Serbia

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

- Law on Medicines and Medical Devices (Official Gazette of the Republic of Serbia, No.30/2010)
- Regulations on the contents of the Request, and/or Documentation on the Clinical Trials Approval for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices (Official Gazette of the Republic of Serbia, No. 64/2011.).
- Guidelines for clinical trials in a paediatric population / ICH-E11
- Annex 13 (Official Gazette of the Republic of Serbia, No. 28/2008)

**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?

Research ethics committees are accredited by the Ministry of Health and are known as Local Ethical Committees (LECs). They are established at hospital level.

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

The sponsor/CRO of the clinical trial submits an application, with documentation, to the Medicines and Medical Devices Agency of Serbia, [http://www.alims sr.gov.yu](http://www.alims sr.gov.yu). The Agency (CA) reviews and assesses the application as the “expert reviewer” and decides within 60 days, with a possible “clockstop” to obtain supplementary documentation. If the LEC makes a negative decision, the CA will not approve the clinical trial.
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

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

The sponsor/CRO or principal investigator of the clinical trial submits the application to the relevant LEC. The LEC acts and decides, usually within 35 days.

**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.

**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 is none. But the two regulatory body websites are:
http://www.alims.sr.gov.yu
The website of the Serbian Medicines and Medical Devices Agency

http://www.zdravlje.sr.gov.yu
The website of the Serbian Ministry of Health

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

No, the LEC makes its opinion on clinical trial applications independently.

**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?

There is no parallel process in Serbia. The Agency (CA) will not consider a clinical trial application before the first positive LEC opinion is received.

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

Hospitals/clinics have their own LEC that reviews CT applications. There are approximately 30 LECs in Serbia.
**Question 10**: How are RECs funded in Serbia? Do they charge fees? If yes, what is their scale of fees?

Four useful websites may be found at:
- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

**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 or CRO submits the application, with documentation, to the appropriate LEC.

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

There is no single opinion facility for multi-site studies. There is no central EC in Serbia.

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

In accordance with local regulations, with a minimum of 5.

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

A majority of appointed members (50% + 1).

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

They are appointed according to local regulations. Four centres with websites are at:
- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

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

This is not regulated by Law.

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

This is not regulated by Law.
**Question 18:** What backgrounds and/or qualifications of members are actively sought?

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.ke-kg.co.rs](http://www.ke-kg.co.rs) (website of Clinical centre of Kragujevac)

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

In accordance with local regulations: four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.ke-kg.co.rs](http://www.ke-kg.co.rs) (website of Clinical centre of Kragujevac)

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

In accordance with local regulations: four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.ke-kg.co.rs](http://www.ke-kg.co.rs) (website of Clinical centre of Kragujevac)

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

GCP courses organised by the ACRP, by the Serbian Health Care Organisation and by individual sponsors.

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

60 days, if documentation is complete,

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

The sponsor or CRO submits any request for substantial amendments approval, with documentation, to the CA.
**Question 24:** How does a REC assess the suitability of investigators and of sites?

According to the Regulations the principal investigator has to be a doctor or dentist with appropriate specialisation in the therapeutic area of the clinical trial. All investigators should have a GCP certificate and experience in conducting a clinical trial.

**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 Regulations require that the LEC should evaluate the basic aspects of the financial arrangements and contracts.

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

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kcv.rs](http://www.kcv.rs) (website of Clinical centre of Vojvodina)
- [www.kcnis.co.rs](http://www.kcnis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

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

The CA does not inspect LECs.

The Ministry of Health is in charge of inspecting hospitals.

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

In accordance with local regulations. Four centres with websites are at:

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- [www.kcv.rs](http://www.kcv.rs) (website of Clinical centre of Vojvodina)
- [www.kcnis.co.rs](http://www.kcnis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)
**Question 29:** How do RECs deal with SUSAR reports and Annual Safety Reports?

If serious and unexpected adverse reactions SUSAR or serious adverse events (SAE) occur during the CT, a sponsor shall immediately notify the Agency and LEC of a legal entity in which the CT is conducted by Law.

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


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

The CA will not consider any application for CT approval without adequate insurance.

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

There are no requirements for insurance of EC members.

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

In accordance with the requirements of EC Directive 2001/20.

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

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

**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?

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kev.rs](http://www.kev.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)
**Question 36**: Do national regulations in Serbia allow research on healthy volunteer children (subjects under 16)?

No.

**Question 37**: Do national regulations in Serbia 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?

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kcv.rs](http://www.kcv.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

**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?

No.

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

In accordance with local regulations. Four centres with websites are at:

- [www.klinicki-centar.rs](http://www.klinicki-centar.rs) (website of Clinical centre of Serbia)
- [www.kcv.rs](http://www.kcv.rs) (website of Clinical centre of Vojvodina)
- [www.kenis.co.rs](http://www.kenis.co.rs) (website of Clinical centre of Nis)
- [www.kc-kg.co.rs](http://www.kc-kg.co.rs) (website of Clinical centre of Kragujevac)

**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 Serbia 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

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