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FROM

REPUBLIC OF MALI

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SUMMARY

ACTS OF THE REPUBLIC OF MALI

DECREES

GENERAL SECRETARIAT OF THE GOVERNMENT

Head of codification materials	Inspector of Finance/ Inspector of Treasury/Tax Inspector/Inspector Economic Services/Administrator Civilian/ Planner/ Technician of Planning work / Controller of Finance/Treasury Comptroller/Comptroller of Taxes/Comptroller of Services Economics/Secretary of Administration/Attached d'Administration / /Deputy of Finance/Deputy of Taxes/Deputy of Economic Services/Deputy of Administration/Secretary Assistant	A/B2/ B1 / C	1	1	1	1	1
File manager holders of the periodic inventory and summary statement quarterly	Inspector of Finance/ Inspector of Treasury/Tax Inspector/Inspector Economic Services/Administrator civil/ Planner/Technician Human Resources/ Technical Work Planning/Controller of Finance/Treasury Comptroller/Comptroller of Tax/Comptroller of Services Economics/Secretary of Administration/ Administrative Assistant / Deputy Finance/Deputy of Taxes/Deputy of Economic services/ Deputy of Administration/Secretary Assistant	A/B2/ B1 / C	1	1	1	1	1
Sheets Officer Lockers	Inspector of Finance/ Inspector of Treasury/Tax Inspector/Inspector Economic Services/Administrator Civilian/ Planner/ Technician of Work Planning/Controller of Finance/Treasury Comptroller/Comptroller of Taxes/Comptroller of Services Economics/Secretary of Administration/ Administrative Assistant / Deputy Finance/Deputy of Taxes/Deputy of Economic Services/Deputy Administration/Secretary Assistant	A/B2/ B1 / C	1	1	1	1	1
TOTAL			**46**	**46**	**48 50**		**5 0**

Article 2: The Minister of Labor and the Public Service, in charge of Relations with the Institutions, the Minister of Industrial Development and the Minister of Economy and of Finance are responsible, each as far as he is concerned, of the execution of this decree which will be registered and published in the Official Journal.

Bamako, March 13, 2017

The president of the Republic,
IbrahimBoubacarKEITA

The Prime Minister,
Modibo KEITA

The Minister of Labor and the Public Service, in charge Relations with Institutions,
MadameDIARRARakyTALLA

The Minister of Development industrial,
MohamedAlyAGIBRAHIM

The Minister of Economy and finance,
Doctor Boubou CISSE

DECRET N ° 2017 - 0245 / P-RM DU 13 MARCH 2017 FIXANTLESMODALITESD'APPLICATIONDELALOI N°09-059 OF DECEMBER 28, 2009 GOVERNING THE BIOMEDICAL RESEARCH ON HUMAN BEINGS

LEPRESIDENTDELAREPUBLIQUE,

Having regard to the Constitution;

Having regard to Law No. 86-11/AN-RM of March 8, 1986 determining the fundamental principles of scientific research and technological;

Having regard to Law No. 86-35/AN-RM of April 12, 1986 on institution of the National Order of Physicians and the Code of ethics appended thereto;

Having regard to Law No. 86-36/AN-RM of April 12, 1986 establishing the National Order of Pharmacists and the Code of Ethics appended thereto; Having regard to Law No. 86-37/ AN.RM of April 12, 1986 establishing a National Order of Midwives and the Code of Ethics appended thereto; Having regard to Law No. 09-059 of December 28, 2009 governing biomedical research on human beings; Having regard to Decree No. 02-200 / P-RM of April 22, 2002 establishing the National Ethics Committee for Health and Life Sciences; Considering Decree No. 2015-0003/P-RM of January 8, 2015 appointing the Prime Minister; Considering Decree No. 2016-0510/P-RM of July 7, 2016, as amended, appointing members of the Government;

STATUANTENCONSEILDESMINISTRES,

CHAPTER 1: GENERAL PROVISIONS

Article 1: This decree sets the terms of application of Law No. 09-059 of 28 December 2009 governing biomedical research on human beings.

Article 2: Biomedical research is carried out on the basis of fundamental ethical principles recognized, nationally and internationally, of respect for the human person, beneficence/ non-maleficence, justice and equity.

CHAPTER 2: RESEARCH CONDITIONS BIOMEDICAL

Article 3: Biomedical research requires the following conditions:

(a) be beneficial to the country in general and to the local populations concerned; b) be conducted by a qualified person and/or team with reference to their proven scientific skills in the field; c) meet internationally recognized good clinical and laboratory practice criteria; d) respect the habits and customs recognized locally; e) be described in a protocol written in French, in easy-to-understand language, describing all the procedures in this area and complying with nationally and internationally accepted standards.

