APPENDIX A

SUBJECT DATA COLLECTION SHEET

Study: Low dose erythromycin in improving the outcome of HIV-infected children

DATA COLLECTION SHEET: Visit 1

1. PATIENT INFORMATION

Name		
Hospital number		
Study number		
Date of admission	DD/MM/YY	
Gender	male	female
Age	Months	
Date of birth	DD/MM/YY	

2. PREVIOUS MEDICAL HISTORY

a. HIV			
	Patient previously tested	Y	N
	If Yes, previous result	positive	negative
	Currently: 1. Consent for ELISA	Y	N
	2. CD4 count	%	total
	3. Viral load		
	Antiretroviral treatment	Y	N
	Specify: 1. Drugs	1. 2. 3. 4.	

	2. Start date ARV		
b. Previous admissions	Previously admitted to hospital	Y	N
c. Treatment	Did the patient receive antibiotics? If yes specify:	Y	N
c. Anthropometric Findings			
Length	cm		
Weight	kg		

d. Examination

General	Temperature on admission		°C
	Generalized lymphadenopathy (0.5 cm present in at least 2 sites, bilateral lymph nodes counting as one site)	Y	N
	Clinically pale	Y	N
	Oedema	Y	N
	Jaundice	Y	N
	Hepatomegaly	Y	N
	Splenomegaly	Y	N
	Oral thrush	Y	N
	Parotomegaly	Y	N
	Eczema	Y	N
	HIV encephalopathy	Y	N

	Neurodevelopmentally normal			Y	N
Respiratory system	Respiratory rate			/ min	
	Heart rate			/ min	
	Peripheral saturation	without oxygen		%	
		with oxygen		%	
	Recession			Y	N
	intercostal	Subcostal	suprasternal		
	Flaring of alae nasi			Y	N
	Clinically cyanosed			Y	N
	Grunting			Y	N
	AUSCULTATORY FINDINGS				
	Focal abnormality			Y	N
	Diffuse abnormality			Y	N
	Clear chest			Y	N
	Hyperinflation			Y	N
	Crepitations			Y	N
	Bronchial breathing			Y	N
	Wheezing			Y	N
	Comments:				

OTHER SYSTEMS	
CVS	
GIT	
CNS	
ENT	

STUDY VISIT COMPLETION FORMS

Study: Low dose erythromycin in improving the outcome of HIV-infected children with bronchiectasis
Pt #: ___ ___ ___Init**:** ___ ___ ___

Visit	CD4 count	Viral load	Sputum MCS	Cytokine assays (blood/ sputum)	Sputum resp virus/TB	Liver function test
Visit 1	X	X	X	X	X	X
Visit 2			X			
Visit 3			X			
Visit 4			X			
Visit 5			X			
Visit 6			X			
Visit 7			X			
Visit 8			X			
Visit 9			X			
Visit 10			X			
Visit 11			X			
Visit 12	X	X	X	X	X	X

STUDY VISIT COMPLETION FORMS

Study: Low dose erythromycin in improving the outcome of HIV-infected children with bronchiectasis

Pt #:_____ Init:_____

	CXR	PET CT	Lung function test	Nitric oxide	Sweat test	Clinical exam
Visit 1	X	X	X	X	X	X
Visit 2			X			X
Visit 3			X			X
Visit 4			X			X
Visit 5			X			X
Visit 6			X			X
Visit 7			X			X
Visit 8			X			X
Visit 9			X			X
Visit 10			X			X
Visit 11			X			X
Visit 12	X	X	X	X		X

APPENDIX B

ETHICAL APPROVAL

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federalwide Assurance. FWA 00002567, Approved dd 22 May 2002 and Expires 24 Jan 2009.
RB 0000 2235 IORG0001762 Approved dd Jan 2006 and Expires 21 Nov 2008.

