COUNCIL OF MINISTERS REGULATION NO. 376/2016

COUNCIL OF MINISTERS REGULATION TO PROVIDE FOR THE ESTABLISHMENT OF ARMAUER HANSEN RESEARCH INSTITUTE

This regulation is issued by the Council of Ministers pursuant to Article 5 and Article 39 of the Definition of Powers and Duties of the Executive Organs of the Federal Democratic Republic of Ethiopia Proclamation No. 916/2015.

1. Short Title
   This Regulation may be cited as the “Armauer Hansen Research Institute Establishment Council of Ministers Regulation No. 376/20016”.

2. Definition
   In this Regulation unless the context otherwise requires:

   1/ “research” means an activity conducted in a laboratory or outside the laboratory, by applying intellectual knowledge to discover, interpret and develop methods and systems, and to adopt or improve research findings;
2/ “medical research” means pre clinical, clinical and translational research conducted to generate new and improved knowledge;

3/ “pre clinical research” means any kind of health related research undertaken before clinical trials; which include but not limited to, bioinformatics, genetics, molecular biology, immunology, microbiology etc., conducted in vitro and in laboratory animals;

4/ “clinical trial” means a controlled experiment involving a defined set of voluntary human subjects intended to yield scientifically valid information about the efficacy and safety of new and improved drugs, vaccines, diagnostic tests, and the like;

5/ “biomedical research” means pre clinical research that includes basic, applied and translational research conducted to develop knowledge in the field of medicine;

6/ “basic research” means a systematic research directed towards greater knowledge or understanding of the fundamental aspects of phenomena;

7/ “applied research” means scientific study and research that can be directly applied to solve practical health problem;

8/ “trans national research” means a research that aims at making findings from basic science useful for practical applications of science in solving practical problems that enhance human health and well being;
9/ “operational medical research” means a research that aims at solving problems in the implementation of medical or clinical care;

10/ “medical biotechnology research” means the use of living systems and organisms or derivatives to develop useful products or generate relevant knowledge that can improve clinical care, health and well being of the public;

11/ “bioinformatics” means a scientific method of storing, analyzing and organizing biological information using computer technology;

12/ “region” means any regional state referred to under Article 47(1) of the Constitution of the Federal Democratic Republic of Ethiopia and includes Addis Ababa and Dire Dawa city administrations;

13/ “Ministry and Minister” means the Ministry of Health and Minister respectively;

14/ any expression in the masculine gender includes the feminine.

3. Establishment

1/ The Armauer Hansen Research Institute (hereinafter the ‘Institute’) is here by established as an autonomous federal government office having its own legal personality.

2/ The Institute shall be accountable to the Ministry.
4. **Head office**
The Institute shall have its head office in Addis Ababa and may have branch offices elsewhere, as may be necessary.

5. **Objectives of the Institute**
The Institute shall have the following objectives:

1/ undertake biomedical, clinical and medical biotechnology research and adopt and implement scientific technologies to improve clinical care, health and well being of the public;

2/ conduct clinical trials on new and improved medical diagnostic methods, vaccines and drugs to improve public health;

3/ build capacity to higher education and other related institutions in the area of biomedical, clinical and medical biotechnology research and

4/ serve as a center of excellence in medical research and training in Ethiopia and Africa.

6. **Powers and Duties of the Institute**
The Institute shall have the following powers and duties to:

1/ develop research agenda on biomedical technology and biotechnology, medical, clinical, genetics, bioinformatics, systems epidemiology and medical technology; which are of primary importance for health care development; and conduct research as per the developed agenda and evaluate their impact;

2/ submit policy recommendation to concerned bodies based on the research findings;

3/ disseminate research findings to relevant bodies; transfer research findings to product development industries; provide technical support as deemed necessary; identify possible sources of funding.
technical support and other inputs to strengthen clinical research programs; establish network with stakeholders and other bodies;

4/ undertake joint clinical research in collaboration with national and international institutes; provide technical support to other organs to undertake a joint research as deemed necessary;

5/ put effort to ensure institutional research findings obtain intellectual property right at national and international level;

