УНИВЕРЗИТЕТСКИ
КЛИНИЧКИ
ЦЕНТАР
РЕПУБЛИКЕ СРПСКЕ
UNIVERSITY CLINICAL CENTRE OF THE REPUBLIC OF SRPSKA

Republika Srpska, Bosna i Hercegovina
Ul. Dvanaest beba bb
78000 Banja Luka
Tel: +387 51 342-100
Tel/fax: +387 51 310-530
E-mail: info@kc-bl.com
www.kc-bl.com

ETIČKI ODBOR
Dvanaest beba bb
Tel: 051 342 176

**PROCEDURE OF FILING A REQUEST TO THE ETHICS COMMITEE OF THE UNIVERSITY CLINICAL CENTRE OF THE REPUBLIC OF SRPSKA**

All requests, reports and letters to the Ethics Committee of the UCC RS (hereinafter referred to as EC) are submitted to the Protocol of the UCC RS, from where they are delivered to the Secretary of the EC. All additional information on activities of EC can be provided by the Secretary of the EC from 8:00 a.m. to 2:00 p.m. in the office of Ethics Committee.
Request for analysing the proposal for pre-registered clinical trials is submitted in two copies, and has to include following information:

- accurate title of the trial for which the approval is requested
- name of the sponsor of the trial and/or CRO (Contract Research Organization)
- phase of the clinical trial
- list of enclosed documents
- name and surname of the principal investigator
- date and signature of the principal investigator

Supporting documents are submitted along with the request. Request and supporting documents are submitted in paper form. Supporting documents have to be submitted in one paper copy and 9 copies written on CDs (for every member of EC). Every CD has to be marked i.e. each of them has to indicate protocol number. Documents copied to the CDs have to be arranged according to defined sequence of submitting. Request, information for patients and patient consent form have to be written in Serbian, while other documents can be written in Serbian or English language. Request and supporting documents have to be submitted no later than 10 days before the session of the Ethics Committee which is held once a month, except August. Upon receipt of request and supporting documents, Secretary of the EC issues a confirmation on receipt setting out all submitted documents to the applicant.

Along with request, the following documents have to be submitted:

• Approval of the General Manager for conducting the clinical trial
• Protocol of the clinical trial
• Summary of the protocol
• Statement on ethical documents that protocol complies with
• Case Report Forms
• Investigator's brochure
• CVs of all investigators (dated and signed)
• Material that will be used for patient recruitment
• Description of the method for obtaining the consent of patients

- Information for patients in Serbian
- Patient consent form in Serbian
- Statement on any form of compensation to patients for participation in study
- Statement on modality of compensation for eventual damage
- Description of insurance of patients (insurance company with branch office in B&H)

Evidence on ownership of ICH –GCP certificate for investigators
• All previous significant decisions in relation to the proposed study (e.g. opinion of other EC or Commission on Medicines)
• Evidence that sponsor and/or CRO paid to the UCC RS a fee amounting to BAM 5.100,00 or equivalent value in Euros for analysing the request and issuing the decision (1st , 2nd and 3rd phase of the clinical trial). Payment should be made at NLB Banka d.o.o. Banja Luka for UCC RS (for Ethics Committee):
Transfer account No.:562100-80000907-71 (BAM)

The Ethics Committee analyses and issues a decision on the submitted request on the next session since the moment of filing the request. Within the same period of time, written opinion signed by the president of the Ethics Committee has to be issued to the applicant. The opinion with protocol number will be issued at Protocol. Upon obtaining the approval for conducting the clinical trial, principal investigator is obliged to submit quarterly reports to the EC regarding the implementation of the trial as well as report on completed trial. Principal investigator is also obliged to inform the EC on serious unwanted occurrence within seven days. If the trial is not approved by the EC, written opinion will be issued to the applicant. The written opinion signed by President of the EC sets out all disadvantages that should be eliminated.

During resubmitting of the request for conducting a trial that was not approved by the EC, after all disadvantages are eliminated, sponsor or CRO are obliged to pay again the same amount which was initially paid (payment regarding the compensation for members of the EC for analysing the request).

Request for analysing and obtaining the approval of amendment of already approved trial is submitted in the same way as a primary request for approval of the trial. Along with request, amendment is submitted in one paper copy and 9 copies written on CDs (for every member of EC); Every CD has to be marked i.e. each of them has to indicate protocol number. Documents copied to the CDs have to be arranged according to defined sequence of submitting. It is necessary to mark a summary of modification in comparison to the initial version; it is not necessary that sponsor and/or CRO pays a fee for analysing the amendment. Target date for issuing the opinion of the EC is the same as for the original request.

Request for analysing and obtaining the approval for conducting clinical trials of the fourth phase (post-marketing studies) is submitted in the same manner as requests for pre-registration studies. For this phase of clinical trials, it is necessary to pay 4.100,00 BAM or equivalent value in Euros.

As enclosure to the request, the following documents are submitted:
• Approval of the General Manager for conducting the clinical trial
• Protocol of the clinical trial
• Summary of the protocol
• Statement on ethical documents that protocol complies with
• Detailed medication instructions
• CVs of all investigators (dated and signed)
• Material that will be used for patient recruitment
• Description of the method for obtaining the consent of patients
• Information for patients in Serbian
• Patient consent form in Serbian
• Statement on any form of compensation for participation in study

• Statement on modality of compensation for eventual damage
• Description of insurance of patients (insurance company with branch office in B&H)
• Evidence on ownership of ICH –GCP certificate for investigators
• All previous significant decisions for the proposed study (e.g. opinion of other EC or Commission on Medicines)

All deadlines for issuing the opinion of the EC are identical as for the request for pre-registration studies. Ethics Committee analyses professional issues and gives the opinion regarding using of human body parts in medical and academic purposes in accordance with law.
Employees in the University Clinical Centre of the Republic of Srpska that intend to conduct scientific research for the purpose of writing a master or PhD thesis have to obtain approval of the Ethics Committee. Along with request for issuing the approval (which is free of charge), applicants have to submit approval of the General Manager for conducting the scientific research for the purpose of writing the master/PhD thesis, preliminary plan for master or PhD thesis and informed consent form of patient for participation in scientific study in 9 copies (for every member of the EC).

Ethics Committee of the University Clinical Centre of the Republic of Srpska on the basis of Rulebook on the Conditions and Procedure of Awarding the Title of Primarius, makes suggestion to the Ministry of Health and Social Welfare of the Republic of Srpska for awarding the title of Primarius (Official Gazette of the Republika Srpska no. 18/12, dated February 29th, 2012).
Candidates for title of Primarius are obliged to submit a request to the Ethics Committee, no later than ten days prior to holding a session.

Ethics Committee also analyses other ethical issues with regard to the activities of the healthcare institution.

President of the Ethics Committee

Professor Svjetlana Stoisavljevic-Satara, MD, PhD