Article 4: The drafting of a biomedical research protocol must respect a framework that complies with international standards.

Article 5: Any protocol for biomedical research on human beings must be submitted for the opinion of the National Ethics Committee for Health and Life Sciences or an approved institutional ethics committee.

The National Ethics Committee for Health and Life Sciences is informed of any research protocol approved by an approved institutional ethics committee.

The conditions for obtaining the free and informed consent of research participants must be clearly defined in the research protocol.

The opinion issued by an ethics committee must be reasoned and notified by confidential mail to the principal researcher.

Article 6: The rights of vulnerable people, such as pregnant or breastfeeding women, people deprived of their liberty, people unable to express themselves in all conscience and minors must be particularly protected when they are participants in a study.

Article 7: Coverage of compensation for damage occurring during biomedical research is provided in accordance with the law.

CHAPITRE3 :DESMODALITESETDESPROCEDURES DELARECHERCHEBIOMEDICALE

Article 8: The consent of the participant is an obligation in biomedical research. It implies the principle of respect for the person and aims to give him the means to decide, in full knowledge of the facts, on a voluntary basis without constraint to participate or not in research.

Article 9: Free, informed and express consent is the consent given by a conscious and potentially capable individual to participate in biomedical research. Under these conditions, the participant:

- has previously received the necessary information on the planned biomedical research and has fully understood it; - reached a decision, after careful consideration, without having been subject to any coercion, undue influence or inducement, or intimidation.

The consent given can be withdrawn at any time, without prejudice to the participant. In this case, the participant may also request his withdrawal from the study and that of his data and biological material.

Article 10: Consent is given in writing. It is collected by the principal investigator or the field investigator after the approval of an approved ethics committee which will have evaluated the implementation of the protocol.

The consent form is validated by this committee. It must, if necessary, be translated into national languages by a translator accepted by the person whose consent is required, under the responsibility of the investigator or his representative. It is signed by the participant.

Article 11: All research participants must, if they wish, be personally informed of their state of health, following what this research may reveal about them.

The principal investigator or his local representative must inform the participant: a) of the context and justification of the research; b) the objectives, procedure and duration of the research; c) foreseeable risks to his health or daily life; d) the possibility for him to terminate his participation in the research before the end and to request the withdrawal of his personal data; e) the expected benefits of the research for him and his community.

Article 12: The process of free and informed consent includes the following elements: a) the description of the biomedical research and the conditions of enrollment of the participants approved by the ethics committee; b) the description **of the risks that can reasonably be foreseen without minimizing them;** c) description **of the expected benefits without exaggerating them;** d) the description of other possibilities, linked or not to his participation, but likely to be advantageous for the participant and the community; e) explanation of the principle of **confidentiality and its preservation;** f) explanation of the principle of **compensation** for the working time devoted to the study; g) an explanation of the management in the event of adverse events occurring during the study; h) explanation of the **voluntary** nature of participation and the right to withdraw at any time without prejudice; i) the communication of the coordinates of the ethics committee, the principal investigator and any organization or person to be contacted about the biomedical research and the rights of the participant.

Article 13: The consent form notifies that **participation is strictly voluntary. It** indicates that refusal to participate in biomedical research, or the desire to withdraw from the study at any time, will not result in any harm to the participant, nor the loss of the benefits provided. This participant can no longer claim the specific advantages linked to his participation in the ongoing research.

The form also indicates that the person may, in the event of withdrawal, request the withdrawal of their data and their human biological material.

Article 14: The responsibility of the researcher is to protect the participants **by placing their individual well-being**

above the interests of science and society. To this end , the following activities are developed:

a) inform the community about the relevance of the research and the constraints associated with it; (b) formulate scientifically sound and technically applicable biomedical research protocols; c) ensure that no adult and conscious human participant participates in biomedical research without having given their free, informed and voluntary consent; d) communicate to the potential participant all information on the planned biomedical research, information necessary and mandatory to obtain consent; (e) maintain the confidentiality of entrants' personally identifiable information to the extent permitted by law; f) conduct biomedical research in accordance with the protocol approved by the ethics committee; g) do not change anything without the agreement of the ethics committee that approved the protocol; h) ensure that all members of the research team are suitably trained for the needs of biomedical research including biomedical ethics. i) comply with all decisions and recommendations of the Ethics Committee; j) communicate to the ethics committee any problem discovered during the conduct of the study, including violations and deviations from the protocol and any complaints from participants in the biomedical research. This information must be communicated immediately to the ethics committee; k) ensure that the local community has access to post-study benefits after its conclusion.