100 1908 - 2008
UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Health Sciences Research Ethics Committee
Fakulteit van Gesondheidswetenskappe Navorsingsetiekkomitee

Date: 3/06/2008

PROTOCOL NO.	100/2008~A
NEW TITLE	Low dose erythromycin in improving outcome of HIV-positive children with bronchiectasis
STUDY DE.G.REE	PhD
SPONSORS POSTAL ADDRESS	Level D3 New Steve Biko Academic Hospital, Malherbe Street, Capital park.
MEETING DATE OF THIS STUDY	28/05/2008

This **Protocol** and **Informed Consent** and **all the attachments** have been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 28/05/2008 and found to be acceptable.

Advocate AG Nienaber	(female) BA (Hons) (Wits); LLB; LLM (UP); Dipl.Datametrics (UNISA)
*Prof V.O.L. Karusseit	MBChB; MFGP (SA); MMed (Chir); FCS (SA): Surgeon
*Prof M Kruger	(female) MB.ChB. (Pta); MMed. Pead. (Pret); PhD. (Leuven)
*Dr N K Likibi	MB.BCh; Med.Adviser (Gauteng Dept.of Health)
*Snr Sr J. Phatoli	(female) BCur (Et.Al) Senior Nursing-Sister
*Dr L Schoeman	(female) BP harm, BA Hons (Psy), PhD
*Dr R Sommers	(female) MBChB; MMed (Int); MPhar.Med;
Mr Y Sikweyiya	MPH; Master Level Fellowship in Research Ethics; BSC (Health Promotions) Postgraduate Dip in Health Promotion
*Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
*Dr A P van Der Walt	BChD, DGA (Pret) Director: Clinical Services of the Pretoria Academic Hospital
*Prof C W van Staden	MBChB; MMed (Psych); MD; FTCL; UPLM; Dept of Psychiatry

DR R SOMMERS; MBChB; MMed (Int); MPhar.Med.
SECRETARIAT of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, Pretoria Academic Hospital

* Members attending the meeting.

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The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* FWA 00002567, Approved dd 22 May 2002 and Expires 24 Jan 2009.
* IRB 0000 2235 IORG0001762 Approved dd Jan 2006 and Expires 13 Aug 2011.

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Faculty of Health Sciences Research Ethics Committee
Fakulteit van Gesondheidswetenskappe Navorsingsetiekkomitee

Date: 20/11/2008

PROTOCOL NO.	100/2008~B
Informed Consent Document	(Give reason for [redacted]
PROTOCOL TITLE	Chronic inflammatory lung disease in human immunodeficiency virus (HIV) infected children. Epidemiological considerations, aetiological determinants and the efficacy of low dose erythromycin in bronchiectasis.
INVESTIGATOR	Principal Investigator: Refiloe Masekela
SUPERVISOR	R.J Green
DEPARTMENT	Dept: Paediatrics Phone: 012 354 5271 Fax: 012 354 5275
	E-Mail: Refiloe.masekela@up.ac.za Cell: 079 489 0936
MEETING DATE OF THIS STUDY	19/11/2008

This **Amendment** has been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 19/11/2008 and found to be acceptable

Members attended & Feedback at the meeting .

*Dr A Nienaber	(female) BA (Hons) (Wits); LLB; LLM (UP); Dipl.Datametrics (UNISA)
*Prof V.O.L. Karusseit	MBChB; MFGP (SA); MMed (Chir); FCS (SA)
*Prof M Kruger	(female) MB.ChB. (Pta); MMed. Pead. (Pret); PhD. (Leuven)
*Dr N K Likibi	MB.BCh; Med.Adviser (Gauteng Dept.of Health)
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*Snr Sr J. Phatoli	(female) BCur (Eet.A) BTec (Oncology Nursing Sience)Snr Nursing-Sister
*Dr L Schoeman	(female) BP harm, BA Hons (PSy), PhD
*Dr R Sommers	(female) MBChB; MMed (Int); MPharMed;
*Mr Y Sikweyiya	MPH; Master Level Fellowship in Research Ethics; BSC (Health Promotion) Postgraduate Dip in Health Promotion
*Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path), PGCHE
*Dr A P van Der Walt	BChD, DGA (Pret) Director: Clinical Services of the Pretoria Academic Hospital
*Prof C W van Staden	MBChB; MMed (Psych); MD; FCPsych; FTCL; UPLM; Dept of Psychiatry

