



'where science & ethics meet'

The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union

EFGCP ETHICS WORKING PARTY SUBGROUP
ON ETHICS COMMITTEES REVIEWING CTIMPs ACROSS THE EU

INDEX OF QUESTIONS

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

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?

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

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

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?

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

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

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

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

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

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

13. How many members serve on an EC?

14. How many members constitute a quorum?

15. How are EC members appointed?

16. How is the independence of members ensured?

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

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

19. How do ECs obtain specialist expertise?

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

21. What training programmes are available for EC members?

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

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

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

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?

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

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

28. Is there an appeal mechanism?

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

30. How are 'substantial amendments' defined?

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

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

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

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

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?