Iceland

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

Act on the rights of patients no. 74/1997 (http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/34).

Regulation on scientific research in the biomedical field, no. 286/2008 (http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/2847).

Regulation on clinical trials of medicinal products in humans no.443/2004: (http://eng.heilbrigdisraduneyti.is/media/Reglugerdirenska/).

Regulation on clinical trials of medicinal_products_in_humans_No443-2004 (pdf).


Rule no. 698/2004 on the obligation to notify and processing which requires a permit: (http://www.personuvernd.is/information-in-english/greinar/nr/441).

Rule no. 299/2001 on security of personal data: (http://www.personuvernd.is/information-in-english/greinar/nr/442).
**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?

Reg. 286/2008 states in Art. 3: “The Minister of Health appoints the National Bioethics Committee, comprising seven members, for a term of four years, to consider scientific research projects in the biomedical field”.

This committee is responsible for assessing the ethical aspects of all scientific health-related research involving humans, including clinical trials, multi-site research projects, medical devices, biobanks, data collection and genetic research.

At the University-Hospital and the Akureyri Hospital there are local ethics committees for reviewing research carried out at these institutions or in cooperation between them and the universities (Reg 286/2008, Art 4, para 1 and 2):

1. **The Ethics Committee of Landspítali University Hospital.** The executive committee of Landspítali appoints an Ethics Committee of seven members for a term of four years.

2. **The Ethics Committee of Akureyri Hospital.** The executive committee of the Hospital appoints an Ethics Committee of seven members for a term of four years.

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

See Reg. 443/2004: An application for a clinical trial of a medicinal product shall be sent to the Icelandic Medicines Control Agency (IMCA) and to the National Bioethics Committee (NBC). See further guidelines on NBC’s homepage (under revision). ([http://www.visindasidanefnd.is/English](http://www.visindasidanefnd.is/English)).

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

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?

No. However all clinical trials need an approval by the NBC which is the only EC in Iceland dealing with clinical trials.

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 Ministry of Health: http://eng.heilbrigdisraduneyti.is/laws-and-regulations/. See further NBC’s homepage (http://www.visindasidanefnd.is/English) and IMCA homepage (http://www.lyfjastofnun.is).

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

The ethics committee submits its decision to the IMCA. No other procedural interaction is defined. The NBC requests for the file a copy of all permits issued for a project approved by the committee, including permits for accessing patient records or other databanks however the NBC’s approval is not depending on these permits or approvals.

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?

No, and in no special order, however a clinical trial may not commence without approval from all competent authorities.

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

Three, see Art. 3 and 4 of Reg. 286/2008.

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

EC’s are publicly funded, 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 Principal Investigator who is also the contact person for all NBC’s correspondence on the project in question.

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

Art. 5 in Reg. 286/2008, reads: “The National Bioethics Committee shall consider collaborative projects, multi-national research projects, clinical pharmaceutical research projects subject to the provisions of the Regulations on Clinical Pharmaceutical Research on Human Beings no. 443/2004, and other planned scientific studies in the biomedical field, which are not within the mandate of ethics committees under Art. 4”.

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

Seven and there are seven substituting members nominated and appointed in the same manner.

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

A simple majority, i.e. four members.

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

1. **The National Bioethics Committee:** One member of the committee shall be appointed on nomination by the Minister of Education; one on nomination by the Minister of Justice and Human Rights, who shall be a law graduate; two on nomination by the Medical Director of Health, of whom one shall be a physician; and one on nomination by the University of Iceland Ethical Research Institute. Two members shall be appointed by the Minister of Health without nomination, one of whom shall be a physician. The Minister appoints the chair of the committee. The committee elects a deputy chair from among the members. Substitutes shall be appointed in the same manner. It shall be ensured that the committee includes individuals with expertise in the fields of biomedical science, ethics of research, human rights and social science.

2. **The University Hospital EC:** The hospital’s Medical Council and Nursing Council, the University of Iceland and the Medical Director of Health shall each nominate one member of the committee; the representative of the Medical Director of Health shall be independent of Landspítali University Hospital. In addition one member of the committee shall represent other healthcare professions, nominated by the executive committee, and two shall be appointed by the executive committee without nomination, one of whom shall be a physician and the other a law graduate. Substitutes shall be
The committee grants permission for research projects in the biomedical field to be carried out at the hospital, and research projects in the biomedical field to be carried out in collaboration between Landspítali University Hospital and the University of Iceland or the University of Akureyri.

3. **The Akureyri Hospital EC:** The hospital’s Medical Council and Nursing Council, the University of Akureyri and the Medical Director of Health shall each nominate one member of the committee; the representative of the Medical Director of Health shall be independent of Akureyri Hospital. In addition one member of the committee shall represent other healthcare professions, nominated by the executive committee, and two shall be appointed by the executive committee without nomination, one of whom shall be a physician and the other a law graduate. Substitutes shall be appointed in the same manner. The committee grants permission for research projects in the biomedical field to be carried out at the hospital or the University of Akureyri, or to be carried out in collaboration between Akureyri Hospital and the University of Akureyri or the University of Iceland.

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

No specific assurances are made; however, EC’s have the status of independent administrative boards, working at an arm's length from the Ministry of Health resp Hospital Authorities. The members receive a modest payment.