6/ organize foray for medical researchers research outputs presentation, review and determine validity to improve clinical care and identify further research needs;

7/ assess current capacity for clinical trials in Ethiopia and identify potential partners;

8/ build national capacity to conduct clinical trials; identify clinical trial sites and types of clinical trials that national and international organizations would like to conduct; conduct clinical trials on new and improved diagnostic methods, drugs and vaccines;

9/ ensure the safety of any research participants, confidentiality and national and international research principles of research ethics in all its research undertakings;
10/ establish institutional structure that can advance innovative, translational, operational and applied researches for improving medical services and increase awareness, fulfill trained manpower and equip with basic state of the art medical research equipments;

11/ cooperate with higher education institutions in providing short and long term trainings in the field of medical research; enhance educational status of professionals, transfer relevant technologies and provide consultancy service;

12/ award researchers who have got outstanding results in the field of medical research;

13/ strengthen cooperation with regions and neighboring countries in medical research and training; boost knowledge transfer and mutual benefit;

14/ provide, upon request, services that are not provided by other bodies on selected diagnostic and analytical tests; charge fee as per the rate approved by the government for the service it provides;

15/ own property; enter into contract and sue and be sued in its own name;

16/ to engage in any other related activities necessary for the attainment of its purpose

7. Organization of the Institute

1/ The Institute shall have;

a) Advisory Board (hereinafter called the “Board”);
8. **Members of the Board**

1/ Members of the Board including the chairperson shall be appointed by the Minister and their numbers shall be determined as necessary.

2/ The members of the Board to be appointed pursuant to sub-article (1) of this Article shall consider different disciplines.

3/ The term of service of the Board members shall be 5 years, and may not be elected for a maximum of two terms.

9. **Duties and Responsibilities of the Board**

The Board:

1/ shall advise the Institute in research policy, strategy and other fundamental issues of the Institute;

2/ may establish scientific and other technical committees as deemed necessary.

10. **Meeting of the Board**

1/ The Board shall meet regularly or as frequent as its function requires.

2/ There shall be quorum where more than half of the members of the Board are present at a meeting.

3/ The decisions of the Board shall be passed by a majority vote and, in the case of a tie, the Chairperson shall have a casting vote;

4/ Without prejudice to the provisions of this Article, the Board may adopt its own rules of procedure.
11. **Powers and Duties of the Director General**

1/ The Director General shall be the chief executive officer of the Institute and shall, subject to the general directions of the Ministry, direct and administer the activities of the Institute;

2/ Without limiting the generality of sub-article (1) of this Article, the Director shall:

a) exercise the powers and duties of the Institute specified under Article 6 of this Regulation;

b) employ and administer employees engaged in support services of the Institute in accordance with the federal civil service laws and, in the case of professionals engaged in the core functions of the Institute, in accordance with directives approved by the Government following the basic principles of the federal civil service laws;

c) prepare and submit to the Ministry the annual work program and budget of the Institute, and implement same upon approval by the Government;

d) effect payments in accordance with the approved budget and work program of the Institute;

e) represent the Institute in its dealings with third parties;

f) prepare and submit to the Ministry the performance and financial reports of the Institute.

3/ The Director General may delegate part of his powers and duties to other officers and employees of the Institute to the extent necessary for the efficient performance of the activities of the Institute.
12. Powers and Duties of the Deputy Director Generals

The Deputy Director Generals shall:

1/ assist the Director General in planning, organizing, leading and coordinating the activities of the Institute;

2/ execute other duties specifically assigned by the Director General;

3/ represent the Director General in his absence, when specifically delegated by the Director General.

13. Budget

The budget of the Institute shall be allocated by the Government.

14. Books of accounts

1/ The Institute shall keep complete and accurate books of accounts;

2/ The books of accounts and financial documents of the Institute shall be audited annually by the Auditor General or by an auditor designated by him.

15. Effective date

This Regulation shall enter in to force on the date of their publication in the Federal Negarit Gazette.

Done Addis Ababa day of 19th February 2016

HAILEMARIRIAM DESSALEGN

PRIME MINISTER OF FEDERAL DEMOCRATIC REPUBLIC ETHIOPIA