Title: Sharing of biomaterials and data for biobank use in exchange for funding in South Africa in international collaborative health research: An ethico-legal analysis.

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Declaration

I, Mantombi Rebecca Maseme, declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Masters of Science in Medicine in 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.

Signature __________________

Signed on the ________ day of ___________ 20 _______ in ________________________

Dedication

I dedicate this Research Report to my parents, Mbali Wilson Maseme and Kelebogile Martha Maseme for your support, endless love and for the countless sacrifices you have made in ensuring that all of your children have opportunities for education, which brings to mind the words of Nelson Mandela that:

> *Education is the great engine of personal development. It is through education that the daughter of a peasant can become a doctor, that the son of a mine worker can become the head of the mine, that a child of farm workers can become the president of a great nation. It is what we make out of what we have, not what we are given, that separates one person from another.*[1]

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Abstract

The development of biobanks over the years have raised ethico-legal controversies and concerns particularly in the context of cross-border transfers of human material. This is due not only to different values, beliefs and notions on commodification of human biomaterials, but also as a result of inadequacies in national and international regulations in addressing this crucial aspect of biobanking. It is common practice for South African biobanks and biobank researchers to seek funding from agencies that are independent of the biobank that often stipulate conditions requiring researchers to grant access and share biomaterials and data as part of the agreement, in particular, in international collaborative health research. As yet, to the author’s knowledge, there has been no study conducted to examine whether these conditions could result in the commercialization of biomaterials and data and whether such practice is considered ethical. This study therefore seeks to answer the question whether such sharing of biomaterials and data for biobank research in exchange for funding from sponsors and funders in international collaborative health research is ethically justified. The research question is answered through the use of ethical principles and theories as well as an analysis and evaluation of relevant ethico-legal frameworks and literature. No research participants are involved in the study and no new data is collected or analysed. Arguments against and for sharing of biomaterials and data in exchange for funding are discussed through exploring fundamental ethical issues that could arise as a result of such sharing, which in turn leads to commodification of the human body and its parts. In countering the effects of such commodification, there is a requirement for an all inclusive benefit sharing model for all stakeholders concerned. Benefit sharing is therefore explored. Ownership of biomaterials is discussed as it has been associated with issues of benefit sharing, with the same ethico-legal issues of ownership apparent in both High Income as well as Low and Middle Income countries. There is a need for the development of a national ethico-legal framework that addresses sharing of biomaterials and data where funding is concerned as a means of protecting against biobank sample exploitation as well as exploitation of the researchers themselves. This study concludes that it is unethical to share biomaterials and data in exchange for funding because this has the potential for exploitation of the participants due to a lack of respect for their dignity and human rights.

Acronyms

AAS	African Academy of Sciences
AESA	Alliance for Accelerating Excellence in Science in Africa
AIDS	Acquired Immunodeficiency Syndrome
ASLM	African Society for Laboratory Medicine
BBMRI-ERIC	Biobanking and BioMolecular resource Research Infrastructure-European Research Infrastructure Consortium
BCNET	Biobank Cohort Network
B3Africa	Bridging Biobanking and Biomedical research across Africa and Europe
CIOMS	Council for International for International Organizations of Medical Sciences
CSIR	Council for Scientific and Industrial Research
DNA	Deoxyribonucleic acid
DST	Department of Science and Technology
EC	Eastern Cape
ESRD	End Stage Renal Disease
HCP	Health Care Professional
HIC	High Income Country
HPCSA	Health Professions Council of South Africa
HREC	Health Research Ethics Committee
HUGO	The Human Genome Organisation
H3Africa	Human Heredity and Health in Africa
ICMJE	International Committee of Medical Journal Editors
INDEPTH	Network for the Demographic Evaluation of Populations and their Health in Low- and Middle Income Countries
ISBER	The International Society for Biobanks and Environmental Repositories
LMIC	Low and Middle Income Country
MCH	Miami Children’s Hospital
MCHRI	Miami Children’s Hospital Research Institute
MTA	Material Transfer Agreement
NDOH	National Department of Health
NMTA	National Material Transfer Agreement
NHA	National Health Act 61 of 2003

NHREC	National Health Research Ethics Council
NIH	National Institutes of Health
NRF	National Research Foundation
OECD	Organisation for Economic Co-operation and Development
PGP	Personal Genome Project
PSA	Prostate Specific Antigen
QMS	Quality Management System
RSA	Republic of South Africa
SA	South Africa
SS Africa	Sub-Saharan Africa
SADC	Southern African Development Community
SOP	Standard Operating Procedure
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organisation
USA	United States of America
USD	United States Dollar
WITS	University of the Witwatersrand
WHO	World Health Organization
WMA	World Medical Association
ZAR	South African Rand

Definitions

Biobank	means an organized collection and storage of biomaterials (human samples) and the associated data.
Data	means information that is associated with biomaterials including, but not limited to biomaterial identifying numbers, demographic information of those that have donated biomaterials as well as disease information.
MTA	is defined as a contractual agreement for the sharing of biomaterials and associated data between two or more parties.
Research participant	means an individual who participates in scientific or health research.

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