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Chest X-ray findings in HIV infected children starting HAART at a tertiary institution in South Africa

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2013
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ASSENT TO PARTICIPATE IN A RESEARCH STUDY

*Each **child age 7 or older** must receive, understand, and sign (themselves or representative) this document **before** any study-related procedure*

STUDY NUMBER: Wits HREC number: FWA Registered No IRB 0001223
UNC IRB number

SHORT STUDY TITLE: TB and IRIS in children receiving antiretroviral treatment

SPONSOR: United States National Institute of Health

PRINCIPAL INVESTIGATORS:
South African co-principal investigators: Tammy Meyers, MD and Harry Moultrie, MD, MPH
US principal investigator: Annelies Van Rie, MD, PhD

INSTITUTION: The University of the Witwatersrand and the University of North Carolina at Chapel Hill

STUDY CONTACT NUMBER: 011 933 9630 or 076 730 1769
STUDY CONTACT EMAIL: harrym@witsecho.org.za

To the child: *This form may contain words that you do not understand. Please ask the study doctor or study nurse to explain any words or information that you do not clearly understand.*

The people named above are doing a research study.

These are some things we want you to know about research studies:

Good day, my name is _____ and I am a _____ at the Harriet Shezi Children's Clinic. I would like to invite you to be in a research study.

Your parent/caregiver also needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission.
You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you. The doctors and nurses will still continue to take good care of you.

Why are they doing this research study?
Many children living in South Africa do not have enough healthy food to eat. We want to study if South African children have more diseases like tuberculosis. Also, some children treated with drugs like the ones you will be taking starting today develop special symptoms (like cough and large glands) in the first three months they take these medications. Doctors call this IRIS. We will study how many children get IRIS. The reason for doing this research is to improve the care of children like you.

Why are you being asked to be in this research study?
You are asked to take part in this study because you receive care at the Harriet Shezi clinic and are not older than 8 years.

How many people will take part in this study?
*Y*ou will be one of about 700 children in this research study.

What will happen during this study?
This study will take place at Harriet Shezi clinic and children will be in the study for up to two years. Every time you come to the clinic, we will carefully check if you have TB or IRIS. During the two years of the study, we will take 30 ml (two table spoons) of blood to see how well the medications work, to check if you have been able to eat well enough, and to help us develop a test for IRIS.
In two weeks, we will do a skin test for TB, and you will be asked to come back two days later to check the result of the skin test.

FOR CHILDREN ON TB TREATMENT AT ENROLMENT ONLY: We will take an X-ray in two weeks, one, two and three months to see how your lungs respond to your treatments.

Who will be told the things we learn about you in this study?
The nurses and doctors will tell you and your parents/caregiver if we learn things in this study that are important for you. We will also tell our findings to other doctors in South Africa and other countries so that children in other clinics can also get better treatment. We will never tell your name to anyone else than those who work in the Harriet Shezi clinic.

What are the good things that might happen?
The good things that may happen to you because you are in this research study is that the nurses could find earlier that you have tuberculosis or that your medications are not working so you can get the right medications and do not get so sick.

What are the bad things that might happen?
You may feel a bit of pain when we take blood or do the skin test.

Will you get any money or gifts for being in this research study?
Your parent/caregiver will receive some money for your participation in this study to refund them for the transport costs to the clinic and the time they lost.

Who should you ask if you have any questions?
If you have questions you should ask the nurses or doctors in the clinic. If you have other questions about your rights while you are in this study you may contact Prof. Cleaton-Jones at (011) 717 2301. He is the Chairperson of the University of the Witwatersrand Human Research Ethics Committee, an independent committee to help protect the rights of research participants.

Title of Study: TB and IRIS in children receiving antiretroviral treatment

If you sign your name below, it means that you agree to take part in this research study.

_____	_____
Write your name here if you want to be in the study	**Date**
_____	_____
Signature and printed name of Person Obtaining Assent	**Date**