



Where science & ethics meet

The EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond

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

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 in Austria?

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

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 REC 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 Austria?

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

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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?

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

13. How many members serve on an REC?

14. How many members constitute a quorum?

15. How are REC members appointed?

16. How is the independence of members ensured?

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

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

19. How do RECs obtain specialist expertise?

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

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

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 REC 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 (research) 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 in Austria?

28. Is there an appeal mechanism?

29. How do RECs 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 (research) 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 RECs assess the progress and outcome of research projects that they have approved?

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?

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

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

38. Do RECs invite or allow a) applicants or b) observers to attend committee meetings?

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

40. Is there any scope for Chairman's actions in between meetings?

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

Validated April 2010