RESEARCH ETHICS COMMITTEE

UNIVEN Informed Consent

Appendix B

LETTER OF INFORMATION

Title of the Research Study :

Principal Investigator/s/ researcher : (*Name, qualifications*)

Co-Investigator/s/supervisor/s : (*Name, qualifications*)

Brief Introduction and Purpose of the Study:

Outline of the Procedures : (*Responsibilities of the participant, consultation/interview/survey details, venue details, inclusion/exclusion criteria, explanation of tools and measurement outcomes, any follow-ups, any placebo or no treatment, how much time required of participant, what is expected of participants, randomization/ group allocation*)

Risks or Discomforts to the Participant: (*Description of foreseeable risks or discomforts to for participants if applicable e.g. Transient muscle pain, VBAI, post-needle soreness, other adverse reactions, etc.)*

Benefits : (*To the participant and to the researcher/s e.g. Publications*)

Reason/s why the Participant May Be Withdrawn from the Study: (*Non-compliance, illness, adverse reactions, etc. Need to state that there will be no adverse consequences for the participant should they choose to withdraw)*

Remuneration : (*Will the participant receive any monetary or other types of remuneration?)*

Costs of the Study : (*Will the participant be expected to cover any costs towards the study?)*

Confidentiality : (*Description of the extent to which confidentiality will be maintained and how will this be maintained*)

Research-related Injury : (*What will happen should there be a research-related injury or adverse reaction? Will there be any compensation*?)

Persons to Contact in the Event of Any Problems or Queries:

(Supervisor and details) Please contact the researcher (tel no.), my supervisor (tel no.) or the University Research Ethics Committee Secretariat on 015 962 9058. Complaints can be reported to the Director: Research and Innovation, Prof GE Ekosse on 015 962 8313 or Georges Ivo.Ekosse@univen.ac.za

General:
Potential participants must be assured that participation is voluntary and the approximate number of participants to be included should be disclosed. A copy of the information letter should be issued to participants. The information letter and consent form must be translated and provided in the primary spoken language of the research population

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, (*name of researcher*), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: _,
- I have also received, read and understood the above written information (*Participant Letter of Information*) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerized system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

Full Name of Participant Date Time Signature

I, …….. …… …… ……..

(*Name of researcher*) herewith confirm that the above participant has been fully

Informed about the nature, conduct and risks of the above study.

Full Name of Researcher

…….. Date**……..** Signature**……**

Full Name of Witness (If applicable)

…….. Date **……..** Signature**……..**

Full Name of Legal Guardian (If applicable)

…… Date**……** Signature**……**

Please note the following:

Research details must be provided in a clear, simple and culturally appropriate manner and prospective participants should be helped to arrive at an informed decision by use of appropriate language (grade 10 level- use Flesch Reading Ease Scores on Microsoft Word), selecting of a non-threatening environment for interaction and the availability of peer counseling (Department of Health, 2004)

If the potential participant is unable to read/illiterate, then a right thumb print is required and an impartial witness, who is literate and knows the participant e.g. parent, sibling, friend, pastor, etc. should verify in writing, duly signed that informed verbal consent was obtained (Department of Health, 2004).

If anyone makes a mistake completing this document e.g. a wrong date or spelling mistake, a new document has to be completed. The incomplete original document has to be kept in the participant's file and not thrown away, and copies thereof must be issued to the participant.

References:

Department of Health: 2004. *Ethics in Health Research: Principles, Structures and Processes*

http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/

Department of Health. 2006. *South African Good Clinical Practice Guidelines*. 2nd Ed. Available at:

http://www.nhrec.org.za/?page_id=14