Norway

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

There are a number of acts that are relevant or made valid for biomedical research, some of them implementing EU-directives, some of them being special national acts.

Clinical Trials are mainly regulated by international and national laws and the European Directive 2001/20/EC, which is fully implemented in the Norwegian Regulation relating to clinical trials on medicinal products for human use, of 24 September 2003, with an update which came into force 2006-06-30. It was last updated on 26th March 2010 and can be accessed in English at: [http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf](http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf).

Other laws include:

- Act on the medical use of biotechnology (2003, last revision).
- Act on Ethics and integrity in research (2006).

**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?

Ethical review of biomedical research was organised in Norway during the late 80s and in 1988-89 the Norwegian Government proposed the establishment of three national committees for research ethics. This proposal was approved by Parliament in 1990, and the Ministry of Education, Research and Church Affairs developed a
mandate. Three independent but coordinated national committees for research ethics cover all scientific disciplines. One is the National Committee for Medical Research Ethics, which is an advisory and coordinating body for the five regional committees but not an appeal body. Its main tasks are to inform and advise scientific communities, governmental authorities and the general public. The others are the National Committee for Research Ethics in Science and Technology and the National Committee for Research Ethics in the Social Sciences and the Humanities.

The five regional committees operate under terms of reference issued by the Ministry of Education and Research. They carry out the ethical review of biomedical research projects. The Ministry of Research and Education is now called The Ministry of Knowledge. It does not have a supervisory function over the regional committees.

For details, visit [http://www.etikkom.no](http://www.etikkom.no).

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

Application is made to the Norwegian Medicines Agency (Legemiddelverk) using a form that can be downloaded from its website ([http://www.legemiddelverket.no](http://www.legemiddelverket.no)) An English translation is available.

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

Application is made to the relevant Regional Ethics Committee using a form that is available on the following website: [http://www.etikkom.no/Engelsk/NEM/REK](http://www.etikkom.no/Engelsk/NEM/REK). An English translation is available.

**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?

Yes, any one of the five Regional Ethics Committees (see Questions 9 and 12).

**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?


The website of the Legemiddelverk is at [http://www.legemiddelverket.no](http://www.legemiddelverket.no).

**Question 7:** Is there a procedural interaction between the national or local competent authority and the (research) ethics committee during the approval process?
No.

**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?

This is up to the discretion of the applicant, as there is nothing stated in laws or regulations.

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

There are five regional committees in Norway, which correspond to the National Health Service organisation are: Eastern, Southern, Western, Central and Northern.

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

They are funded by the State. No fees are charged.

**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 investigator.

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

A decision from any of the five Regional Ethics Committees will form that single opinion (only one Committee needs to review any clinical trial for an investigational medicinal product; which one depends on the location of the Chief Investigator).

**Question 13:** How many members serve on a REC?

Eight.

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

The committees are quorate when six members/ deputies are present. In the event of equality of votes, the chairperson shall have the casting vote.

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

By the Ministry after cumbersome nomination procedures.

**Question 16:** How is the independence of members ensured?
By the organization of the committees, apart from institutional affiliation and also by Standard Operating Procedures (see www.etikkom.no).

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

The (Norwegian) Public Administration Act chaps. I-III (scope of the Act, rules governing disqualification, rules governing administrative procedures) and ss.18 -20 (on parties’ right of access) apply to the committee’s dealings.

Standard Operating Procedures (see www.etikkom.no) also apply.

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

The research ethics committees shall be composed of the following members:

- A medical professional from the faculty of medicine in the region.
- A medical professional from the official health authorities of the region.
- A member with qualifications in psychology from the department or faculty of psychology in the region.
- A member with officially recognised nursing qualifications.
- A representative of the regional hospital owners.
- A member with professional expertise in ethics.
- A lawyer.
- A lay representative.

Eight personal deputies shall be appointed.

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

See Question 18.

If the necessary expertise is not represented on the committee, by consultation.

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

None.

**Question 21: What training programmes are available for REC members in Norway?**

There are programs developed and available at the University of Oslo and at the University of Bergen.

