Russia

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

The main following documents regulate CT in Russia:

- Ministry of Health Order from 25.08.1992 “Establishment the departments for clinical trials the medicines on volunteers”.
- Ministry of Health Order from 26.08.2010 №748 “The order for approval of the clinical trials on the medicines for medical use”.
- Ministry of Health Order from 26.08.2010 №748 “The order for approval of the clinical trials on the medicines for medical use”.
- Ministry of Health Order from 31.08.2010 №774 “About the Council on ethics”
- [http://www.minzdravsoc.ru/find](http://www.minzdravsoc.ru/find) and electronic legislative base “Consultant plus”.

**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?

Ministry of Health and Social Development. Within this legislation different sections are specific for the different types of biomedical research.
**Question 3:** What is the process for achieving clinical trial authorisation from the competent authority in Russia?

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

NB: It is appropriate for Russia that Questions 3 and 4 should be answered together.

The sponsor should submit an application both to the Competent Authority (Scientific Centre for the Evaluation of Products for Medical Use) and the Council on Ethics of Ministry of Health and Social Development. A clinical trial cannot be started without a positive decision from both of these bodies.

The sponsor is responsible for submitting the request to the Council on Ethics of Ministry of Health and Social Development and the principal investigator is responsible for submitting the request to the local research ethics committee.

**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, the Council on Ethics of Ministry of Health and Social Development.

**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?

There are two:

http://www.minzdravsoc.ru/find
http://www.roszdravnadzor.ru

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

Yes.

**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 application is submitted in parallel.
**Question 9:** How many (research) ethics committees are there in Russia?

One central committee, the Council on Ethics of Ministry of Health and Social Development and a lot of local research ethics committees (in Hospitals, Universities and etc). The exact number is not listed.

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

Usually RECs are funded by the organisation under what they are established, but they do also charge fees, which are variable.

**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 sponsor is responsible for submitting the request to the Council on Ethics of Ministry of Health and Social Development and the principal investigator is responsible for submitting the request to the local research ethics committee.

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

The only committee that provides the single opinion for Russia is the Council on Ethics of Ministry of Health and Social Development, responsible for review of Protocols on a national level.

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

Council on Ethics of Ministry of Health and Social Development consists of 17 members. There is no standard number for other research ethics committees.

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

For the Council on Ethics of Ministry of Health and Social Development - 2/3 of members constitutes a quorum (according to a specific SOP). The same applies to other research ethics committees.

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

The list of the member of NEC approve by the special order of Ministry of Health and Social Development. EC consists of the representatives from main medical and scientific institutes, universities, media, religions organizations. The number of the representatives from medical organization could not be more then the half all members.
For other committees, the Chairperson, and Vice chairperson, and Secretariat are recommended by the head of the organisation under which they are established, other members are recommended by Chairperson and other (active) members of the REC according to the SOPs.

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

There is a specific article in the Law (and regulations and SOP) under which every member of the research ethics committee must declare any conflicts of interest (if they occur).

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

See Question 16 (the members of EC who have any conflict of interest cannot participate in the decision making process).

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

Normally an REC includes different kinds of specialist with high medical education certificated for conducting CT, if it is necessary to have any unique expertise the consultants in this area could be invited. It should be the knowledge and experience on the ethical and legal aspects of CT (human right and etc.).

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

See Question 18.

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

There is an internal training course on Research Ethics for members of the Council on Ethics of Ministry of Health and Social Development - 2/3 constitutes a quorum (according to a specific SOP). The same applies to other research ethics committees - which members are required to attend. There are no requirements for local RECs.

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

There are the courses in the main Universities.

Thirty working days for review documents, decision making and approval (not depending on the number of sites).
Question 22: What are the timelines for the assessment of single- and multi-site studies?

Within 15 days after submission to the Ethics Committee under Federal Authority (not depending on the number of sites).

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

They are handled separately in accordance with a specific SOP.

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

For the investigator, a CV is submitted. For the site – there is an accreditation system for sites at which clinical trials may be conducted.

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.

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

Yes.

Question 28: Is there an appeal mechanism?

Yes.

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

The Reports are reviewed by the REC Secretariat and appropriate experts, if needed.

They file what is sent to them.
Question 30: How are ‘substantial amendments’ defined?

Under the SOP: if they increase the risk for trials subjects or there is a significant impact on the safety or physical or mental integrity of the subject; or they alter the scientific value of the trial.

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

According to the Law they must be specified in the application documents.

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

These are included in a specific SOP.

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

According to the Law there are specific procedures involving the Legal Guardian or, for children, their parents.

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

The local REC is responsible for monitoring the clinical trial, and for a long term clinical trial an intermediate report is required.

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?

It is a requirement of the research ethics committee that these reports are submitted.

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

No.

Question 37: Do national regulations in Russia 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?

a) Applicants can attend only for answer the questions, but they can not participate during discussion, decision making and voting.

b) An REC may invite nonmembers with experience in special arias, but these experts should not participate in the vote.

**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 is responsible for all the REC activities, including time between meetings: SOP compliance, participation of REC members in specialized conferences, education of REC members, etc.

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

Yes, if necessary. For example, there is a subcommittee on nonclinical studies in Local REC of Medical University.

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

Yes.

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

The approval of EC is one of the obligatory documents before the start of conducting CT.

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


*EFGCP May 2011*