APPENDIX 6:

SUBJECT INFORMATION SHEET AND INFORMED CONSENT FORM

Introduction:

Good day, my name is Dr Colin Menezes. I am a medical registrar at the Johannesburg General Hospital, in the department of Internal Medicine.

I would like to ask you to consider participating in a research study entitled "The role of increased gastrointestinal alcohol production in obese patients: implications for the pathogenesis of non-alcoholic fatty liver disease."

It is important that you read and understand the purpose of this study, procedures, benefits, risks and discomforts.

This information leaflet is to help you to decide if you would like to participate. If you have any questions, do not hesitate to ask me. It is important that you are truthful with me regarding your health history.

If you decide to take part, you will be asked to sign this document to confirm that you understand the study.

Purpose of the study:

Obesity is a chronic condition characterised by an excess of body fat. It is a health hazard because it is associated with numerous metabolic complications such high cholesterol, diabetes, heart disease and liver disease. The purpose of this study is to look at one possible cause of liver disease.

Procedures:

If you agree to take part, you will be asked a few questions, and examined to see if you qualify for this study. Your qualification will depend on your body mass index and medical history. You will be asked to sign the informed consent form. You may require an ultrasound. This is a painless procedure which will not cause you any harm. You will also have some blood drawn which will be about approximately 4 teaspoons and you will also have to provide a urine and breath sample.

Risks:

Drawing blood is normally done as a part of routine medical care and may present with a slight risk of discomfort. It may result in faintness, inflammation of the vein, pain, bruising or bleeding at the puncture site.

Benefits:

Your participation will contribute to a better understanding of this disease that may help identify future therapies.

Your rights:

Your participation is voluntary, and refusal to participate will result in no penalty or affect your access to medical care.

Contact:

If you have any questions, please do not hesitate to contact me on 083 995 3931 or Prof Raal at 011 488 3538 or Prof Song at 011 488 3627.

Confidentiality:

All information obtained in this study, including your hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

Informed consent:

I, ……the undersigned hereby consent to the participation in this study, the nature, conduct, benefits and risks of which have been explained to me and which I understand, on myself/ my spouse/ the patient……
I have also read received, read and understand the above information regarding the clinical study.
Signature of the patient/ spouse/ near relative:

……..

Witness 1……

2……

Date ……

Time……