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APPENDIX C

PATIENT INFORMATION LEAFLET, CONSENT FORM AND ASSENT FORM

A. CONSENT FORM AND PATIENT INFORMATION SHEET

Study title: Low dose erythromycin therapy in improving outcome of HIV-positive children with bronchiectasis

Dear Parent / Guardian

Your child _____is currently suffering from a problem of the chest and lungs that has come about because of HIV infection. This letter serves to request your permission to enrol your child in a study to investigate treatment options for children with this condition.

What is the purpose of the study?

This condition is usually treated with antibiotics when your child gets sick. We would like to test the effect of using a small quantity of a common antibiotic known as erythromycin on the disease process. Erythromycin is a medicine that reduces inflammation, and is often used in a number of other conditions and is generally tolerated well. It is possible that erythromycin may reduce the chances of your child getting sick and may have a good effect on improving his general condition and prevention infections in the lung. Your child may or may not get the antibiotic as we would like to see if will have any effect in the improvement of his/her lung status.

What is the duration of the study?

The duration of this study will be 12 months. Your child will need to give one tablet every evening for this whole time.

Procedures to be followed

Participating in this study would imply that your child would be treated with usual antibiotics in a standard way and the erythromycin as well. Your child's condition and response to the treatment will be monitored monthly at the usual clinic you attend.

Simultaneously, a small volume of the blood, urine and sputum, that are routinely collected, will also be tested for specific cytokine responses to infection.

Cytokines are specific substances released by the fighting cells of the body during stress situations like infection. Some of these cytokines are pro-inflammatory, or causing inflammation, while others are anti-inflammatory, or regulating this immune response by opposing the inflammatory response. These two groups of agents are usually working in a balanced way, and should something like specific chest infections impair this balance, damage to the cells may occur. We will be following your child up very closely at monthly intervals. We will then collect the normal sputum samples and monitoring his/her progress as well as looking for complications that the medication can cause. After 12 months we will repeat the sputum, urine and blood testing for the cytokine levels as well as the chest x-rays and CT scans. This information will guide us in better understanding of the lung damage caused by chest infections in your child.

What will be done at each visit will be as follows:

Visit 1:

- Sputum samples
- Blood tests
- Lung function tests
- Nitric oxide measurements
- Chest x-ray
- PET CT scan
- Sweat test
- Clinical examination

Visit 2-11

- Lung function test
- Sputum sample
- Clinical examination

Visit 12 (study ends)

- Lung function test
- Nitric oxide measurement
- Chest x-ray
- PET CT chest

- Sputum sample
- Blood sample
- Clinical examination

Risks and discomfort involved

It is important to note that no additional discomfort will be caused to the usual blood tests and investigations performed on a child with this condition.

We do not expect side effects from short-term erythromycin use and the risk is very small. Erythromycin used for a long time may cause some nausea, vomiting or diarrhoea. It is also possible that this antibiotic may make the other bugs in your child's lung resistant (stop responding) to some of the antibiotics we may need to use for pneumonia. In rare cases erythromycin can cause an allergic reaction and it may also cause damage to the liver which results in swelling of the liver and abdominal pains.

Drug interactions

Erythromycin can also interact with other medicines your child may be taking for example midazolam (Dormicum) by decreasing the level in the blood. Erythromycin can also increase the level of the following drugs in the blood: ebastine, carbamazepine (Tegretol), ciclosporin, ergotamine and warfarin. Should your child be taking any of these drugs the doctor will monitor the levels of these drugs closely and may not enrol your child in the study.

As mentioned previously, erythromycin is used in a number of other conditions and generally tolerated well. Should your child's condition deteriorate or an adverse (bad) reaction happen with the medication you are to contact Dr Masekela immediately at any time of day or night on the number 079 489 0936/ 012 354 5271. The medication will be stopped in case of a severe reaction to the medication; that is an allergic reaction or evidence of liver damage form the medication.

