

**ETHICS AND HUMAN RIGHTS IN HIV-RELATED  
CLINICAL TRIALS IN AFRICA WITH SPECIFIC  
REFERENCE TO INFORMED CONSENT IN  
PREVENTIVE HIV VACCINE EFFICACY TRIALS IN  
SOUTH AFRICA**

**BY**

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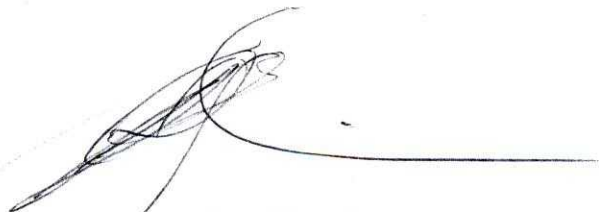
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**PRETORIA**

**2007**

I declare that the thesis, which I hereby submit for the degree Doctor Legum (LLD) at the University of Pretoria, is my own work and has not previously been submitted for a degree at another university.

Signed at Pretoria on this the 26<sup>th</sup> day of June 2007.



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THUS SIGNED AND SWORN BEFORE ME ON THE 26<sup>TH</sup> DAY OF JUNE 2007 AFTER THE DEPONENT DECLARED THAT THE CONTENTS OF THIS AFFIDAVIT IS TRUE AND CORRECT AND THE OATH IS BINDING ON HER CONSCIENCE.

  
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## SUMMARY

This thesis examines the regulation of HIV-related clinical research in Africa, with special emphasis on preventive HIV vaccine efficacy trials in South Africa. The discussion centres on aspects of the South African economic, social and political context, which increase not only certain communities' vulnerability to HIV infection, thereby accelerating the spread of the disease, but also those communities' vulnerability to exploitation and abuse during clinical research.

Human rights law is suggested as a viable alternate model to bioethical regulation to protect participants in HIV-related clinical trials. It is demonstrated that, in certain instances, human rights law has important advantages over bioethics, not only because it has the force of law, but also because it positions the research participant within a specific social context. It is proposed that a normative model derived from human rights' principles adds value to the bioethical debate in the context of clinical research in South Africa and the rest of the world.

The thesis concludes that in order to make clinical research more responsive to circumstance, bioethics should be inspired by a broader social, economic and political perspective, such as is provided by a human rights-based analysis.

The thesis recommends that bioethics and human rights law, rather than being seen as different systems, should be unified into a single system of protection under the Constitution and the Bill of Rights. In order to do this, legislation that integrates ethical guidelines and human rights law needs to be drafted to give effect to the constitutional guarantee in section 12(2)(c). At the international level, the adoption of a convention which integrates human rights law and ethical guidelines is proposed.

## OPSOMMING

Die proefskrif ondersoek die regulering van MIV-verwante kliniese navorsing in Afrika, met spesifieke verwysing na kliniese proefnemings in Suid-Afrika om die doeltreffendheid van voorkomende MIV-entstowwe te bepaal. Die bespreking gee aspekte van die Suid-Afrikaanse ekonomiese, sosiale en politieke konteks weer, wat nie net sekere gemeenskappe se kwesbaarheid vir MIV-infeksie bevorder nie, en dus die verspreiding van die siekte aahelp nie, maar wat ook daardie gemeenskappe meer kwesbaar maak om uitgebuit en misbruik te word gedurende kliniese navorsing.

Menseregte word voorgestel as 'n lewensvatbare alternatiewe model teenoor bio-etiese regulering om die belange van deelnemers aan MIV-verwante kliniese proefnemings te beskerm. Die proefskrif wys daarop dat, onder sekere omstandighede, menseregte belangrike voordele bo die bio-etiek het, nie net omdat dit regsrag het nie, maar ook omdat dit die deelnemer aan navorsing posisioneer binne 'n spesifieke sosiale konteks. Daar word aan die hand gedoen dat 'n normatiewe model, afgelei vanaf menseregte-beginsels, waarde sal toevoeg tot die bio-etiek-debat in die konteks van kliniese navorsing in Suid-Afrika en die res van die wêreld.

Die proefskrif bevind dat, om kliniese navorsing meer responsief tot omstandighede te maak, die bio-etiek geïnspireer moet word deur 'n breër sosiale, ekonomiese and politieke perspektief, soos wat voorsien word deur 'n menseregte-gebaseerde analise.

Die proefskrif maak die aanbeveling dat die bio-etiek en menseregte, eerder as om as twee verskillende stelsels gesien te word, saamgevoeg moet word in 'n enkele stelsel van beskerming ondergeskik aan die Grondwet en die Menseregtehandves. Ten einde hierdie doel te bereik, moet wetgewing aangeneem word wat effek gee aan die grondwetlike waarborg in artikel 12(2)(c) en sodoende etiese riglyne en menseregte integreer. Op die internasionale vlak word aan die hand gedoen dat 'n internasionale konvensie aangeneem moet word wat menseregte en etiese riglyne integreer.

for

E, who cooked a roast  
W, who was patient  
and  
my parents, who would have been so proud

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## ABBREVIATIONS AND ACRONYMS

ACHPR	African Charter on Human and Peoples' Rights
ADCC	antibody-dependent cellular cytotoxicity
AIDS	Acquired Immune Deficiency Syndrome
ART	anti-retroviral therapy
ARV	antiretroviral
AU	African Union
AZT	Zidovudine
CAT	Convention Against Torture
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CIOMS	Council for International Organizations of Medical Sciences
CMI	cell-mediated immunity
CRC	Convention on the Rights of the Child
CSA	Centre for the Study of AIDS, University of Pretoria
DNA	deoxyribonucleic acid
DH	Department of Health (South Africa)
DWB	Doctors Without Borders
FDA	Federal Drug Administration (United States of America)
GC	General Comment
GDP	Gross Domestic Product
HAART	Highly Active Anti-retroviral Therapy
HAVEG	HIV Vaccine Ethics Group
HCP	health care providers
HIV	Human Immunodeficiency Virus
HSRC	Human Sciences Research Council
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IDU	injection drug user
IRB	Institutional Review Board
IUD	intra-uterine device
MCC	Medicines Control Council (South Africa)
MDG	Millennium Development Goals
MP	Member of Parliament
MRC	Medical Research Council (South Africa)

MSM	men who have sex with men
MTCT	mother-to-child transmission
NEPAD	New Partnership for Africa's Development
NGO	non-governmental organisation
NIH	National Institutes of Health
OAU	Organisation of African Unity
OHCHR	UN Office of the High Commissioner for Human Rights
PI	principal investigator
PIL	patient / participant information leaflet
PLWHA	people living with HIV/AIDS
PLWV	people living with the virus (HIV)
PMTCT	prevention of mother-to-child transmission
REC	research ethics committee
RCCT	randomised controlled clinical trial
RNA	ribonucleic acid
SADC	Southern African Development Community
SAAVI	South African AIDS Vaccine Initiative
SIV	Simian Immunodeficiency Virus
STI	sexually transmitted infection
STD	sexually transmitted disease
TB	Tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
USA	United States of America
VCT	voluntary counselling and testing
WHO	World Health Organisation
WHA	World Health Assembly
WMA	World Medical Association
WSW	women who have sex with women