

REPUBLIC OF GUINEA

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WORK – JUSTICE – SOLIDARITY

NATIONAL ETHICS COMMITTEE FOR
HEALTH RESEARCH (CNERS)

Request form for ethical evaluation of a research project/protocol

SECTION 1 — GENERAL PROJECT INFORMATION/ RESEARCH PROTOCOL

Project title / research protocol

Principal Investigator/ Investigator

Last name and first names :

Address :

Code postal :

City:

Pays :

Phone :

Email :

Diplomas, rank and institution(s) of affiliation:

Collaborators/ research team

First and last names	Title/diplomas	Function in the project/protocol	Institution (s) d'affiliation	E-mail	Phone

Partner institution(s):

name	Address	Function in the project	E-mail	Phone

Summary of the project (8 to 10 lines)

Keywords :

Field of research

Biomedical Public health Socio-anthropological Environmental

Project scope

Local National Regional/International

Tenderer

NGO research institution Pharmaceutical firm Individual

Type of research

Fundamental / Theoretical Clinical Applied/Operational

Epidemiological Evaluative Others (*to be specified*)

Expected timeline Start of the research project:

End of the research project:

SECTION 2 — FUNDING

- Total project cost:
- Source of funding :
- Subsidized, specify the organization(s):
- Total grant amount:
- Not subsidized, specify:

SECTION 3 — DOCUMENTS TO ATTACH TO THE ETHICS REVIEW APPLICATION

ÿ Documents to submit

The documents listed below must be presented in French and bound in a single copy. Eight (08) copies and an electronic version must be submitted to CNERS. The electronic version must be transmitted in a single file. The writing must be in Arial 12. Each copy to be submitted (initial or corrected protocol, extension of approval, amendment) must contain the documents below:

- Research protocol submission letter, dated and signed by the principal investigator;
- Ethics review request form duly completed, dated and signed by the principal investigator;
- Full protocol including;
 - Free and informed consent and/or free informed assent form;*
 - Data collection instruments;*
 - Investigator's Brochure for Clinical Trials;*
 - Detailed project budget in Guinean francs;*
 - Profile of investigators in 5 lines;*
 - Curriculum vitae of all the investigators of the research project (summary in four (4) pages maximum per CV);*
- Previous ethical decisions: Guinean CNERS Other countries
- Letters from associated partners;
- Other documents.

ÿ For corrected versions,

ÿ send a letter transmitting the corrected version (including the version number) summarizing the corrections made to the protocol with an indication of the pages;

ÿ attach the form duly completed, dated and signed by the principal investigator;

ÿ attach all the documents required above (including the corrections).

All these documents must be bound in a single copy. Three (03) copies and an electronic version will be submitted to CNERS. Corrections should be in bold, or highlighted in yellow in the protocol.

ÿ **For amendments,** ÿ send a

letter transmitting the amended version as well as the number of the version;

ÿ attach the form duly completed, dated and signed by the principal investigator;

ÿ attach the full amended protocol (see documents to be submitted).

All these documents must be bound in a single copy. Three (03) copies and an electronic version will be submitted to CNER. Changes should be in bold, or highlighted in yellow in the protocol.

ÿ **For the renewal of approvals,**

ÿ send a letter requesting renewal of the approval, ÿ attach the form duly completed, dated and signed by the principal investigator;

ÿ attach the study progress report;

ÿ attach the complete protocol (see documents to be submitted).

All these documents must be bound in a single copy. Three (03) copies and an electronic version will be submitted to CNER.

Commitment of the principal investigator

I hereby certify that the information declared is accurate and sincere. I undertake to respect the fundamental ethical principles of research involving human beings.

Name and signature of the principal investigator

Date

IMPORTANT TO REMEMBER

The request for evaluation of the research protocol as well as all related documents must be submitted to the CNER headquarters located at the Dixinn Bluezone. Contact Ms. Diallo Aissatou BAH at the telephone number +224 622 25 31 27, email: «aissatou_dalaba07@yahoo.fr »

NB. Applications can be submitted at any time. Files submitted during the first week of each month will be examined at the regular monthly CNER meeting. A minimum period of three weeks is required between the submission of applications and their examination. The CNER meets on the last Thursday of each month to review research projects/protocols

The file examination fees are set at three million (3,000,000) GNF. The fees for amending a protocol or extending the validation of the approval are set at one million five hundred thousand (1,500,000) GNF.

It should be noted that the approval of a protocol is valid for one year.

Ms. Diallo Aissatou BAH, CNER assistant, provides an acknowledgment of receipt of the documents submitted and a payment receipt, copies of which are kept in the CNER archives. This acknowledgment can only be provided if all the required documents are complete and after payment.

Conakry, July 2021