethics Committee) and one in each hospital (Local Ethics Committee).

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

The NEC is funded by Ministerial Decision. No fees are charged.

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 applicant can be the sponsor or in case of non-sponsored trials by the investigator.

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

From the Greek NEC.

13. How many members serve on the NEC?

Nine.

14. How many members constitute a quorum?

Five, as set out in the legislation.

15. How are EC members appointed?

By the Minister of Health. Vacancies are not advertised.

16. How is the independence of members ensured?

The members complete an indemnity statement immediately after they are appointed.

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

Members are obliged to declare any conflicts of interest before each meeting, if there is a problem of this kind, the member is substituted.

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

Six are scientists in the health sector, one is a lawyer, one is a priest and one is a sociologist. There is no statutory requirement for a statistician or a pharmacist.

19. How do ECs obtain specialist expertise?

By agreeing on suitable experts usually in government and university employment, who are also independent of the trial study. Health Scientists Experts should have clinical research experience and actively involved in patient treatment.

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

None defined apart from their professions. Their curricula vitae should be published and updated yearly.

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

None.

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

60 days, in accordance with the legislation (see 1 above) in both cases.

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

They are reviewed within 35 days, in accordance with the legislation (see 1 above).

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

The local EC from each hospital is requested to raise any objections to the NEC within 30 days of notification of the trial in written by the Investigator. The SOPs of December 2004 (see 1 above) allow the NEC to ask the EOF to conduct a site visit accompanied by a member of the NEC. The NEC can also request any information it wants (undefined) from an investigator.

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?

One of the documents requested by the NEC is the study budget for each site, which must be notified to the Regional Health Authority, this authority is responsible to review and approve the budget.

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

Payment to volunteer subjects in Phase I studies is included in the study budget. Patient subjects are not expected to be paid.

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

No.

28. Is there an appeal mechanism?

No.

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

SUSARS are routinely received and Annual Safety Reports are required. However, the NEC is not yet experienced in dealing with these reports, but it can ask for any report it wants during the course of a study.

30. How are 'substantial amendments' defined?

These are defined (in Greek) in the legislation (see 1 above) and in EC detailed guidance on CT applications of Oct 05 which has been translated into Greek.

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

An insurance policy is required and a copy of the insurance certificate must be submitted to the NEC.

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

Not applicable.

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

This is specifically covered in the legislation (in Greek) (see 1 above).

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

This is covered in the SOPs of December 2004 (but see 29 above).

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?

Not yet defined.

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

No, it is not allowed.

*Validated April 2009*

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