REPUBLIC OF RWANDA/REPUBLIQUE DU RWANDA

NATIONAL ETHICS COMMITTEE / COMITE NATIONAL D'ETHIQUE

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FWA Assurance No. 00001973

IRB 00001497 of IORG0001100

Kigali, 19th February 2024.

Insights into the Development of the Draft Law Relating to Research on a Human Being in Rwanda.

I. Introduction

I.1. A Preliminary Note

Back then in 2018, an assessment of the Rwanda National Ethics Committee (RNEC) by the World Health Organization (WHO) had recommended to change the legal provisions instituting the ethical regulatory body (RNEC) and gear toward a law that erects RNEC as an independent entity. It took 4 years to see the first draft worked out by multiples stakeholders (form legal advisors at the Ministry of Health, EDCTP-BRECOR project partners, Law reform reviewers, Parliament commission) and finally gazetted on August 12th 2022, thus establishing the RNEC legal authority to regulate research on Human beings. In line with the law, two ministerial orders were also drafted defining the modalities of the law implementation with regard to regulating research involving human participants. The process was lengthy and bumpy but the product was of golden value. This necessitated advocacy in order to enact, first the law and second write guidelines on clinical trial oversight in the country.

I.2. The Making of the Law

In Rwanda, all research that was conducted on a human beings was previously regulated by the Ministerial Instructions N°003/2010 of 09/12/2010 regulating research activities in Rwanda by the Ministry of Education, and later the Rwanda National Ethics Committe, the Commitee, established through a Ministerial Instructions N°20/37 of 3/10/2008 of the Ministry of Health, with the mandate to review all medical research-related projects.

The two Ministerial Instructions, much as they were considered as legal tools, they could not serve as sources of an enabling law that required to recognize or regulate research activities and protect the rights of human participants as well as establish a Committee that was expected to be multidisciplinary and autonomous in nature as well as enforce internationally accepted research ethical standards and principles.

Furhter more, article 14 of the Constitution of the Republic of Rwanda of 2003 revised in 2015, requires a specific law to determine modalities of consent and experiments on human participants, prior to conducting research on humans.

It was against that background that the Committee members, with suport from the Ministry of Health and the Rwanda Food and Drugs Authority and consortium members of the EDCTP funded BRECOR project, embarked on a task of collecting view and information and drafted the law regulating research on human beings. The Committee members come from different academic backgrounds and experiences. Several wide consultative meetings were held with key stakeholders. The draft law was expeditiously approved by the Cabinet on 1st September 2021 and was passed by the Parliament with support of the Committe members. It was published in the Offical Gazette on 12/08/2022.

The drafting process coincided with the formal assessment of the Rwanda Food and Drugs Authority to attain the WHO regulatory system classification of medical products "Maturity Level 3" which implies having a legal instrument regulating research on human beings.

Therefore the draft law was drafted to replace the Ministerial Instructions stated above in order to align with the Constitution and recognize ethical standards such as informed consent in health related research on human participants.

II. Challenges in the Legal Framework and reasons to initiate a new Law

According to the hierarchy of laws, the Ministerial Instructions stated above, were of lesser legal hierarchy to serve as a source of legal basis for establishing a body like the National Ethics Committee whose work impacts the activities of other national institutions that play a role in research on human participants.

Human participants in research activities must be protected against researchers who do not comply with research standards as well as internationally recognized principles. In order to attain this goal, ethical research activities needed to be regulated by a legal framework that complies with the Constitution as well as other laws that protect the rights of human participants.

The draft law was drafted to address the issue of having no robust legal framework that recognized ethical standards and protecting the rights of participants in health research activities conducted on humans. Most importantly, the law established the Committee that reviews and approves the ethical component of such researches before they are conducted.

III. Issues that were resolved by the Law

The law, upon publication in the official gazette, solved the following issues among others:

1° recognition and enforcement of the internationally recognized principles of research on human participants and it laid down key guiding principles that every researcher must comply with, in conducting research on human participants;

2° The law serves as a reference to entities that intend to conduct research in the area of medicines and related clinical trials and other researches that fall within the mandate of the law;

3° it establishes an independent and multidisciplinary Ethics Committee whose responsibility is to enforce the rules and ethical standards set out in the law and its regulations.

IV. Power of the Minister to establish Ministerial Orders

The law delegates the Minister of Health powers to draft the following Ministerial orders:

1. An Order of the Minister determines the Organization, competence, functioning and composition of the Committee.

2. Guidelines to determine the procedures for the submission, analysis and approval of research protocols.

The Ministerial Order has been drafted by the Committee as well and was approved by the Cabinet meeting that was held on 31st January 2023. The Order is awaiting publication in the Official Gazette. The Committee is now embarking on finalizing the remaining legal instruments of the Committee.

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