ETHICS COMMITTEE
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STANDARD PROCEDURE FOR WORK of the ethical committee of the Clinical Center (KC)

1. Purpose

This document regulates the work of the Ethics Committee of the Clinical Center of Banja Luka (hereinafter: the Ethics Committee)

2. Application

This document is applied to all aspects of the functioning of the Ethics Committee

3 The work of the Ethics Committee

3. 1. Appointment of members

Members of the Ethics Committee (EC) name the Managing Director of the Clinical Center of Banja Luka. The term of office of members of the EC takes 1 year. EC has nine members and the Secretary.

3. 2. The functions and duties of the Ethical Committee

Ethics Committee considers in detail proposals submitted clinical trials of medications, ancillary medicinal resources, consumable medical supplies and medical equipment (hereinafter: the clinical examination) and make comments about their ethical justification. EC issued its opinion to the applicant proposals in the consent form, which may give or withhold. The EC also considers periodic, special and final reports on the approved clinical studies for which it gave its consent.

Amendments to the approved clinical studies are also subject of consideration and decision on their ethical justification.

EC has an obligation to follow the conducting clinical studies for which consent is given, by request of the main examiners to submit regular periodic reports and a final report. The Chief Examiner of each approved study is also required to inform the EC on the serious adverse effects within seven days. Members of the EC must keep confidentiality of data to which they came to inspect documents submitted by the proponent of clinical studies.

In its work, the EC follows the guidelines given in documents listed in paragraph 7 of this document.

3. 3. Submission of proposals for clinical studies to ethical committee

The chief examiner submits a proposal of clinical studies to the ethical committee for consideration. It is necessary that the chief examiner attach the following documents:

• request for review and decision on the proposed clinical study (signed and dated by the chief examiner),
• clinical study protocol,
• protocol summary,
• a statement of ethical documents which adhere to the protocol,
• Case Report Forms,
• written information for patients (in Serbian language),
• a written statement of consent form of the patient for participation in the study,
• a description of how the patient will get consent
• Brochure of examiners
• Patient recruitment procedures and materials that will be for use,
• a statement about how compensate any damage,
• information about material compensation respondents (if any),
• proof of insurance of the patients who will participate in the study,
• Biographies of the main and other examiners (dated and signed)
• all significant previous decisions related to the study (eg. the opinion of another EC or the Commission for drugs).

Periodic reports and the final report on the study, for which the EC has given its consent, submits the principal investigator.
Periodic reports are submitted every three months and the final report no later than the three months from the moment when the last patient completed the entire protocol.
Amendment to the already approved study is submitted to the ethical committee for consideration by request of the chief examiner.
Extended manner of submission of clinical study proposals, amendments and reports to EC is described in the document ''Procedure of filing the request to ethical committee of the Clinical Center of Banjaluka.”.

3. 4. The sessions of the Ethics Committee

The sessions of the Ethics Committee are held on the last Thursday of the month, except July and August, when the session is not maintained. Schedule The session puts on a schedule its president (in the absence of Vice-President) and determines the proposal of the agenda. Secretary of the EC in writing invites all members of the EC and at least 7 days before the session, enables a detailed insight into the proposed agenda and submited documentation. Sessions leads the EC President, and in his absence that does the Vice President of the EC. At the beginning of each session the agenda is adopted. The quorum for work and for decision-making of the EC is 5 members. The quorum shall not be the only members of one profession or one gender. In the quorum must be at least one lay person, and at least one person who is not employed by the CC in Banja Luka. Decisions are made by majority vote of all members of the EC, ie, with at least 5 votes. Decisions can not be adopted if the application is not completed. Secretary of the EC leads the record. Each member of the EC can get the word up to

3 times per agenda. Every single conversation can take 5 minutes. In the decision, by voting, may participate only members of the Ethics Committee who are thoroughly examined the documents and who participated in the discussion. Investigator or sponsor may be invited to the session for additional explanations.

In each study the EC proposal review and consider the following:

i) Research design and implementation of the study
(1) Is the methodology appropriate?
(2) Are the predictable risks for patients justified?
(3) Is it necessary to use control groups?
(4) The criteria for early withdrawal of patients from the study
(5) Criteria for the termination of the entire study
(6) Are there any conditions for the proper monitoring and control of implementation of studies, including the establishment of the Commission for monitoring adverse events?
(7) adequacy of the site
(8) Method of publication the results

II) Recruitment of patients

(1) Characteristics of patients
(2) Method of recruitment
(3) The method of informing patients
(4) Criteria for inclusion of patients
(5) The criteria for exclusion of patients

III) Protection of patients in the study

(1) Are the qualifications of researchers appropriate?
(2) Plans to discontinue the standard therapy because of the study and justification of such an act
(3) Care provided to patients during and after the study
(4) Are medical supervision and psychosocial support for patients adequate?
(5) What is undertaken if patients have come forward from the study by themselves?
(6) Criteria for obtaining a prolonged study medicine
(7) Plans that the study medicine is given to the patients after completion of the study, too
(8) Description of costs and / or compensation for patients
(9) Description of compensation in case of damage / death and a description of the insurance of patients

IV) The protection of patient data

(1) List the persons who will have access to data about the patient
(2) Measures to ensure security and confidentiality of patient data

