THE ROLE OF PHARMACOGENOMICS IN CLINICAL RESEARCH IN SOUTH AFRICA: ETHICAL, LEGAL AND SOCIAL CHALLENGES

ABSTRACT

Marzelle Haskins

738136

A research report submitted to the Faculty of Health Sciences, University of Witwatersrand, Johannesburg, in partial fulfilment of the requirements of the degree of Masters of Science in Medicine in the file of Bioethics and Health Law.

Johannesburg, 2021.

DECLARATION

I, Marzelle Haskins declare that this Research Report is my own, unaided work. It is being submitted for the Degree of MScMed (Bioethics and Health Law) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Marzelle Haskins
cn=Marzelle Haskins, o=Pharma-Ethics,
email=marzelle@pharma-ethics.co.za, c=ZA
I attest to the accuracy and integrity of this document
Centurion
2021.11.12 12:03:18 +02'00'

_____

(Signature of candidate)

10 day of November 2021

in Pretoria

ABSTRACT

Pharmacogenomics (PGx) is a research field where a person's genes are connected to their response to medicine. PGx research can positively influence the way people respond to treatment and treat disease more effectively. PGx research shows promise in clinical trials as better knowledge of the cause for a specific medication response can improve the medicine's safety and therapeutic index. With South Africa's high incidence of communicable and non-communicable diseases, interventions are contingent on prevention and treatment, including drug therapy, leading to toxicity. The South African population exhibits distinctive genetic profiles, and consequently, pharmacogenomics may positively influence the disease burden. With advances in pharmacogenomic research comes social, ethical, and legal challenges and the potential for exploitation. This research report aims to explore these challenges and suggest ethically justified guidelines or criteria that can be incorporated into current health research ethics guidelines when conducting PGx research in clinical trials in South Africa. There are three challenges investigated in this report. The first is the ethical challenges of PGx research. Following this is the legal challenges and, lastly, social challenges. The final chapter consists of suggested ethical guidelines and recommendations when conducting PGx research on human participants in South Africa.

Human Research Ethics Committee (Medical)

Research Office Secretariat: Senate House Room SH10005, 10th floor. Tel +27 (0)11-717-1252
Medical School Secretariat: P V Tobias Building, 2nd floor Tel +27 (0)11-717-2700
Private Bag 3, Wits 2050, www.wits.ac.za. Fax +27 (0)11-717-1265

Ref: W-CJ-141001-1 01/10/2014

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Marzelle Haskins.**

Project title: **Pharmacogenomic research in industry-sponsored clinical trials in South Africa: ethical, social and legal challenges..**

Reason: This study is an analysis of information in the public domain. There are no human participants

UNIVERSITY OF THE WITWATERSRAND
PROTECTION ... ONES
HREC (MEDICAL)
2014 -10- 01
JOHANNESBURG

Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy - HREC(Medical) Secretariat: Zanele Ndlovu.