

REPUBLIC OF GUINEA
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 WORK – JUSTICE – SOLIDARITY

NATIONAL ETHICS COMMITTEE FOR HEALTH RESEARCH (CNERS)

Title: Standard operating procedure (SOP) for reviewing a health research protocol.

The evaluation of health research projects must be done before, during and after the implementation of the research protocol.

CNERS	Procedure for reviewing a health research protocol	Revision/Release 6.0/February 2021
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Written by	National Ethics Committee for Health Research (CNERS)	
Approval		
Pr Oumou Younoussa BAH	President of CNERS	Date and signature

HISTORY :

The first version of the SOP was drafted when CNERS was set up in 1999. It was subsequently revised during various workshops in XXX and XXXX at the Ignace Deen University Hospital (version 2 and 3), in 2018 at the Department of Health of the City of Conakry (version 4), and in XXX at the Blue zone of Dixinn in Conakry (version 5).

These workshops brought together CNERS members and other resource persons.

With each revision, the changes made have been incorporated into the document. This version is the 6th of the ^{SOP} ;

I - OBJECTIVE

This document aims to facilitate the evaluation of a health research protocol by the members of the National Ethics Committee for Health Research (CNERS) of the Republic of Guinea. The role of the ethics committee is to ensure the broadest possible protection of potential research participants and to contribute to the highest possible level to the scientific and ethical quality of health research.

II - FIELDS OF APPLICATION OF THE PROCEDURES

The fields of application of these procedures are biomedical, socio-anthropological and environmental research.

III - PRINCIPLES

The CNERS must ensure that the research protocol complies with the applicable regulatory requirements, good clinical practices, the ethical principles arising from the Declaration of Helsinki, the guidelines of the research harmonization conference and the code of ethics for health research namely:

- the principle of respect for the human person,
- the principle of beneficence in its two aspects: avoiding harm and promoting good,
- the principle of justice,
- the principle of the scientific and social quality of research,
- the principle of confidentiality,

IV- SUBMISSION PROCEDURE

This procedure indicates to the sponsor and main investigators the list of documents to be provided and the waiting times to enable the CNERS to independently examine the protocols submitted by the researchers.

The investigator submits the documents to be examined to the CNERS secretariat. An acknowledgment of receipt and a payment receipt will be given to him by the secretariat.

V – DOCUMENTS TO BE EXAMINED

- The letter of submission of the research protocol , dated and signed by the principal investigator;
- The research project ethics review request form duly completed, dated and signed by the principal investigator;
- The table of contents ;
- Acronyms and abbreviations;
- The summary of the project in a maximum of 10 lines;
- The identity of the research sponsor and investigators;
- The documents allowing to assess the level of qualification of the promoters and investigators (CV);
- The precise statement of the problem, objectives and research hypotheses;
- The presentation of the methodology including the sampling;
- Description of the ethical considerations of the research
- Presentation of data collection tools;
 - including any material used to inform and recruit participants (posters, messages, image boxes, etc.) dated and with a version number;
 - translated into the relevant languages according to the target population of the study.

- The participant compensation mechanism as well as the benefits related to the research;
- Measures taken to mitigate research-related risks;
- The measures taken to ensure the compensation of participants in the event of damage;
- Data analysis techniques and tools;
- Documents relating to free and informed consent including:
 - a description of the strategies for recruiting participants and obtaining consent;
 - participant protection and data privacy measures ;
 - the presentation of the risks incurred by individuals and communities with regard to their beliefs and social habits and the benefits derived by the population;
- Modalities for sharing results (including publications), data and biological materials collected in Guinea and transferred outside;
- The methods for disseminating the results and sharing with the participating populations;
- The involvement of health authorities and communities;
- The methods of sharing the benefits of research with the populations involved in the research;
- The schedule of activities;
- The detailed project budget;
- Bibliographic references;
- The investigator's brochure for clinical trials if applicable together with published data and a summary of product characteristics. ;
- The documents enabling the level of qualification of the sponsors and investigators to be assessed, in particular the CVs;
- Previous decisions of the Guinean CNERS and/or other ethical opinions obtained by the research regulatory authorities, including from other countries;
- Letters from associated partners;
- Other additional documents :
 - Details of the changes that have been made to the protocol since the last notice was issued;
 - a declaration in which the sponsor and the principal investigator undertake to respect the ethical principles and standards relevant to their research.

