



ETHICAL COMMITTEE
12 BEBA bb Street
Phone: 051 342 176

PROCEDURE FOR SUBMISSION OF APPLICATION TO ETHICS COMMITTEE OF Clinical Center

All requests, reports and letters to the Ethics Committee of the CC Banja Luka (hereinafter the EC) should be delivered in the protocol of CC, and a courier delivers them to the Secretary of EC. All additional information on the work of the EC, can be obtained from the Secretary of the EC, who is available every day from 8 am to 2 pm at the office of the EC.

1. Request for consideration of the proposal pre-registration clinical studies must be submitted in two copies, in a form which must contain the following information:
 - The exact name of the study for which approval is required
 - the name of the sponsor studies and / or CRO's (Contract Research Organization)
 - phase of clinical studies
 - list of documents which are attached to
 - name of the main examiner
 - date and signature of the main examiner

Together with an application should be submitted and accompanying documents. The request and the supporting documents are submitted in a paper form. Supporting documents must be submitted in a paper copy and 9 copies on CD (for each member of the EC). Request, information for patients and patient consent form must be in the Serbian language, while other documents may be in Serbian or English. The request and supporting documents must be submitted no later than 10 days before the session of the Ethics Committee, which is held on the last Thursday of the month, except July and August. Upon receipt of the request and accompanying documents, Secretary of the EC

issues a certificate of receipt of the applicant in which are listed all the attached documents:

Together with an application must be submitted the following documents:

- The protocol of clinical studies
- Abstract protocol
- Statement of ethical documents which comply with the protocol
- Case Report Forms
- Investigator's brochure
- CVs of all researchers (dated and signed)
- Material which will be used for patients recruitment
- description of how to get a patient's consent
- Information for patients in Serbian language
- patient consent form in Serbian language
- Statement on any form of compensation to patients for participation in the study
- Statement on how to compensate any damage insurance
- Description of patient's insurance
- All significant previous decisions relating to the proposed study (eg, opinion of any other EC or Commission for Medicines)
- A proof that the sponsor and / or CRO paid to the CC Banja Luka a fee of 4 000 BAM, or the equivalent in euros, to review the request and the decision-making (1, 2 and 3 phases of clinical trials).

A payment should be done in the COMMERCIAL BANK on the name of CC Banja Luka (for the Ethics Committee):

Transfer account no.: 571 - 010-00001112-26 (BAM)

Foreign-exchange account no. :544000-0121275

If together with the request are not submitted all the documents, the EC will not be considered an incomplete application. Ethics committee reviews and decides on the request submitted at its next session from the time of filing the application. In the same period the applicant must be issued a written opinion of the EC, which is signed by the President of the EC. Opinion is issued by a CC-protocol with recording in the protocol.

Upon approval of the study, the main researcher is required to submit quarterly reports to the EC on the implementation of the study, report after completion of the study, and within seven days inform the EC on the occurrence of serious adverse events.

2. The request for review and approval of the amendment of the approved study should be submitted in the same manner as the primary application for approval of the study. Together with the request must be submitted the amendment in paper copy and 9 copies of the CD (for each member of the EC); It is not necessary that the sponsor and / or CRO studies pay a fee to review the amendments. All deadlines for the issuance of opinions of the EC are the same as at the original request.

3 The request for review and approval of clinical studies 4th phase (postmarketing studies) should be submitted in the same manner as requests for pre-registration studies, but that for this phase of clinical testing is required to pay the amount of 3 000 BAM or the equivalent in euros.

In addition to the request must be submitted the following documents:

- Protocol of clinical studies
- Abstract protocol
- Statement of ethical documents which comply with protocol
- Detailed instructions for the use of medication
- Biographies of all researchers (dated and signed)
- Material to be used for recruiting patients
- description of how to get a patient's consent
- Information for patients in Serbian
- patient consent form in the Serbian language
- Statement on any form of compensation to patients for participation in the study
- Statement on how to compensate any damage insurance
- Description of patient's insurance
- All significant previous decisions relating to the proposed study (eg . the opinion of another EC or the Commission for Medicines)

All deadlines for the issuance of opinions of the EC are the same as the request for pre-registration studies.

President of the Ethics Committee
Professor Dr. Svjetlana Stoisavljević-Šatara