V) The process of obtaining patient consent

(1) A detailed description of the procedure of obtaining consent and a list of people who will work on it
(2) Understandability, completeness and adequacy of information for the patient
(3) If you include patients who can not give consent, a detailed description of obtaining consent from the guardian and / or parents
(4) Is it ensured that the patients during the study receive any new information on remedies that are examined, and relevant for them
(5) Description of the ways in which to answer the questions and complaints of patients

VI) Relation to the local community

(1) The influence and importance of study for the local community and the rest of society
(2) Was there any community consultation during the preparation of design studies?
(3) Impact of the community on the consent of the patient
(4) Will there be community consultation during the study?
(5) The way the study contributes to improving health care and research in the community
(6) whether the remedy will be available to the local population after the studies?
(7) The manner in which study results will be available to the population

Independent experts

In the case that the technical clarifications of the protocol are required in order to issue a qualified decision, the EC may engage independent experts. Independent experts may be recruited among the specialists of the Clinical Center of Banja Luka, and if there is no adequate profile of experts, among the teachers and assistants of Faculty of Medicine in Banja Luka. An independent expert will be chosen by the President of the EC. Before getting to know the documentation related to clinical studies, the independent expert must sign a statement by which is committed to keep as a secret all information known about the research during the documentation study.

3. 5. Conditions that must be met by the members of the Ethics Committee in order to be appointed

• Each member must agree to his / her name, occupation and employer will be announced
• A member of the EC can not be a person convicted of criminal offenses or a person who is under the investigation at the moment of appointment; also a member of the EC can not be a doctor who was seized a license.
• Each member must agree to any material compensation for work in the EC being recorded and published, if required.

• Each member must sign a statement with the President of the EC, by which is committed to keep as a secret all know in connection with applications for clinical studies.
• Each member of the EC must pass initial training on Good Clinical Practice and the Helsinki Declaration

3. 6. Characteristics of the mandate of the members of the Ethics Committee

The mandate of members of the Ethics Committee lasts 1 year. Upon expiry of the mandate, new members of Ethics Committee are appointed by the Head Director of the Clinical Center. President of the EC shall notify the Head Director of the CC-and the fact that the term has expired.
A member of the Ethics Committee may be dismissed from the office before the expiry of the mandate that is set in the following cases:

If he/ she resign by himself/ herself, the resignation is submitted in writing, signed and dated by the member who submitted his resignation. The resignation must be enticed in the CC protocol and submitted to the Secretary of the Ethics Committee, which forward it to the President. The president informs the Head Director of the CC about the resignation, who approves or not the resignation. In the case of adoption the resignation, the Head Director l of the CC sets a new member of the Ethics Committee. •

If he/ she submits an irrevocable resignation, the resignation is not discussed, but finds that the member ceased a membership in the EC and the Head Director is notified to appoint a new member.

• If he/ she does not meet the obligations stipulated in this procedure, more than in one case, or if he/ she does not come on more than two sessions without any justification. Then the president of the Ethics Committee put on the agenda of the next session of the EC issue of trust to such a member. If the EC denies such a trust to that member, the President addresses to the Head Director of the CC for the request to resolve the duties of that member and appoint the new one.

If there is an investigation against him in front of the competent court of the Republic of Srpska or other countries. Then the membership of the EC freezes, and the President refers the request to the Head Director of the CC to appoint a deputy member of member which function is frozen, with a mandate to making final judgments or giving up the investigation. If the member of the EC is convicted, his membership shall be ceased definitively; if he is released from the prosecution or the court waive the investigation, his membership and mandate extends for the time for which his function was frozen.

In case of death, serious and long illness of the EC member, or prolonged absence from Banja Luka (over one year), the President refers the request to the Head Director of the CC that such member must be resolved on duties and appoint a new one.

3.7. Conflict of interest

In decisions regarding the specific cases, can not participate those EC members who have any interest (moral or material) in connection with the object of which is decided.

4. Secretary of the Ethics Committee

Secretary of the Ethics Committee is responsible for keeping the documentation of the EC, for the technical part of the convening the sessions, the regular record keeping, admission requirements and the technical part of the conversation of EC. The secretary works from 8 am to 2 pm every working day. The secretary of the EC is appointed and dismissed by the Head director of the CC.

5. Course of the documentation

Requests to the Ethical committee are submitted via CC protocol. From the protocol they are submitted to the Secretary of the EC via courier. The secretary seduces requirements in the EC protocol and submits them to the President. The president, after an insight into the writing documentation, puts the session of the EC on the schedule. The Secretary records the documents of the EC. Based on the record, the President of the EC writes the decision, which is delivered to the main examiner via the secretary and protocol. All the records and the filed documentation of the EC are kept in the archive by the secretary of the EC, introduced by the EC protocol. Documentation is stored for 4 years.

6. Responsibility for application

For the application of this document the responsible persons are the president, the secretary and the members of the Ethics Committee.

7. Links with other documents

This document follows the guidelines for work of the ethical committees given in the publications:

- ICH secretariat. ICH harmonized Tripartite Guideline for Good Clinical Practice. Brookwood Medical Publications Ltd., Richmond, 1996.
- European Forum for Good Clinical Practice. Guidelines and Recommendations for European Ethics Committees, 1997.
- Operational Guidelines for Ethics Committees That Review Biomedical Research, World Health Organization, Geneva, 2000.

The President of the Ethics Committee of the Clinical Center of Banja Luka
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