The file must include all the documents mentioned in order for it to be admissible and evaluated by the committee. The file must be submitted no later than 15 days before the day of the evaluation session . This period may be exceptionally shortened for health emergency reasons.

VI- CONDITIONS TO BE FULFILLED BY THE CNERS FOR THE APPROPRIATE EXAMINATION OF A RESEARCH PROTOCOL

In accordance with the internal regulations of the CNERS of the Republic of Guinea, the requirements relating to the examination of a research protocol retained are:

- the minimum number of nine (9) members —is required to reach a quorum in respect of diversity;
- , the CNERS can call on independent consultants likely to provide specific expertise in the examination of the proposed research protocols. These consultants may be specialists in ethics, law or a specialist in a particular disease or methodology, or they may be representatives of communities, patients or particular interest groups;
- if necessary, the CNERS can invite the principal investigator;
- in the event that the examination of the protocols entered on the agenda is not completed, the president sets the date of the next extraordinary meeting;
- the decisions resulting from the deliberations of the CNERS are consensual and confidential;
- after the meeting, the minutes are adopted and the response letters are sent to the principal investigators.

The minimum and maximum deadlines for the review of the research project after its submission are respectively two weeks and one month.

In the event of an emergency (epidemic, disaster, etc.), an accelerated procedure is adopted without prejudice to the requirements of the submission of the protocol and comprising:

- the reduction of the minimum and maximum periods to 48 hours and one week respectively;
- the reduction to 5 of the required quorum of CNERS members;
- the possibility of calling on other national and international experts;
- acceptance of online submission and evaluation;
- the sending of the response letter within 48 hours after evaluation.

VII- RESEARCH PROJECT EVALUATION GRID

The health research protocol review process should check whether:

- The competence of the team of investigators is well documented
Yes Nope
- The title clearly identifies the research
Yes
- Acronyms and abbreviations are well presented
Yes

- The summary is included
Yes
- The relationship of the problem to the literature is clearly established
Yes
- The relevance and importance of the study are clearly established
Yes
- The research question is clearly defined
Yes
- Assumptions are well formulated
Yes
- The objectives are clear, precise and realistic within the limits of the defined time and budget
Yes
- The proposed research methodology is appropriate to answer the research question
Yes
- Population and sample are well specified and fit
Yes
- The study procedure is well described
Yes
- Method of recruiting participants is appropriate and fair
Yes
- Special protective precautions for vulnerable populations are taken
Yes
- The research has benefits for the participant and for the community
Yes
- The information contained in the informed consent/assent is complete and understandable
Yes
- Data collection tools are appropriate
Yes
- Confidentiality of study subjects and study data is guaranteed
Yes

- The data analysis plan is well specified and appropriate
Yes
- The limitations of the methodology are indicated
Yes
- The expected results are able to answer the question asked
Yes
- Dissemination of results is planned
Yes
- The management of the risks incurred by the participants is clearly described
Yes No
- The procedure for transferring biological material is well described and appropriate
Yes No
- The budget and sources of funding are mentioned and realistic
Yes Nope
- The timeline is realistic
Yes Nope
- The place and setting of the study are well suited
Yes Nope
- National skills are taken into account
Yes Nope
- National capacity building is taken into account (technology transfer, equipment, training, remuneration, etc.)
Yes Nope
- Compensatory measures are clearly mentioned
Yes

VII I- OUTCOMES OF THE EVALUATION, DECISION-MAKING AND COMMUNICATION OF THE DECISION

8.1. Decision

Following its assessment of the validity of the scientific and ethical aspects of the research protocol, the CNERS may accept or refuse the research protocol submitted for

assessment. He can also request that the research protocol be modified in order to meet current scientific and ethical standards.

The following results are possible:

- approval without modifications to be made to the submitted research project;
- request for modifications and/or clarifications to be made to the research project before its approval;
- disapproval for the implementation of the submitted research project.

Any decision of the ethics committee must be motivated and presented in writing.

8.2. Communication of the decision

The result of the scientific and ethical evaluation is transmitted in writing within 10 days after deliberation to the principal investigator of the research protocol submitted. In case of emergency, it is transmitted within 48 hours.

