Finland

**Question 1:** What laws or regulations apply to an application for conducting a clinical trial in Finland?

A number of national laws, some of them incorporating EU Directives.

These include the Medical Research Act 488/1999 and the subsequent amendment 295/2004 which incorporates the requirements of the clinical trials directive 2001/20/EC.


The website for the Ministry of Social Affairs and Health, which is responsible for this Act, is at [http://www.stm.fi](http://www.stm.fi).

The Medical Research Act has been followed by the Medical Research Decree (898/1999) and its amendment (313/2004).

The Ministry of Social Affairs and Health has given a Decree on Clinical Trials (316/2005). It was amended in 2010 (841/2010).

The [Government has given a Decree on the National Committee Medical Research Ethics (820/2010)](http://www.stm.fi).

There are also statements concerning clinical trials in the Act on Medicines (395/1987, amendment 296/2004).

National Committee on Medical Research Ethics (TUKIJA) was set up on 1 October 2010. Its’ office is situated under the auspices of the National Supervisory Authority for Welfare and Health (Valvira). TUKIJA's responsibilities include:

- Issuing national opinions on clinical drug trials, unless the duties have been delegated to regional ethics committees;
- Issuing opinions on previously rejected trial proposals to regional ethics committees where these are resubmitted unchanged;
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- Advising regional ethics committees in matters of ethical principle, especially as regards clinical drug trials and provision of related training;
- Participating in international cooperation on research ethics;
- Gathering and conveying information on research ethics issues and provide information on the international debate on research ethics in the form of publications, training sessions and other such activities; and
- Promoting the public debate on medical biomedical research.


The National Agency of Medicines has given orders (Order 2/2004).

The forming research registries need to follow the rules of the Personal Data Act (523/1999).

**Question 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?

Under Section 16 of the Medical Research Act, each university hospital district (5 regions) in Finland shall have at least one ethics committee. They are responsible for prior evaluation of medical research projects and for delivering an opinion on them. A single opinion on clinical trials on medicinal products shall be given by the National Committee on Medical Research Ethics (TUKIJA) unless this has been delegated to one of the Regional Ethics Committees.

The Regional Ethics Committees also evaluate tissue studies, epidemiological studies, studies based on interviews and nursing studies, and consider any other studies involving human subjects even where these are not required to be their responsibility.

There are other voluntary based ethics committees for other fields (humanities, etc) in universities and research centres.

**Question 3:** What is the process for achieving clinical trial authorisation from the competent authority in Finland?

Application is made to the National Agency for Medicines (Lääkelaitos) using a form that can be downloaded from its website
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(http://www.fimea.fi/healthcare_professionals/clinical_drug_trials) or from the EMA
website (https://eudract.ema.europa.eu/eudract/index.do). The form can be completed
in English, Finnish or Swedish.

**Question 4: What is the process for obtaining ethical review of a clinical trial protocol by a competent (research) ethics committee in the Czech Republic?**

The first step in all clinical trials is for the sponsor to apply for a ruling from TUKIJA on whether the ethical admissibility of the proposal is to be reviewed by TUKIJA or by one of the regional ethics committees. Sponsors can apply for a ruling on jurisdiction as soon as it becomes likely that the trial in question will be run in Finland, even if the actual application is not yet complete. Depending on the ruling, the sponsor then applies for an ethics review to be carried out either by TUKIJA or by the relevant regional ethics committee.

The Finnish Ministry of Social Affairs and Health has produced a form to be used in connection with rulings on jurisdiction. The same form is used both by the applicants and by TUKIJA. Applicants are also requested to submit their applications to TUKIJA’s secretary in electronic format (as pdf or rtf files) by e-mail to tukija(at)valvira.fi

More information:
http://www.tukija.fi/en/operations/meetings/rulings

Depending on the ruling, the sponsor then applies for an ethics review to be carried out either by TUKIJA or by the relevant regional ethics committee. All applications for ethics reviews of clinical trials must be made using the form issued by the Finnish Ministry of Social Affairs and Health according to the instructions provided. The documents listed on the form must be included in all applications.

All documents pertaining to trials must be submitted to TUKIJA no later than two weeks before the meeting during which the proposal in question is to be reviewed.

More information (e.g. TUKIJAs operating procedures):

**Question 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?**

All the clinical trials on medicinal products must be evaluated by one EC in Finland.
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Question 6: What is the website for the organisation that issues guidelines on the ethical review of a clinical trial for an investigational medicinal product?

http://www.tukija.fi/en/

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

In the case of clinical trials on MPs the REC’s must send a copy of their opinion to the Finnish Medicines Agency (Fimea):
http://www.fimea.fi/healthcare_professionals/clinical_drug_trials

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

Applications may be submitted in parallel.

Question 9: How many (research) ethics committees are there in Finland?

There are 9 districts or research institute ethics committee, established by the university hospital districts.

Question 10: How are RECs funded in Finland? Do they charge fees? If yes, what is their scale of fees?

They are funded by hospital districts that collect fees from opinions based on a Decree issued by the Ministry of Social Affairs and Health (46/2012).

Question 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?

The person in charge of the investigation (“principal investigator”). It can be submitted also by a sponsor.

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

According to the Medical Research Act each medical research study needs only one opinion of a research ethics committee. In the Medical Research Act it is stated that the study is evaluated in the REC of the region where the person in charge of the research (principal investigator) works or where the majority of the research is performed.
**Question 13: How many members serve on a REC?**

There must be a chairperson and at least six other members. Disciplines other than medicine must be represented (philosophers, lawyers, etc.) and there must be at least two lay members. Many RECs of the hospital districts have more than 10 members.