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

The regulations state that the timeline, for single site and multi-site studies, is 60 days from the acknowledgement of the application. It is however more likely to be approximately 30 days.
**Question 23:** How are substantial amendments submitted during the review process dealt with?

They are fully reviewed by the Committee.

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

It assesses the suitability of the investigator, usually by CV. It does not assess 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?

See the application form and its guidance ([www.etikkom.no](http://www.etikkom.no)). It requires copy of agreements as well as a self declaration of economic interests and of possible conflicts of interests.

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

Compensation is allowed depending on the context and the type of project.

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

No.

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

Yes. Decisions of a regional EC may be appealed to the National EC.

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

They are received and reviewed by the committee, but this is usually delegated to the chairman.

There are attempts to exempt SUSAR reports from the REC – and to leave their review only to the Norwegian Medicines Agency.

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

Not defined.
**Question 31:** What are the indemnity insurance requirements for research projects?

Regulated by two acts, one on medicinal products and one on patient liability

**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?

It depends on a number of factors, but a set of guidelines on research on vulnerable subjects has just been developed. (see www.etikkom.no).

The legal situation is complicated and sometimes not clear.

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

They do not assess any progress or outcome. They ask for annual reports, and in some types of research projects they do follow-up in terms of interim reports, monitoring and the like – but this is only in rare instances.

**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?

There is no system to ensure reception or follow up of missing reports.

**Additional information:**

The Act of 30 June 2006 No 56 on ethics and integrity in research.

*Section 1: Purpose of the Act*

This Act seeks to ensure that research carried out by public and private institutions is conducted in accordance with recognised ethical standards.

*Section 2: Autonomy*

Committees and commissions appointed pursuant to this Act shall be state bodies that are autonomous in professional matters.

*Section 3: National research ethics committees*

National research ethics committees that collectively cover all disciplines shall be established. These committees shall serve as advisory bodies on research ethics. The
Ministry will establish such committees, determine the committees’ fields of responsibility and appoint members.

The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Section 4: Regional committees for medical and health research ethics

Regional committees for medical and health research ethics shall be established. The Ministry will establish such committees, determine the committee’s fields of responsibility and appoint members. Members shall be appointed on the basis of proposals from relevant bodies. The committees shall have expertise in relevant research disciplines, ethics and law. They shall also have lay members.

Research projects in Norway that involve experiments on human subjects shall be submitted to the committee for approval. Research projects conducted outside Norway shall be submitted to the committee for approval if the research is being carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Appeals against decisions made by the committees may be lodged with the National Committee for Medical and Health Research Ethics. The decision of the National Committee is final and may not be further appealed.

Section 5: The National Commission for the Investigation of Scientific Misconduct

A national commission for the investigation of scientific misconduct shall be established. The commission shall give a statement as to whether scientific misconduct has occurred in research conducted in Norway. The commission shall also give a statement on research conducted outside Norway if the research has been carried out by a researcher employed by a Norwegian employer or if a substantial portion of the funding comes from Norway.

Scientific misconduct is defined as falsification, fabrication, plagiarism and other serious breaches of good scientific practice that have been committed wilfully or through gross negligence when planning, carrying out or reporting on research.

The members of the commission shall be appointed by the Ministry. The commission chair shall have judicial experience. The composition of the commission shall ensure that the commission has the necessary expertise in the field of research and research ethics.

The commission may in individual cases decide that the documents relating to a case shall not be made public until a final statement has been given.

The Ministry is the administrative appeals body for appeals regarding the administrative procedures of the commission. Appeals regarding the content of the statement shall be dealt with by a specially appointed commission. A special commission shall be appointed for each appeal and shall comprise members with the necessary professional or technical, research ethics and legal expertise. The decision of the special commission is final.
The Ministry may make supplementary regulations regarding the appointment and administrative procedures of committees and commissions pursuant to this Act.

Section 7 Commencement

This Act shall enter into force from the date decided by the King.

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

Yes.

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

Yes, but only in kind in the shape of a small toy or other inexpensive gift, as a way of say ‘thank you’ but not as coercion.

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

Applicants are invited, but observers are not invited.

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?

Yes, when considering minor protocol amendments. Otherwise only the full committee can make decisions, including those based on responses from applicants to queries raised.

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

No.

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

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