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

ANNELIZE G NIENABER

Thesis submitted in partial fulfilment of the requirements for the degree

DOCTOR LEGUM

in the

FACULTY OF LAW

UNIVERSITY OF PRETORIA

Supervisor:
PROF F J VILJOEN

Co-supervisor:
PROF P A CARSTENS

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 26th day of June 2007.

ANNELIZE G NIENABER

THUS SIGNED AND SWORN BEFORE ME ON THE 26TH 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.

COMMISSIONER OF OATHS

NAME : FRANCISCUS STEYN HAUPT

ADDRESS : Regakinek/Law Clinic
UNIV VAN PRETORIA/UNIV OF PRETORIA
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 regulerings 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 uitgebult en misbruik te word gedurende kliniese navorsing.

Menseregte word voorgestel as 'n lewensvatbare alternatiewe model teenoor bioetiese regulerings 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 regsreg 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 toevergelyk 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 en politieke perspektief, soos wat vooraf gestel is deur 'n menseregte-gebaseerde analyse.

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
ACKNOWLEDGEMENTS

I have been given great intellectual, moral and practical support.

The International Clinical, Operational, and Health Services Award (ICOHRTA) and the NIH sponsored my Post-Doctoral Fellowship at CIRA, Yale University, in 2003 where I did research and wrote the first chapters of the thesis.

The supervisor, Professor Frans Viljoen, and co-supervisor, Professor Pieter Carstens, provided valuable guidance. Professor Viljoen, especially, has been unstinting in his advice, support and humour.

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