HIV testing

This letter then further serves to ask your permission to do a HIV test on your child if it was not done before. A specific consent form in the ward will also be used. It is important that the doctor who presents this form to you explain the following to you:

- The reasons we want to test your child
- That HIV is virus or bug that attacks the fighting cells of your body and make the body weak so that it can't fight infections as well as before
- How HIV is transmitted: through sexual contact, blood transfusions or dirty needles e.g. drug users or from mother to child. Transmission from mother to child can happen either during the pregnancy, the birth process or breastfeeding
- The stages of HIV in an adult and how it differs in children
- Currently there is no cure for HIV. We can however treat the infections the child gets because the body is weak. The doctor should also explain to you how anti-retroviral drugs can improve the quality of life and where they are available
- If your child's test is positive, the probability that you are also positive is high, and you should yourself be tested as well. Advice regarding future pregnancies and the availability of any treatment should also be given.

It is important to know that the results may only be given to you and that post-test counselling will also be done. You may decline the HIV test and the treatment of your child will not be influenced by that decision.

Has the study received ethical approval

The study protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, and that committee has granted written approval.

The study has been structured in accordance with the Declaration of Helsinki, which deals with the recommendations guiding doctors in biomedical research involving humans.

Confidentiality

All information obtained during the course of this trial is strictly confidential, and personal information will remain confidential at all times. Data that may be reported

in scientific journals will not include any information, which identifies your child as a patient in this study.

Source of additional information

During your child's stay in hospital she will be under the care of Dr Masekela on 012 354 5271/079 489 0936, If you have any questions, which were not fully explained by the doctor obtaining consent, please do not hesitate to ask him/her.

This letter serves to request your permission to enrol your child in this study group. You may refuse such permission and your child's management will not be affected in any way.

INFORMED CONSENT

I, _____

the parent/guardian of

_____ *(Name of patient)*

_____ *(Hospital Number)*

Have been informed about and understand the nature, benefits, risks and purpose of the trial, and all my questions have been answered. I hereby give permission that my child may participate in the above study.

I further have been fully informed regarding HIV and all my questions have been answered. I therefore give / do not give consent to perform an HIV test on my child

_____

Signature of the parent/guardian Date

I hereby confirm that the above parent / guardian have been fully informed about the nature, conduct and risks of the above trial.

_____

Name of the investigator

_____ _____

Signature of the investigator Date

_____

Name of witness

_____ _____

Signature of witness Date

B. ASSENT FORM

Name of study: Low dose erythromycin in improving outcome of HIV-positive children with bronchiectasis

I understand that I have been asked to participate in a study about my chest problem (bronchiectasis). I understand that I will use erythromycin (the new medicine), in addition to my normal medicines that I take for my chest.

I will be asked to have a check up of my chest by the doctor and I will be asked to blow in the two machines to check the size and the swelling of my lungs.

I will be asked to come for visits to the doctor regularly in order that the doctor can check how my chest is doing and a photograph will be taken of my chest to see how far my chest problem is. I will have to ask questions about my illness with every visit. I will also give my mucus to the doctor to check with every visit. I will be blowing into the machine with every visit so that the doctor can check my lungs. I will also have blood taken from me at the beginning of the study and after 12 visits (one year). A new photo of my chest will also be done after one year.

I understand that the medicine that the doctor wants to give me can make me feel sick. I can vomit or my stomach can work a lot from taking the medicine. This medicine may also give me a rash or bad reaction. The doctor will check me to see if it's very bad in which case she will decide to stop it if I get too sick.

I understand that I do not have to participate. If I do participate, I can quit at any time. I also understand that I do not have to answer any questions I don't want to answer or do anything I don't want to do.

My parents, teachers or anyone else will not know what I have said or done in the study. No one but the researchers will know.

This study is being done by Dr Refiloe Masekela of Pretoria Academic hospital. Her phone number is 012-354 5271 or 079 4890936.

If I have any questions or concerns about the study, I can call and ask her about them. When I sign my name, this means that I agree to participate in the study and

that all of my questions have been answered. I have also been given a copy of this form.