Article 15 : National sponsors are responsible for creating an environment conducive to integrity, objectivity and respect for ethical standards in biomedical research.

This responsibility covers the design of biomedical research, its execution and the submission of required reports. In particular, sponsors must undertake to protect participants in any biomedical research study.

They are required: a) to have a written commitment of acceptance and collaboration from the team leader of each establishment where the research activities take place; b) provide insurance for the study, researchers and research participants; c) to monitor approved research in accordance with the advice of the ethics committee; (d) to inform the national authorities of the results of the research.

Article 16: The international sponsors have the following responsibilities: a) take charge of the scientific and ethical evaluation of biomedical research protocols; b) ensure that the proposed biomedical research is **compatible with national** ethical, regulatory and legal requirements ; (c) provide assistance, including financial, resource and educational, to promote the building of ethics review capacity; d) develop reasonably appropriate activities to make the results available to participants;

e) assist in defining policies and procedures **to promote the integrity of biomedical research** and to provide guidance in the event of allegations or evidence of scientific misconduct.

Article 17: The promoting institution and the ethics committee consulted must take the necessary measures to minimize the impact of conflicts of interest.
The institution must: - ensure the training **of personnel who take part in the conduct of biomedical research ;** - require researchers to disclose their conflicts of interest in advance; - have the declarations of conflicts of interest examined by an ethics committee and, if necessary, formulate an appropriate strategy.

Article 18: All biomedical research engages the moral responsibility of the State. To this end, the competent administrative authorities, as far as they are concerned, must:

- ensure strict compliance with ethical standards, good clinical and laboratory practices by researchers; - proceed to an arbitration between the participants in the biomedical research and the/or the researchers in the event of the occurrence of offence(s) and/or deviation(s); - apply the law in force for any infringement(s) and deviation(s) of the protocols by the researchers. However, the State will favor the search for an amicable solution, in any case.

CHAPTER 4: THE ETHICS COMMITTEE

Article 19: The moral responsibility of the State in biomedical research is assumed by the Ethics Committee which will have examined then adopted the protocol of the said research.

Also, this Ethics Committee is required to monitor the progress of the implementation of the protocol adopted at any time, at its own expense.

Article 20: The restitution of the results of biomedical research is done in the form of a workshop, a progress and/or final report and a publication.
The ethics committee must, in all cases, receive a copy of the final report of the research activity. When the

he research lasts more than a year, an annual progress report will be sent to him.

Reports received are kept for at least ten years.

Article 21: The requested ethics committee must diligently render its opinion on the protocol of the research project submitted to it. He must let the researchers know, in writing, in a sealed envelope.

In case of refusal, this decision must be justified in writing.
The researcher has the right to request a re-evaluation of the protocol after integrating the observations and any changes requested. The ethics committee has an obligation to respond diligently.

Amendments to the running protocol should be submitted to the ethics committee.

The favorable opinion of the Ethics Committee is mandatory for any principal investigator, before beginning any biomedical research on human beings. This opinion must be communicated, by the principal investigator, to the competent authorities and to any body that may request it.

The notice of rejection of a research protocol must be notified to the principal investigator, communicated to the other ethics committees and to the competent authorities.

Article 22: Funding and capacity building of Ethics Committees are provided by the State, local authorities, development partners and promoters.

CHAPTER 5: FINAL PROVISIONS

Article 23: A joint decree of the ministers in charge of Health and Scientific Research sets the terms of application of this decree.

Article 24: The Minister of Health and Public Hygiene, the Minister of Justice and Human Rights, Keeper of the Seals and the Minister of Higher Education and Scientific Research, are each responsible for which concerns him, of the execution of this decree which will be registered and published in the Official Journal.

Bamako, March 13, 2017

The president of the Republic,
IbrahimBoubacarKEITA

The Prime Minister
Modibo KEITA

The Minister of Health and Public Hygiene,
Doctor Marie Madeleine TOGO

The Minister of Justice and
Human Rights, Keeper of the Seals,
MasterMamadouIsmaïla KONATE

The Minister of Higher Education and
Scientific Research,
ProfessorAssetorFurner SAMAKE MIGAN

DECRET N ° 2017 -246 / P-RM DU 13 MARCH 2017
APPOINTING THE AMBASSADOR
EXTRAORDINAIREETPLENIPOTENTIAIREDUMALI
ANOUAKCHOTT(MAURITANIE)