The EFICGP Report on
The Procedure for the Ethical Review of Protocols
for Clinical Research Projects in Europe
(Update: April 2011)

Switzerland

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


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?

There is another law pending, known as the “Federal Law on Research with Human Beings” that is expected to come into force during the next few years,- the necessary constitutional amendment has been accepted in the popular vote of march 7th 2010.

The law requires that Ethics Committees (called Research Ethics Committees in Switzerland) are appointed and supervised by the cantonal authorities. These RECs cover all aspects of biomedical research, but for certain types of procedures such as gene therapy, xenotransplantation, genetic testing or research with embryonic stem-cells, there are additional requirements including specific authorisation from the federal health authorities.

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

Approval of all clinical projects by a REC is mandatory, subsequently the projects dealing with investigational medicinal products are submitted for authorisation to the Swiss Agency for Therapeutic Products, known as Swissmedic, on forms only available in German or French. These forms are available on-line on the Swissmedic website: http://www.swissmedic.ch.
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: May 2011)

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

Projects are submitted for review to the authorized REC of the investigator.

**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?

In multiple site studies the principal investigator submits the research protocol to the REC locally responsible. This REC becomes the Lead Ethics Committee and reviews the clinical trial protocol. The REC’s of the subsequent sites may form their opinion on local items only (adequate expertise of the investigator, infrastructural requirements, acceptance by the local community). The Lead REC is alone competent for the final ethical judgement. Until today this regulation is voluntary and is legally not mandatory but highly recommended.

**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.swissethics.ch

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

Communication between Swissmedic and the RECs has improved with the adoption of a common guideline on the way to review a research project. This is available on the website of the Swiss Academy of Medical Sciences http://www.samw.ch.

Regular consultations are held between Swissmedic and the Association of REC’s, (AGEK - Arbeitsgemeinschaft Ethikkommissionen).

**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?

The approval of the REC is a prerequisite for the submission to the competent authority.
**Question 9:** How many (research) ethics committees are there in Switzerland?

Twelve with full responsibilities, recognised by the Cantonal authorities. Several act for two or more cantons. However in three cantons (Geneva, Vaud and Zurich) the cantonal RECs are subdivided in sub-commissions, but without the competence to finally approve a protocol. A complete and updated list of Swiss EC’s is maintained at http://swissethics; http://www.swissethics.ch.

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

REC requires a fee (between CHF 1000 and CHF 5,000-) for reviewing industry-sponsored projects. Projects that are only sponsored by the investigator or by non-profit organisations are charged with a fee between 0 and 500 CHF. In addition the Cantons guarantee that REC’s are properly funded.

**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?

The Lead Ethic Commission makes the ethical decision on the study. The secondary REC’s can accept or refuse this decision or eventually add locally determined minor supplements.

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

Twelve to twenty-four. See http://www.swissethics.ch for a complete and updated list of all Swiss RECs as well as their composition.

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

At least five, in most instances seven or more, with representatives of physicians, specialists in biostatistics, lawyers, ethicists and healthcare professionals as well as a proper gender balance.

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

The governments of the cantons appoint the REC members on recommendations from the members already appointed.
**Question 16: How is the independence of members ensured?**

Article 57 of the Law on Therapeutic Products states that RECs “must be independent and possess the necessary knowledge and experience to assess the trials submitted to them”. Apart from the appointment the RECs in Switzerland are independent from government, commercial entities, applying researchers and supporting institutions (largely as a result of the cantonal geographic model for their jurisdiction). Independence of the RECs rulings from influence of the authorities is guaranteed by law.

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

The Ordinance on Clinical Trials provides that each REC member must acknowledge any conflict of interest prior to discussing a project in the REC meeting and abstain from decision. The notification to investigators of the REC’s opinion includes a list of all REC members present participating in the decision process. This allows an external control both by the investigator or the sponsor, and also by the competent health authorities including Swissmedic (the Swiss drug regulatory authority).

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

An REC should be composed of at least three physicians with a large professional experience in conducting or reviewing clinical trials, four non-physicians with special knowledge in the fields of ethical, legal or healthcare personnel, and a specialist in biostatistics.

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

If the members do not possess specialist knowledge relating to the evaluation of a clinical trial, the EC must call upon experts. These experts are not entitled to vote.

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

The Ordinance on Clinical Trials requires that all REC members must have training in research ethics. The AGEC (Arbeitsgemeinschaft Ethikkommissionen) the association of the Swiss Ethics Committees organises biannual educational meetings for beginners and advanced members. Guidelines for the mandatory GCP training are in preparation.

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

These are the responsibility of AGEC. Besides the regular courses (item 20) a web-based self-training programme is in preparation.
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: May 2011)

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

Initial review and feedback to the investigator within 30 days after submission of the study documents to the REC.

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

Within the ordinary REC sessions.

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

The REC members know the local investigators and their professional and structural resources. RECs can interrupt a project in case of an important breach of GCP regulations. However, Swissmedic with its inspections is the main agency involved in sanctioning those who depart from the spirit of the law. Exceptionally the Federal Officer of Public Health or the local authorities are also involved in the control of research activities.

**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?

The full agreement between the sponsor and the investigator must be submitted to the REC.

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

The amount of the concerted compensation must be declared to the REC.

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

RECs are required to provide the competent authorities with an Annual Report. They are under the surveillance of both the health authority of the canton and of Swissmedic.

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

Yes, an REC decisions may be challenged in court (According to EMRk, BV and others: Norms, meaning legal options need to be accepted).
**Question 29:** How do RECs deal with SUSAR reports and Annual Safety Reports?

The REC take notice mainly on the local events.

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

Alteration of the protocol.

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

Under the Law on Therapeutic Products, trial subjects are guaranteed full compensation for injuries suffered in the course of the trial. The sponsor is legally responsible for this compensation. RECs review the suitability of the proposed amount of compensation.

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

There is no insurance for REC members because they are considered public employees covered by the state.

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

Articles 55 and 56 of the Law on Therapeutic Products cover clinical trials on minors, persons under judicial disability or persons incapable of judgement (Article 55) and clinical trials in medical emergencies (Article 56).

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

By spot check.

**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?

Control by the secretary of the REC.

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

Research in children – sick or healthy – must be in agreement with the requirements of the European Bioethics Convention concerning particularly vulnerable individuals. The convention has been signed by the Swiss Authorities.
**Question 37**: Do national regulations in Switzerland allow payment, (other than expenses), to children taking part in research?

There is no national regulation that explicitly allows payment, (other than expenses), to children.

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

Applicants yes, in case of differences in ethical appreciations.

Observers: No.

**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?

Collecting information: Yes.

Decisions with the co-signature of the Vice-Chairman concerning minor amendments of the protocol: Yes.

Ethical issues: No

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

Rarely in case of very voluminous protocols. The subcommittee is only entitled to submit propositions to the entire REC.

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

Provided for invasive trials by the pending “Federal Law on Research with Human Beings”

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

No.
Question 44: If the answer to Question 42 is ‘yes’, is this register of clinical trials made available to the public?

No.

EFGCP May 2011