Appendix 1

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

COMMITTEE FOR RESEARCH ON HUMAN SUBJECTS (MEDICAL)
Ref: R14/49 Shead

CLEARANCE CERTIFICATE **PROTOCOL NUMBER** M02-05-40

PROJECT Neurodevelopment And Growth of Institutionalised Children With Vertically Transmitted Human Immunodeficiency Virus

INVESTIGATORS Mrs G Shead

DEPARTMENT School of Therapeutic Sci, Private Practice

DATE CONSIDERED 02-05-31

DECISION OF THE COMMITTEE Approved unconditionally

Unles otherwise specified the ethical clearance is valid for 5 years but may be renewed upon application
This ethical clearance will expire on 30 July 2007.

DATE 02-08-30 CHAIRMAN.....(Professor P E Cleaton-Jones)

* Guidelines for written "informed consent" attached where applicable.

c c Supervisor: Ms J Potterton
Dept of School of Therapeutic Sci Johannesburg Hospital
Works2\Iain0015\HumEth97.wdb\M 02-05-40
==========
DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10001, 10th Floor, Senate House, University.

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress form. I/we agree to inform the Committee once the study is completed.

DATE 17/9/2002 SIGNATURE .....

PLEASE QUOTE THE PROTOCOL NO IN ALL QUERIES .: M 02-05-40

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix II

CONSENT FORM

To the Head of the Institution,

I, Gillian Shead, would greatly appreciate assistance from your Institution for my research entitled **"Neurodevelopment and growth of institutionalised children with vertically transmitted human immunodeficiency virus".** This research will be for a Masters degree in physiotherapy through the University of the Witwatersrand.

The purpose of the study is to identify the level of development and growth of institutionalised children who are HIV infected and those who are HIV uninfected. This will determine if the children are developing at the expected rate or whether they are in need of early intervention programmes.

In order to complete the study I would need access to 23 HIV negative and 23 HIV positive children aged between 18-36 months. These children will be re-evaluated 6-8 months later when they are 24-36 months of age. Each child will be evaluated developmentally using the test called "Bayley Scale of Infant Development II" This test is a reliable and valid test of a child's development. The child's height, weight and head circumference will also be recorded. Your institution will receive all the children's growth and developmental scores. The evaluation will take approximately 2 hours and will be carried out at your institution. I will complete the evaluations myself where I am blinded to the HIV status of the children. For those children whose status I know, an independent evaluator will be used to record the scores. I undertake to show concern and empathy towards the needs of your institution and to the child being evaluated.

If possible, I would like to make use of one of your rooms to carry out the evaluation. I will be providing all the test materials. Your children would probably feel more comfortable if a caregiver was present throughout the evaluation. The caregiver would also be able to assist me in determining whether the behavior and responses were appropriate for that child. I plan to begin in July 2002 and plan to be completed by April 2003.

Should your institution agree to be involved in the study I would appreciate it if you could complete the form entitled "Child's details". Only the child's first name will be used and he/she will be allocated a number for ease of identification at the follow-up visit. Each child's details and results will be kept confidential. A copy of the final research report will be given to your Institution. Your participation in this study is entirely voluntary and you may withdraw at any time, without prejudice to your institution. If you have any queries or concerns please feel free to contact Gillian on (011) 475-0942 or 082-8537098.

Your involvement would be greatly appreciated. I am certain that the research study will benefit the greater South African community.

Gillian Shead

Please complete:

I/~~We~~ DR. F. CHRISTY on behalf of THE SALVATION ARMY SOUTHERN AFRICA TERRITORY

hereby agree to be involved in the above research project.

Signed by _____ Date 27/7/02

DR. F. CHRISTY
M.B.Ch.B. (UCT), MCFP, MPH
Pr. No. 1510479
121 RISSIK STREET
JOHANNESBURG 2001

CONSENT FORM

To the Head of the Institution,

I, Gillian Shead, would greatly appreciate assistance from your Institution for my research entitled **"Neurodevelopment and growth of institutionalised children with vertically transmitted human immunodeficiency virus".** This research will be for a Masters degree in physiotherapy through the University of the Witwatersrand.

The purpose of the study is to identify the level of development and growth of institutionalised children who are HIV infected and those who are HIV uninfected. This will determine if the children are developing at the expected rate or whether they are in need of early intervention programmes.

In order to complete the study I would need access to 23 HIV negative and 23 HIV positive children aged between 18-36 months. These children will be re-evaluated 6-8 months later when they are 24-36 months of age. Each child will be evaluated developmentally using the test called "Bayley Scale of Infant Development II" This test is a reliable and valid test of a child's development. The child's height, weight and head circumference will also be recorded. Your institution will receive all the children's growth and developmental scores. The evaluation will take approximately 2 hours and will be carried out at your institution. I will complete the evaluations myself where I am blinded to the HIV status of the children. For those children whose status I know, an independent evaluator will be used to record the scores. I undertake to show concern and empathy towards the needs of your institution and to the child being evaluated.

will be providing all the test materials. Your children would probably feel more comfortable if a caregiver was present throughout the evaluation. The caregiver would also be able to assist me in determining whether the behavior and responses were appropriate for that child. I plan to begin in July 2002 and plan to be completed by April 2003.

Should your institution agree to be involved in the study I would appreciate it if you could complete the form entitled "Child's details". Only the child's first name will be used and he/she will be allocated a number for ease of identification at the follow-up visit. Each child's details and results will be kept confidential. A copy of the final research report will be given to your Institution. Your participation in this study is entirely voluntary and you may withdraw at any time, without prejudice to your institution. If you have any queries or concerns please feel free to contact Gillian on (011) 475-0942 or 082-8537098.

Your involvement would be greatly appreciated. I am certain that the research study will benefit the greater South African community.

Gillian Shead

Please complete:

I/We J Schoeman on behalf of Cotlands

hereby agree to be involved in the above research project.

Signed by J Schoeman Date 28/6/02

Appendix III

Child's details

All information is kept confidential

Name of Institution:

Child's first name only:

Date of Birth:

Date of admission to the institution:

Allocated number:
(Researcher to complete)

Child's HIV status

Please give HIV test results. The test used and the date of testing.

Child's antiretroviral treatment

Is the child on antiretroviral treatment?

If yes, as of what date?

Competed by Sister:_____