Appendix 1

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Kern

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M060343**
PROJECT	The Effect if a Munula Compression Foot-Pump on Dialysis Efficacy and the Quality pf Life of Patients with End Stage Renal.....
INVESTIGATORS	Mr LJ Kern
DEPARTMENT	Dept of Physiotherapy
DATE CONSIDERED	06.03.31
DECISION OF THE COMMITTEE*	Approved subject to inclding what exercising with a manual foot pedal in the information sheet

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 06.04.03 **CHAIRPERSON** .....

(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof A Stewart

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 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 report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2

Information Sheet

Hello, my name is Jeremy. I am a physiotherapist currently studying towards a Masters degree in Physiotherapy. Part of the requirements to complete this degree is the completion of a research project.

The research project I am conducting involves measuring what effects exercising with a manual compression foot pump will have on dialysis efficacy and quality of life.

I wish to invite you to take part in this study. Current research has shown that exercise during dialysis is both safe and recommended to improve dialysis efficacy and quality of life, but none has used exercising with a manual compression foot pump.

Participants in this study will be required to exercise for 20 minutes per hour, for the first 3 hours of each dialysis session, for an eight-week period and will be required to keep an exercise diary to record exercise times, changes in heart rate and exercise intensity.

The exercise involves sitting in an upright position with your feet on the floor and alternatively raising your heels up and down while your feet are placed in the manual compression foot-pumps ("vascular slippers").

The outcome of this study will greatly assist in the development of exercise programmes for other patients on dialysis.

If you do decide to participate in this study, please remember that your identity will at all times be kept anonymous and participation will be at no additional cost to you or your medical aid.

If you do not wish to participate in this study, you will not be discriminated against in any way and it will not affect your treatment at the renal unit.

Information required for this study includes your age, gender and urea clearance levels that will be taken from your usual monthly blood tests, at no additional cost to you or your medical aid.

Additional information required on your quality of life will be established from a standardized questionnaire that you will need to complete at the beginning, middle and end of the study.

Please note that your safety, privacy and identity will be maintained at all times.

If at any stage during the study you wish to withdraw, you are free to do so and you will not be discriminated against in any way and it will not affect your treatment at the renal unit.

Your co-operation is greatly appreciated and a copy of the results of this study will be left at the renal unit if you wish to follow it up.

Thank You!

Jeremy Kern
B.Sc (Physiotherapy)

Appendix 3

A Pilot Study to determine the Effects of a Manual Compression Foot-pump on Dialysis Efficacy and the Quality of Life of patients with End Stage Renal Disease (ESRD).

Consent form

I _____ have read the information sheet and understand what is required of me to participate in this study. I chose to participate in this study of my own free will and understand that I can withdraw at any stage during the study without discrimination towards me regarding my treatment at the renal unit.

_____
Date

_____
Signature

_____
Witness

Appendix 4

A Pilot Study to Determine the Effects of a Manual Compression Foot-pump on Dialysis Efficacy and the Quality of Life of patients with End Stage Renal Disease (ESRD).

Consent to conduct a research project at the Flora Clinic Renal Unit

Dear Sir, Madam & Doctor,

I am currently studying towards a Masters degree in Physiotherapy at the University of the Witwatersrand. Part of the requirements to complete this degree is the completion of a research project.

The research project I would like to conduct involves the implementation of an eight-week exercise program for patients with End Stage Renal Disease (ESRD) using a manual compression foot pump.

The aim of the study is to establish what effect the aforementioned exercise program using the manual compression foot pump will have on dialysis efficacy and the quality of life of patients with End Stage Renal Disease (ESRD).

Please note that no additional costs will be incurred by any of the patients or their respective medical aids.

Similar studies have been safely conducted on renal patients in the past, but none have incorporated a manual compression foot pump in the routine.

I am ethically obligated to, and hereby do, formally request your permission to conduct this research project at the Flora Clinic Renal Unit.

Your assistance and co-operation in this regard is greatly appreciated.

Sincerely,

Jeremy Kern
Physiotherapist

Informed Consent

Mr. A. Daneel	Sr. A. Voigt	Dr. B. M. Bloy
Hospital Manager	**Renal Unit Manager**	**Specialist Physician / Nephrologist**
3/4/2006		

EQ-5D

Jeremy Kern
Physiotherapist
Wits University (South Africa)
P.O. Box 1904 Florida Hills
1716
Johannesburg
South Africa

Rotterdam, February 27, 2006

Dear Mr. Kern,

Thank you for your interest in using EQ-5D.

