

RULES OF PROCEDURE OF THE FMPOS ETHICS COMMITTEE

The Rule of Procedure sets out the modalities for the application of the no-numbered text, dated 25 March 1994, concerning the establishment, organization and functioning of an ethical committee at the ENMP (National School for Democracy Pharmacy) in Mali.

Chapter I: Missions headquarters and duration

Article 1:

The provisions concerning the missions of the Ethics Committee provided for by the aforementioned creation text are supplemented as follows:

- the ethical evaluation of research protocols submitted by Malian and / or foreign researchers shall be carried out in accordance with the operational guidelines issued by WHO and the International Harmonization Conference and the provisions foreseen, by the Helsinki Declaration and by the texts in force at Mali on the other hand;
- the evaluation of research protocols through the ethical, social, societal and cultural moral values observed by the population of mali

Article 2:

The Seat of the ethics committee is fixed at the FMPOS in Bamako.

Article 3:

The lifetime of the FMPOS Committee is unlimited. Provided, however, that the Dean of the Faculty may dissolve in exceptional circumstances and shall be required to name the following within thirty (30) days:

Chapter II: Organization and Functioning of the FMPOS Ethics Committee

SECTION I: ORGANIZATION

Article 4:

The Ethics Committee of the FMPOS is composed of 14 members: a president, a vice president, a permanent secretary and members from all the social strata of Mali. these members are divided as follows: the 2/3 coming from the FMPOS and the 1/3 of the social strata. If necessary, the Ethics Committee may consult any resource person it deems necessary. Article 5: The chairman shall be the chief committee chairman. In this capacity, he represents the Ethics Committee, chairs meetings and other policing bodies. The chairman and members of the committee shall be appointed by the Dean of FMPOS and the members of civil society on the proposal of the institutions represented, and their terms of office shall cover a period of four years renewable three times.

Article 6:

The vice-president is elected by his peers; he replaces the President in case of

Article 7:

The permanent secretary shall be a permanent secretary, an assistant and support staff. it is headed by a permanent secretary appointed by the chair of the ethics committee on the proposal of the dean of the faculty.

Article 8:

The committee meets regularly on convocation of the president or the request of the majority of the members. The Ethics Committee shall hold two (2) sessions per month and a maximum of two (2) protocols per session.

But it may meet in extraordinary session upon convocation of the President.

The cost of revenue per copy deposited at twenty thousand CFA francs (20,000 francs CFA).

The sessions are suspended from 01 to 31 August of each year due to the university holidays

Article 9:

The committee can deliberate only if a quorum is reached.

The quorum shall be one half plus one of the members present or having.....

SECTION II (Instead of Chapter II) Procedures

REFERRAL

Article 10:

the request for referral for ethical development of a research project must be formulated by a qualified researcher responsible for the scientific and ethical conduct of the research.

Article 11:

The referral shall be made by means of a request addressed to the President and shall include the elements annexed to this Regulation. The ethics committee can self-identify when necessary.

Article 12:

the committee shall rule on the protocol within a minimum period of fifteen (15) days. Only those members who have attended or have given their opinion at the evaluation session of a protocol are entitled to take a decision. the documents required for a review of the application must be complete and in accordance with the elements listed in the Annex.

Only the members who participated in the examination of the file participate in the decision-making process.

Article 13:

The decision shall be taken by the consensus after hearing all the members. However, it may be taken as a result of a vote; in such a case the vote of the chairman shall prevail when there is an equal division of votes.

Article 14:

After examining the file, the decision of the Ethics Committee may be:

1) favorable

(2) conditional: in this case, clear suggestions for revision shall be made and, where appropriate, the procedure for the request shall be indicated;

3) rejected: this is motivated by clearly stated arguments.

The definitively accepted protocol is to be deposited in paper and electronic form. the subject of a protocol in plenary brings to the conditions of the restricted review by five (05) members appointed by the president in addition to the secretariat.

Article 15:

The chairman of the FMPOS Committee shall be seized for an examination of the research protocols according to the nature of the request, the amendment or any other acceptable consideration for such examination.

Article 16:

The President of the EC shall decide on the protocol adapted to the restricted review and on the composition of the review group according to the research theme.

the restricted review is subject to the same conditions as the plenary but for six (06) persons repaties as follows:

changes of review 05 (04 + president)

expenses of secretariat 01

the report letter is returned to the researcher after seven (07) working days.

The trainees 'and students' protocols are revised to 1/4 of the usual amount.

The result of the deliberations of such a select committee shall be communicated to all members of the ethics committee at its next session.

the journal is free of charge for the graduate student whose protocol is not covered by the training institution or structure,

Article 17:

The decision taken by the committee shall be notified in writing to the requestor within seven (07) working days.

The notification of the decision includes, in particular, the elements referred to in the Annex

SECTION III: FOLLOW-UP

Article 18:

The EC shall establish a procedure for the follow-up evaluation of all the research Protocol which has been the subject of a favorable decision. This follow-up runs from the date of decision-making to the end of the research.

Article 19:

Follow-up monitoring intervals are determined according to the nature of the studies and events. However, each protocol must be monitored at least once a year. a copy of the follow-up report will be sent to the researcher. The researcher must submit an annual progress report to the ethics committee.

Article 20:

The conclusions of the follow-up control must be communicated to the researcher. They indicate any modification, suspension, realization or confirmation of the initial decision.

Article 21:

In the event of suspension or premature termination of the research, the researcher must indicate

Serious adverse events occurring in the conduct of the study should be notified within 72 hours at the latest.