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

Conflicts of interest are resolved according to the Administrative Procedures Act No. 37/1993 ([http://eng.forsaetisraduneyti.is/acts-of-law/nr/17](http://eng.forsaetisraduneyti.is/acts-of-law/nr/17)).

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

Art 3 of Reg. 286/2008 states: “It shall be ensured that the committee includes individuals with expertise in the fields of biomedical science, ethics of research, human rights and social science.”

The current composition of the NBC is listed at [www.visindasidanefnd.is](http://www.visindasidanefnd.is).

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

According to Reg. 286/2008, the National Bioethics Committee may seek expert opinion when necessary.
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: May 2011)

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

See Items Nr. 15 and 18 (above). Formal requirements are made to the representatives nominated by the Ministry of Justice and Human Rights, and to one of two members nominated by the Director of Medical Health and one of the members appointed by the Minister of Health (without nomination).

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

None specifically for EC members, an Applied Bioethics program is taught at the University of Iceland.

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

Multi-site studies are regarded as “a single” application in this context. According to Reg. 443/2004, the ethics committee has 60 days to assess clinical trials, barring special circumstances (see Art. 6). The NBC may make one request for additional data after it receives a valid application; the application process shall be suspended until the committee receives the data requested. Subjects brought to the NBC come preferably on the agenda of the next meeting, usually within 14 days. Approvals are issued within 50 days on the average - depending chiefly on the time applicants need for responding to remarks and requests for clarification, as applies.

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

All amendments are reviewed and approved by the ethics committee (as well as by the IMCA in the case of clinical trials). Substantial amendments can be made to a study which has been approved by the Committees. Amendments shall be decided upon within 35 days from submission to the NBC.

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

CV’s and bibliographies are obtained for principal investigators. Research sites are visited.

**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?

Information is requested and assessed. Decisions by the EC concern ethical aspects and scientific quality.
**Question 26:** How are the requirements for (research) ethics committees to review the compensation arrangements for study subjects handled?

Remuneration of studies subjects is prohibited, except as compensation for costs resulting from the participation. The amount allowed is the subject of discussions of the NBC in each case.

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

No. Initial steps are being taken in developing such a procedure (NBC and LSH).

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

Art. 11 of the Reg. 286/2008: “The National Bioethics Committee under Art. 3 and the bioethics committees under Art. 4 shall comply with the provisions of the Public Administration Act in their decisions. A decision of an ethics committee under Art. 4 may be appealed to the National Bioethics Committee. A decision of the National Bioethics Committee may be appealed to the Minister.

See further the Public Administration Act No. 37/1993: ([http://eng.forsaetisraduneyti.is/acts-of-law/nr/17](http://eng.forsaetisraduneyti.is/acts-of-law/nr/17)).

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

The sponsor must see to that the Icelandic Medicines Control Agency (IMCA) and the NBC receive notification of any serious adverse reactions which may arise. If no sponsor is connected to the clinical trial, cf. sub-paragraph i of Art. 2, this shall be the responsibility of the principal investigator or, as the case may be, the investigator. The following time limits shall apply for such notifications:

a) For an adverse reaction resulting in death or an unexpected life-threatening situation caused by the trial medicinal product, notification must be given immediately or within one week (7 days) of the occurrence of the reaction.

b) All suspected serious and/or unexpected adverse reactions must be notified within 15 days.

If a clinical trial lasts for more than one year, an annual report must be sent to the IMCA and the NBC, giving an account of the status of the clinical trial and a summary of all serious adverse events.

No later than one year following the conclusion of the clinical trial, the final report must be sent to the IMCA and the NBC.
**Question 30:** How are ‘substantial amendments’ defined?

All amendments not mentioned in or substantially deviating from the original plan must be submitted to the ethics committee, for assessing their impact.

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

A valid insurance must be obtained as to insure participants for damages resulting from participation in the clinical trial. Insurance coverage is assessed by the NBC; however specific general indemnity requirements have not been defined. It is requested that those affected can raise their claims before an Icelandic court.

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

No specific coverage, the committee is a public administrative board and covered as such.

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

Legal guardians protect the well being of minors (up to 18) and other subjects not capable of consenting and consent on their behalf. Teenagers 12-17 years are party to such consent. Care is taken to protect the autonomy of vulnerable subjects capable of consenting, by e.g. giving them time to consult with family members and others.

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

Reports are sought from researchers, interim and final.

**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?

Researchers are reminded to send reports when final approval is given, and prompted for such reports in they are not sent in.

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

Research involving children should not be carried out unless the research will be of benefit for the participants involved and given that the results can not be obtained without their participation.
**Question 37:** Do national regulations in Iceland allow payment, (other than expenses), to children taking part in research?

There is no reference made to payment to children in the present legislation.

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

No. In exceptional cases, however, external experts on particular issues are called upon at the meetings and sit in during deliberations on those issues.

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

The approvals of the NBC are made public. The minutes are otherwise not made public.

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

Not without the Committee’s detailed instruction from a meeting. All such actions are taken to the protocol of the following meeting.

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

No, not in a formal manner.

**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

*EFGCP May 2011*