I am enclosing some general information that I hope you will find useful. If you need further help, please contact the EuroQoL Executive Office at userinformationservice@euroqol.org.

Kind regards,

Rosalind Rabin
Executive Officer
EuroQol Group Foundation

EuroQol Group
P.O. Box 4443
3006 AK Rotterdam
The Netherlands

Phone | +31 (0)10 408 1545
Fax | +31 (0)10 452 5303
Email | userinformationservice@euroqol.org

Appendix 5b

From: Euroqol Executive Office Assistant [egas@frg.eur.nl]
Sent: 27 February 2006 11:15 AM
To: Cheryl Kern
Subject: Jeremy Kern: EQ-5D South African version
Attachments: EQ book (chapter 2).pdf; southafrica_english.pdf; southafrica_afrikaans.pdf

Dear Mr. Kern,

Thank you for registering your research at the EuroQol Group's website.

I assume that the study in which you intend to use the EQ-5D is not funded by the pharmaceutical industry or by any other commercial stakeholders. If this is the case, you may use the EQ-5D instrument free of charge. If this is not the case, however, please inform us as the EuroQol Group Foundation has a specific sponsorship policy for studies funded by pharmaceutical industry or by other commercial stakeholders.

Please find attached the South African version, in English and in Afrikaans, of the EQ-5D (pdf format), as well as a chapter from a recent EuroQol book on EQ-5D use. I will also send you an EQ-5D information package by post.

If you have any further questions, please do not hesitate to contact us.

Kind regards,

S. Dur-Acar
Executive Office Assistant
EuroQol Executive Office

Appendix 6

EQ - 5D

Health Questionnaire

(English version for South Africa)

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility

- I have no problems in walking about ❑
- I have some problems in walking about ❑
- I am confined to bed ❑

Self-Care

- I have no problems with self-care ❑
- I have some problems washing or dressing myself ❑
- I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

- I have no problems with performing my usual activities ❑
- I have some problems with performing my usual activities ❑
- I am unable to perform my usual activities ❑

Pain/Discomfort

- I have no pain or discomfort ❑
- I have moderate pain or discomfort ❑
- I have extreme pain or discomfort ❑

Anxiety/Depression

- I am not anxious or depressed ❑
- I am moderately anxious or depressed ❑
- I am extremely anxious or depressed ❑

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health today

Because all replies are anonymous, it will help us to understand your answers better if we have a little background data from everyone, as covered in the following questions.

1. Have you experienced serious illness?

	Yes	No
yourself	❑	❑
in your family	❑	❑
while caring for others	❑	❑

PLEASE TICK APPROPRIATE BOXES

2. What is your age in years ? ☐☐

	Male	Female
3. Are you.	❑	❑

PLEASE TICK APPROPRIATE BOX

4. Are you.

- *a current smoker* ❑
- *an ex-smoker* ❑
- *a person who has never smoked* ❑

PLEASE TICK APPROPRIATE BOX

	Yes	No
5. Do you now, or did you ever, work in health services or social welfare?	❑	❑

PLEASE TICK APPROPRIATE BOX

If so, in what capacity? .....

6. Which of the following best describes your main activity?

- *in employment or self employment* ❑
- *retired* ❑
- *housework* ❑
- *student* ❑
- *seeking work* ❑
- *other (please specify)* ❑

PLEASE TICK APPROPRIATE BOX

	Yes	No
7. Did your education continue after the minimum school leaving age (15 years / grade 9 / standard 7)?	❑	❑

PLEASE TICK APPROPRIATE BOX

	Yes	No
8. Do you have a degree or a diploma?	❑	❑

PLEASE TICK APPROPRIATE BOX

9. If you know your postal code, would you please write it here ☐☐☐☐

THE BORG PERCEIVED EXERTION SCALE

VERBAL EXPRESSION	SCALE
NOTHING AT ALL	0
VERY, VERY LIGHT (Just Noticeable)	0,5
VERY LIGHT	1
LIGHT	2
MODERATE	3
SOMEWHAT HEAVY	4
HEAVY	5
	6
VERY HEAVY	7
	8
	9
VERY, VERY HEAVY	10

Exercise Diary

Session		Week 1				Week 2				Week 3				Week 4				Week 5				Week 6				Week7				Week 8			
		min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R	min	Borg	H/R	H/R
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