Name: _____ Signature_____

Name of Witness_____

Witness signature_____ Date_____

APPENDIX D

BHALLA SCORE

Category	0	1	2	3
Severity of bronchiectasis	Absent	Mild (luminal diameter slightly greater than accompanying vessel)	Moderate (lumen 2-3 times the diameter of vessel)	Severe (lumen >3 times diameter of vessel)
Peribronchial thickening	Absent	Mild (wall thickness equal to diameter of adjacent vessel)	Moderate (wall thickness greater than and up to twice the diameter of adjacent vessel)	Severe (wall thickness >2 times the diameter of adjacent vessel)
Extent of bronchiectasis*	Absent	1-5	6-9	>9
Extent of mucous plugging*	Absent	1-5	6-9	>9
Sacculations or abscesses*	Absent	1-5	6-9	>9
Generations of bronchial divisions involved (bronchiectasis/plugging)	Absent	Up to 4th generation	Up to the 5th generation	Up to 6th generation and distal
No of bullae	Absent	Unilateral (not >4)	Bilateral (not >4)	>4
Emphysema*	Absent	1-5	>5	
Collapse/consolidation	Absent	Subsegmental	Segmental/lobar	

No of bronchopulmonary segments affected: for the calculation of the CT score is subtracted from 25 [108]

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TERMINOLOGY AND ABBREVIATIONS

ABPA	Allergic bronchopulmonary aspergillosis
AIDS	Acquired immunodeficiency syndrome
CAP	Community acquired pneumonia
CCR3	CC chemokine receptor-3
CCR5	CC chemokine receptor-5
CDC	Centre for Disease Control
CF	Cystic fibrosis
CFTR	Cystic fibrosis transmembrane regulator
COPD	Chronic obstructive pulmonary disease
CRF	Circulating recombinant forms
CXR	Chest x ray
D_{LCO}	Pulmonary diffusion capacity for carbon monoxide
FEV_1	Forced expiratory volume in one second
FEF_{25-75}	Forced expiratory flow over 25-75% of expiration
$F_{c\varepsilon}R1$	Human F epsilon R positive cells
FVC	Forced vital capacity
G-CSF	Granulocyte colony stimulating factor
GM-CSF	Granulocyte macrophage colony stimulating factor
HAART	Highly active anti-retroviral therapy
H. influenzae	*Haemophilus influenzae*
HIV	Human immunodeficiency virus
H. parainfluenzae	*Haemophilus parainfluenzae*

HRCT	High resolution chest tomography
ICAM-1	Intracellular adhesion molecule-1
Ig	Immunoglobulin
IL	Interleukin
INF-γ	Interferon gamma
IP-10	Interferon gamma inducible protein-10
IPT	Isoniazid prophylaxis treatment
LRTI	Lower respiratory tract infection
MCP-1	Monocyte chemotactic protein-1
MIP-1	Macrophage inflammatory protein-1
MMP	Metalloproteinase
MRSA	Methicillin resistant staphylococcus aureus
NE	Neutrophil elastase
NFκβ	Nuclear factor kappa-beta
NTM	Non-tuberculous mycobacteria
PA	Pseudomonas aeruginosa
PAMPs	Pathogen associated molecular patterns
PcP	Pneumocystis jerovicii pneumonia
PET	Positron emission tomography
PMTCT	Prevention of mother to child transmission
PRP	Pattern recognition proteins
RAST	Radio Allergo Sorbent Test
rhDNAse	Recombinant DNAse

RSV	Respiratory syncytial virus
S. aureus	Staphylococcus aureus
sTNFR1	Soluble tumour necrosis factor receptor-1
sTREM	Soluble triggering receptor expressed on myeloid cells
Tat	HIV-trans-activating protein
TB	Tuberculosis
Th1	T helper-1
Th2	T helper-2
TLR	Toll-like receptors
TNF-α	Tumour necrosis factor alpha
URF	Unique recombinant forms
VCAM-1	Vascular cell adhesion molecule -1
WHO	World Health Organisation