Law No. 09-059 / of December 28th , 2009

Governing biomedical research on humans

The National Assembly deliberated and adopted at the meeting of December 15th, 2009;

The President of the Republic promulgates the following law:

Title 1: General provisions

Chapter 1: The Purpose of the Scope

Article 1: This law governs biomedical research on human being.

The provisions of this Act apply to researches on living persons, embryos and fetuses, biological material of human origin, identifiable personal information, corps, embryos or fetuses resulting from pregnancies or spontaneous abortion and stillbirths.

Chapter 2: Definitions

Article 2: **For the purposes of this Law, we mean by:**

Research committee: A center approved by the Minister in charge of health for one or more types of biomedical research.

Institutional Ethics Committee: Ethics committee planned in the organic texts of a national research institution.

National Ethics Committee: A committee set up at the national level to investigate biomedical research files on the ethical level, on its own initiative, at the request of the President of the Republic, the Prime Minister, a member of the Government , presidents of institutions or presidents of foundations and NGOs recognized as public utility and research investigators.

Research Coordinator: A physical person in charge of coordinating the actions of investigators working on the same project and in different centers.

Research institution: Any specialized body with moral personality whose mission is to promote and conduct biomedical research.

Research investigator: An individual who is responsible for directing and overseeing the implementation of the research project of the promoter that is authorized under the Malian law. A lead investigator is required per research project.

Promoter: A physical or moral person, institution or organization that initiates and finances a research project on human being.

Biomedical research: Any clinical, biological or surgical experiment organized and practiced on the human being with a view to the development of biological or medical knowledge.

Research with direct benefit: Research supposed not bringing any direct benefit to the person who leads to it. It is also called research with direct finality.

Research without direct benefit: Research supposed to bring no direct benefit to the person who leads to it. It is also called research without direct finality. It can increase knowledge in a biomedical field, with the possibility of application in the medium and long term.

Personal identifiable information: Information about a person that allows him to be identified or re-identified by a combination of indirect identifiers (such as date of birth, residence or unique personal characteristics).

Title 2: Conditions of biomedical research on humans

Article 3: No biomedical research can be carried out on human being unless the following conditions are met:

- the research is scientifically based and clearly described in a protocol;
- the available pre-clinical and clinical information is sufficient to justify the conduct of the projected research;
- the foreseeable risk incurred by researchers is disproportionate to the expected benefit to them or the interest of this research;
- it aims to extend the scientific knowledge of human being and the means likely to improve his condition;
- it is authorized under this act.

Article 4: Biomedical researches may only be carried out:

- Under the direction and supervision of an investigator with appropriate training and experience;
- In material and technical conditions adapted to the study and compatible with the requirements of scientific rigor and safety of the people who lead to this research.

Article 5: Researches without direct individual benefit to pregnant women or who breast feed are admitted only if there is a balance of advantages and prejudices favorable to the woman and her embryo, her fetus or her child.

Article 6: People deprived of liberty may only be solicited for biomedical research if they are expected to have a direct and major benefit for their health.

Article 7: Minors, adults under guardianship, people staying in a health or social institution and patients in emergency situations may be solicited for biomedical research only if they can benefit individually or collectively.

However, researches without direct individual benefit are allowed if the following three conditions are met:

- Presenting no predictable serious risks on their health;
- Be useful to people with the same age, illness or disability characteristics;
- Results that cannot be achieved otherwise.

Article 8: In the case of biomedical researches without direct individual benefit, the promoter assumes, even without fault, the compensation for the harmful consequences of the research for the person who leads to it, without being able to oppose the act of a third party or the voluntary withdrawal of the person who had initially consented to lead to the research.

For biomedical researches with direct individual benefit, the promoter assumes, even without fault, the compensation for the harmful consequences of the search for the person who leads to it, except evidence of his discharge that the damage is not his/her fault or that of any stakeholder without being able to oppose the act of a third party or the voluntary withdrawal of the person who had initially consented to lead to the research.

For any biomedical researches on human being, the promoter subscribes an insurance guaranteeing his civil responsibility as it results from this article and that of all and that of any intervener, regardless of the nature of the links existing between the parties and the promoter.

The provisions of this article are of public order.

Article 9: Biomedical research does not entitled to any direct or indirect financial compensation for the people who lead to it, except for the reimbursement of the exposed expenses and subject to planned special provisions.

However, in the case of a commercial benefit of a research, refunds must be negotiated

for the community under the study.

Title 3: Modalities and procedures for biomedical research

Article 10: Prior to carrying out a biomedical research on a person, the free, clear and express consent of the person must be obtained after the investigator, or the physician who represents him, has made known to him:

- The objective of the research, its methodology and its duration;
- Expected benefits, constraints and foreseeable risks, including in the termination of research before its expiry;
- The opinion of an approved ethics committee.

He or she informs the person whose consent is sought of his / her right to refuse or participate in a research or withdraw his / her consent at any time without incurring any liability, without detriment to the overall scientific quality of the results.
In exceptional cases, where, in the interest of a sick person, the diagnosis of his illness has not been revealed to him, the investigator may, in the respect confidentiality and the anonymity keep certain information relating to this diagnosis.

In this case, the research protocol must mention this eventuality. The information provided is summarized in a written document transmitted to the person whose consent is sought

The consent is given in writing, or in case of impossibility, attests by a third party.
The latter must be completely independent of the investigator and the promoter.
The consent may also be recorded or screened.

