THE NATIONAL HEALTH RESEARCH ACT, 2013

ARRANGEMENT OF SECTIONS

Section

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GOVERNMENT OF ZAMBIA

ACT

No. 2 of 2013

Date of Assent: 21/03/13

An Act to establish the National Health Research Authority and provide for its functions and powers; establish the National Health Research Ethics Board and provide for its functions and powers; provide a regulatory framework for the development, regulation, financing and coordination of health research and ensure the development of consistent health research standards and guidelines for ethically sound health research; provide for the establishment of health research ethics committees and the regulation and management of research institutions, health researchers and health establishments involved in or undertaking research; provide for the regulation of biological material for health research; provide for ethical approval for the conduct of clinical trials; provide for the use of traditional, complementary and alternative medicines in health research; provide for data management and intellectual property rights in health research; provide for the designation of bio banks; and provide for matters connected with, or incidental to, the foregoing.

[22nd March, 2013

ENACTED by the Parliament of Zambia. Enactment

PART I

PRELIMINARY

1. This Act may be cited as the National Health Research Act, 2013. Short title

2. In this Act, unless the context otherwise requires— Interpretation

" accreditation " means a process of certification of competence in health research;

" animal subject " means an animal which is used for health research or clinical trial;

" Authority " means the National Health Research Authority established under section *four*;

" Board " means the National Health Research Ethics Board constituted under section *thirteen*;

" bio-bank " means a collection of biological materials and the associated data and information which is stored in an organised system;

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" biological materials " means organs and parts of organs, cells and tissue, sub cellular structures and cell products, blood, saliva, sputum, gametes (sperm and ova), embryos and foetal tissue, waste, including urine, feaces, sweat, hair, epithelial scales, nail clippings, placenta and cell lines from human or animal tissue;

" blood product " means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;

" Board Chairperson " means the person appointed as Chairperson of the Board in accordance with section *thirteen*;

" Cabinet " has the meaning assigned to it in the Constitution;

" central health research repository " means the central health research repository as prescribed by the Minister under section *thirty-three*;

" Chairperson " means the person appointed Chairperson of the Council under section *seven*;

" clinical trial regulations " means regulations made under section *fifty-four*;

"clinical trial " means a systematic study, involving human participants or animal subjects, that serves to answer specific questions about the safety or efficacy of a medicine, vaccine or method of prevention or treatment;

" committee " means a committee of the Council established under section *nine*;