**Question 14: How many members constitute a quorum?**

Half of the members. There must be at least one lay member and two from outside the unit where the research is planned to be performed.

**Question 15: How are REC members appointed?**

The boards of the university hospital districts are responsible for appointing members in accordance with Section 18 of the Medical Research Act 488/1999.

**Question 16: How is the independence of members ensured?**

There is a specific law with details, under which everyone in a governmental body must declare conflicts of interest (when they occur) (Governmental Act 434/2003).

**Question 17: How are conflicts of interest of REC members avoided?**

According to Governmental Act (434/2003) conflicts of interests need to be declared.

**Question 18: What backgrounds and/or qualifications of members are actively sought?**

Based Act on Medical law (488/1999, amended 794/2010) the committees shall contain representatives from research ethics, medicine, health science or nursing science, and science of law. At least two members shall be laypersons.

If the REC evaluates clinical trials on minors, paediatric expertise need to be present (either as a member or an external consultation), the same when evaluating research with incompetent persons.

**Question 19: How do RECs obtain specialist expertise?**

See 18 above. For specific needs a written statement from an external expert may be asked for.

**Question 20: What are the training requirements for members of RECs?**

There are no specified requirements as such. However, TUKIJA supports regional ethics commissions in ethical matters of principle related to medical and other health care research and assists it in providing suitable training in these fields.
**Question 21:** What training programmes are available for REC members in Finland?

The hospital districts and the national committee (TUKIJA) organise training. National seminars are held twice yearly (one by (TUKIJA) and one by one of the university hospital region ethics committees). The national committee also issues instructions and recommendations in ethical issues related to research.

**Question 22:** What are the timelines for the assessment of single- and multi-site studies?

Timelines are based on Directive 2001/20/EC.

**Question 23:** How are substantial amendments submitted during the review process dealt with?


**Question 24:** How does a REC assess the suitability of investigators and of sites?

For the investigator, his/her CV must be submitted. The principal investigator gives a statement on the quality of the sites.

**Question 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?

They are included in the application and reviewed during the process.

**Question 26:** How are the requirements for (research) ethics committees to review the compensation arrangements for study subjects handled?

They are included in the application and reviewed during the process. Monetary compensation for healthy subjects is evaluated according to the Decree 82/2011.

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

No.

**Question 28:** Is there an appeal mechanism?

Yes. If the researcher wishes the study that has got a negative opinion to be evaluated
as it is he/she can resubmit the application to the REC that has to ask for an opinion of the National Committee on Medical Research Ethics (TUKIJA).

**Question 29:** How do RECs deal with SUSAR reports and Annual Safety Reports?

Finnish ECs do not evaluate individual SUSARs.

**Question 30:** How are ‘substantial amendments’ defined?

They are not defined in legislation but treated according to guidelines in Directive 2001/20/EC. TUKIJA has defined substantial amendment as follows:

Such amendments significantly influence e.g. the following aspects of the trial:

- The safety or physical or mental integrity of the subjects.
- The scientific value and significance of the trial.
- The conduct of the management of the trial.
- The quality or safety of any investigational medicinal product used in the trial.

**Question 31:** What are the indemnity insurance requirements for research projects?

Projects need to have an insurance (given by a pool of companies). Most of the trials are covered by treatment injury insurance and insurance of injury caused by medicinal product. Many trials have also a private extra insurance to cover additional issues (such as accidents etc.) not connected to the investigational product.

**Question 32:** What are the indemnity insurance requirements for (research) ethics committee members themselves?

There are none.

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

Extensive guidelines on research involving adults unable to consent for themselves (Section7) and research on minors (Section 8) is given in the Medical Research Act itself (available, in English translation, at [http://www.finlex.fi/en/laki/kaannokset/1999/en19990488](http://www.finlex.fi/en/laki/kaannokset/1999/en19990488)).

If minors less than 15 years are studied, the consent is given by the guardian. Minors older than 15 years of age can give an individual consent, if the research is supposed to give direct benefit for research participants. In this case guardians are informed about the trial. If direct benefit is not expected, the consent from guardians is required. If the minor understands the purpose, risks and benefits of the trial, the consent/assent of the minor is also required.
If an adult is not able to give his/her consent, it will be sought from his/her family member or other person closely connected with the person or his/her legal representative.

**Question 34:** How do RECs assess the progress and outcome of research projects that they have approved?

From the annual safety reports and final reports. Otherwise they are not meant to monitor the research.

**Question 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?

They note them as they are received.

**Question 36:** Do national regulations in Finland allow research on healthy volunteer children (subjects under 16)?

Yes. See 33 above.

**Question 37:** Do national regulations in Finland allow payment, (other than expenses), to children taking part in research?

No.

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

Applicants can be invited to present their projects. Observers are not allowed to attend REC meetings, which are confidential.

**Question 39:** Are the minutes of (research) ethics committee meetings made public?

No.

**Question 40:** Is there any scope for Chairman’s actions in between meetings?

The Chairman may consider responses received from applicants in answer to queries raised by the REC. He/she also represents committee in different occasions. Otherwise none.
Question 41: Do (research) ethics committees ever appoint subcommittees for any specific purpose?

When needed.

Question 42: Is there a national policy on the registration of clinical trials before they start?

No.

Question 43: If the answer to Question 42 is ‘yes’, do (research) ethics committees have any role to play in reviewing such registration?

N/A

Question 44: If the answer to Question 42 is ‘yes’, is this register of clinical trials made available to the public?

N/A

Question 45: With regard to Clinical Trial Insurance, do research ethics committees in Finland work to a set template of requirements?

No.

Question 46: If the answer to Q45 is ‘yes’, how are these requirements
   a) Decided upon?
   b) Cross referenced to statutory requirements?
   c) Updated?

N/A