Article 22:

The researcher must notify the closure of a study within 72 hours of the decision the ethics committee is among the recipients of the final research report and reprints of the articles published.

Article 23:

The ethics committee with the participation of the researchers organizes an annual training and information workshop.

SECTION IV: DOCUMENTATION AND ARCHIVING

Article 24:

All communication and correspondence of the ethics committee must be dated and archived according to written and electronic procedures. The consultation of the various documents, files and archives is subject to the prior authorization of the chairman of the ethics committee.

The documents are archived for a minimum of 10 years after the end of the search.

Bamako on 14th January 2012.

The ethic committee President

The oldest person or dean of faculty

ANNEX TO THE EC RULES OF PROCEDURE / FMPOS

I. Requirements for a request for examination

the requirements for the submission of a research project must be clearly described in a request for evaluation procedure. They include the following:

I.1. President of the EC to whom the application file is to be filed;

I.2. Letter of request;

I.3. Documentation;

I.3.1. the essential documents to be filed must be drafted in French;

I.3.2. the number of copies to be filed is 15 (fifteen);

I.3.3. the application must be filed at least 15 days before the date of the protocol examination;

I.3.4. Acknowledgment of receipt of applications, including disclosure of the incompleteness of an application, shall be issued to the applicant;

I.3.5. Examination fee of one day: twenty thousand francs (20,000 francs CFA) per copy deposited for the journal;

I.3.6. Procedure for requesting amendments to the protocol recruitment methods information to potential participants and the voluntary, free and informed consent form.

II. Documentation required

all documentation required for a complete and in-depth evaluation of the ethical aspects of the proposed research must be submitted by the applicant. This includes, but is not limited to, the following:

II.1. A dated and signed application form;

II.2. protocol of the proposed research (clearly identified and dated) with supporting documents and annexes;

(If possible in a technical language), synopsis or simplified re-elucidation of the protocol in the form of a schema;

II.4. Description (generally included in the protocol) of ethical considerations related to research

II.5. Observation booklet, patient agenda and other questionnaires for research participants;

II.6. when research involves a product under consideration (such as a medicinal product or medical device), an adequate summary of all pharmacological, pharmaceutical and toxicological tolerance data available on the product summary of the clinical experience acquired to date with This Product (eg recent investigator's brochure, publication, product characteristics summaries);

II.7. Curriculum vitae of the investigator (up-to-date and signed) and their percentage of time involved in the project;

- II.8.Measures for the recruitment of potential research participants;
- II.9.description of the procedure followed to obtain the consent of the subjects;

Information (clearly identified and dated) and other forms of information for potential participants;

II.11. Voluntary, free and informed consent form (clearly identified and dated) in the language understood by the potential participants

II.12. Declaration of possible compensation for participants participating (including reimbursement of expenses and access to medical care);

II.13.description of the measures taken, where appropriate for compensation in the event of damage.

II.14.description of the arrangements made, where applicable for the insurance coverage of participants;

II.15. declaration of the investigator he / she undertakes to respect the ethical principles laid down in the appropriate guidelines;

II.16. Any significant previous decisions (eg unfavorable decision or request for modification of the protocol) made by other EC or regulatory authorities regarding the research in question (whether at the same or another research site) and indication of the change to the Protocol in this respect. The reasons for the previous unfavorable decisions must be given;

II.17.transmit the opinion of the scientific committee of the applicant institution if available;

II.18.the budget and information on the sponsor.

Bamako on 14th January 2012.

The ethic committee President

The oldest person or ean of faculty

GUIDE TO REVIEW OF THE PROTOCOL BY THE ETHICS COMMITTEE

(check each section and provide where necessary the additional information in you about your area of expertise)

	Yes	No	comments
Is there a scientific basis for initiating of this study?			
Does it have a social value?			
Is it just / fair?			
Is this research part of the national is priority?			
Is this research relevant to the health study community?			
Does this research include special or vulnerable subjects (minors, prisoners, disabled, mental, pregnant women etc.)?			
If so, is it possible to exclude them and still answer the same research questions?			
If not, include in the project the appropriate measures to ensure that these populations are well protected.			
the study presents: -Minimum risk..... <input type="checkbox"/> -More than one minimum risk.... <input type="checkbox"/> Minimal risk meeting in everyday life or during physical, psychological and routine analyzes (CFR)			comment briefly:.....

	N/A	satisfactory	requires clarifications	unfinished /missing	No satisfaction	comments
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Clear and achievable objectives						
Review of literature						
Design of the study						
Methods / procedures						
Materials (congruence of methodology)						
Statistical considerations study population (appropriate or not) selection and recruitment procedure (equity)						
Motivation to participate in the study (appropriate or coercive)						
Consent form						
Procedures to ensure consent or assent is voluntary						
anonymity and confidentiality						
materials and research papers						
risks / benefits						
access of study population to research products / results after the						

clinical trial						
Becoming collected material (preservation, future studies)						
Investigator Qualifications and % of Study Time						
Budget Elements and Sponsor						
Community Authorization / Permission						
Project insurance if it involves more than the minimum risk						

OTHER CONCERNS / REQUIREMENTS

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RECOMMENDATIONS

check one

1. Approve the research project as submitted
2. Approve the research project with minor modifications (please specify in the space below)
3. Approve the research project with the indication that the final research papers are to be submitted for further review and approval before any direct contact with the participants is started.

- 4. Approve the research project subject to the following revisions (please specify below)
- 5. Reject the research project (please explain in the space provided below)

COMMENTS:

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Name / first name and signature of the examiner

Day

Note for the examiner: Please use additional sheets provided with additional comments if necessary.