Article 11: In the case of biomedical research to be implemented in emergency situations which do not allow the prior consent of the person to be submitted to it, the protocol presented to the opinion of an approved ethics committee may predict that the consent of such person shall not be sought and that only of the relatives, if present, shall be solicited under the conditions set out above.
The interested party will be informed as soon as possible and his / her consent will be requested for the possible pursuit of this research.

Article 12: When a biomedical research is carried out on minors or on adults who are prohibited with direct individual benefit or without direct individual benefit, not presenting a serious foreseeable risk, consent must be given by their legal representatives.

Article 13: Before carrying out a research on the human being, every investigator is obliged to submit the project to the opinion of a scientific committee and an approved ethics committee.

The scientific committee gives its opinion on the scientific validity of the research protocol.

The ethics committee gives its opinion on the conditions of validity of the research, in particular the protection of the participants, their information and the methods of collecting their consent, any compensations due, the general relevance of the project and the adequacy between the pursued objectives and the means used and the qualification of the investigator (s) as well. It shall communicate to the Minister in charge of health any favorable or unfavorable opinion given to a research project according to the level of research and the national interest.

Prior to its implementation, the sponsor or main investigator shall send to the Minister of Health an application describing the essential data of the research, accompanied by the opinion of the committee or committees consulted. This opinion does not relieve him of his responsibility.

When the research is to be carried out in one or more public or private establishments, the sponsor or main investigator shall inform the director(s) of those institutions before the research is carried out.

The promoter shall inform the Minister of Health of any effect that may have contributed to the occurrence of a death, caused hospitalization or resulted in lasting organic or functional consequence and likely to be due to research. He shall also inform him of any premature termination of the investigation, indicating the reason of the termination.

Article 14: Subject to any ethical or legal obligation to reveal confidential information, members of committees, people called upon to collaborate in their work and agents of the state who own them should keep secret the information they may be knowledgeable about because of their duties and that lead to it or ongoing or objects or experimented methods.

People who are not independent of the sponsor and the investigator cannot valuably participate in a deliberation of the examined research.

Researchers must maintain the confidentiality of the personal information regarding participants to the research, under reserve to any ethical or legal obligation to reveal confidential information.

Article 15: Biomedical researches without direct individual benefit must not involve any serious and predictable risk to the health of the people who lead to it. They must be preceded by a medical examination of the people concerned. The results of this diagnosis are communicated to them through the main investigator.

Article 16: In the case of a research without direct individual benefit to the people who lead to it, the promoter pays to these people an indemnity in compensation for the constraints underwent. The total amount of compensation that a person may receive in the same year taken for its application.

Article 17: Health inspectors, the Pharmaceutical and Medicines Directorate and the members of the approved ethics committee shall be responsible for ensuring compliance with the provisions of this law and the regulations adopted for its application.

Article 18: The information relating to the search shall be recorded in registers, processed and stored in such a way as to the presentation of complete and accurate reports on research and its interpretation as well as its checking.

These information must be available at the body that conducted the research and at the researcher.

Title 4: Prohibitions and penalties

Article 19: No one can simultaneously lead to several biomedical researches which could harm his health or the results of the research.

For each research, the protocol submitted for the advisory opinion of the scientific committee and the approved ethics committee determines a period of exclusion during which the person who leads to it cannot participate in another research.

Article 20: Biomedical researches can only be carried out by a competent team, in a place equipped with material and technical means suitable for the research and compatible with the safety requirements of the people who lead to it.

Article 21: The fact to practice or make practice of biomedical research on a person without the consent of the person or his legal representatives under the conditions provided for in this Law shall be punished by:

- One (01) to three (3) years imprisonment and a fine of 300,000 to 1,000,000 francs or one of the two penalties only and the prohibition, for a maximum period of five

years, to exercise the professional or social activity in respect of which or in the course of which the offense was committed may be imposed.

- If it has resulted in mutilation, amputation, deprivation of use of a limb or a sense, loss of the eye or other infirmities or sickness, the punishment will be from five to ten years of imprisonment and the prohibition on the pursuit of the occupational or social activity on the occasion of which the offense was committed must be pronounced.
- In case of death the guilty shall be punished with life imprisonment and the prohibition to engage in the professional or social activity on the occasion of which the offense was committed must be pronounced.

The provisions of the criminal code are applicable in relation to complicity, recidivism and mitigating circumstances.

Article 22: Anyone undertaking research without the authorization of the Minister of Health shall be punished by five to ten years' imprisonment, without prejudice to the temporary or permanent closure of the research establishment.

Article 23: The promoter whose civil liability is not guaranteed by the insurance provided for in article 8 of this law is punishable by imprisonment of one to six months and a fine of 300,000 to 1,000 000 francs or one of these two penalties only.

The promoter who carries out or makes carried out biomedical research without having sent to the Minister for Health the application provided for in section 13 of this Act shall be punished by the same penalties.

Article 24: The Minister of Health may, at any time, suspend or prohibit biomedical research in case of a public health risk or failure to comply with the provisions of this act.

Title 5: Final provisions

Article 25: A decree taken in Council of Ministers determines the modality of application of this law.

Bamako, December 28th, 2009

President of the Republic

Amadou Toumani TOURE