The communication of the decision must include the following elements in particular:

- Exact title of research proposal reviewed;
- Clear identification of the research protocol or proposed amendment with date and version number;
- Possible suggestions made by the committee;
- In the event of a conditional decision, description of all the requirements posed by the committee with the suggestions for revision and the procedures for reconsidering the application;
- In the event of a favorable decision, state the commitments of the investigator:
 - submission of progress and final research reports;
 - obligation to report serious and unexpected adverse events related to the conduct of research;
 - period of the approval: one year renewable;
 - Notification to the committee of the end of the study.
- In the event of an unfavorable decision, clearly state the reasons;
- In the event of contestation of the decision rendered by the CNERS, the principal investigator has 10 days to make a complaint in writing to the CNERS with the reasons for –not accepting the decision. The CNERS responds to it within 10 days. In the event of non-satisfaction , a final working session is then organized between the CNERS, the sponsor and the principal investigator.
- Place and date of the decision;
- Signature and stamp of the president/vice-president or any other authorized person of the committee.

IX- MONITORING/EVALUATION OF THE IMPLEMENTATION OF THE PROTOCOL

9.1. Monitoring and evaluation during research

The committee should assess the following:

- modifications /amendments to the research protocol, informed consent/assent form;

- additions of new study sites;
- them changes in procedures for recruiting study participants;
- increasing or decreasing the study sample size;
- the methods of conservation and transfer of the biological samples taken;
- the functions assumed by each member of the research team;
- review of progress reports;
- the adverse events that have occurred and the measures taken for the safety of the participant and information from the CNERS (pharmacovigilance file).

A monitoring and evaluation guide has been drawn up for this purpose by the CNERS (see appendix).

A monitoring and evaluation visit is carried out for all approved research projects.

Urgent follow-up visits may be prompted by:

- any amendment to the protocol likely to affect the rights, safety and/or well-being of the participants, or the conduct of the research;
- serious or unexpected adverse events related to the conduct of the research or the product tested;
- actions taken by investigators, sponsor and regulatory bodies;
- any event or new information likely to modify the benefit/risk ratio of the research;
- a decision of an independent safety committee.

In the event of serious shortcomings observed in the field (non-compliance with the protocol or modification of the latter), the CNERS may suspend the implementation of the project. In this case, a new protocol will be submitted to CNERS for review.

9.2. Evaluation after research implementation

- the reactions of subjects who participated in the study;
- the methods of conservation and transfer of the biological samples taken;
- management methods;
- the final report of the study;
- publications completed or planned ;
- local or national dissemination .

X- ARCHIVING

The CNERS must ensure that all the documents processed by the committee relating to the research protocols and the decisions it takes are archived in paper format/ in electronic format for a period of 10 years in a secure manner. In addition to CNERS members, only persons authorized by law may have access to these documents.

XI APPENDICES

1. Acknowledgment of receipt form for submission files for review at CNERS;
2. Standard Response Template for Final Research Protocol Approval without Modification;
3. Response template conditional on requested changes/clarifications;
4. CNERS approval refusal model for a research protocol submitted for review;
5. Guide for monitoring – evaluation of the implementation of research protocols;
6. Resume template;
7. Protocol plan template.

XII. BIBLIOGRAPHIC REFERENCES

- Law No. 021/AN/97 of June 19, 1997 promulgating the code of ethics for health research;
- Decree N/D 218 PRG/SGG of October 29, 1998 on the creation, powers and organization of the National Ethics Committee for Health Research (CNERS);
- Decree No. D /99/078/PRG/SGG of August 2, 1999 appointing members of CNERS;
- Rules of procedure, version 6 of February 2021;
- Ethics review request form developed by CNERS, version 5 of 2019;
- WMA Declaration of Helsinki- Ethical Principles for Medical Research Involving Humans, October 2013;
- International Ethical Guidelines for Health Research Involving Human Participants CIOMS 2016;
- ICH-GCP Guidelines 2016;
- Operational Guidelines for Ethics Committees responsible for the evaluation of Biomedical Research”, WHO -TDR/PRD/ETHICS/2000.1.

Done in Conakry, July 2021