19

APPENDIX 7:

ETHICS APPROVAL



UNIVERSITY

PO Box 77000, Nelson Mandela University, Port Elizabeth, 6031, South Africa mandela. ac.za

Chairperson: Research Ethics Committee (Human) Tel: +27 (0)41 504 2347 sharlene.govender@mandela.ac.za

NHREC registration nr: REC-042508-025

Ref: [H20-HEA-PSY-002] / Approval]

18 August 2020

Prof L Stroud Faculty: Health Sciences

Dear Prof Stroud

CATATONIA AS A MANIFESTATION OF SERIOUS MENTAL ILLNESS: PREVALENCE, PRESENTATION, MANAGEMENT AND OUTCOMES OF CATATONIA IN A MENTAL HEALTH UNIT

PRP: Prof L Stroud PI: Dr Z Zingela

Your above-entitled application served at the Research Ethics Committee (Human) (meeting of 29 July 2020 2020) for approval. The study is classified as a high risk study. The ethics clearance reference number is H20-HEA-PSY-002 and approval is subject to the following conditions:

- The immediate completion and return of the attached acknowledgement to <u>imtiaz.Khan@mandela.ac.za</u>, the date of receipt of such returned acknowledgement determining the final date of approval for the study where after data collection may commence.
- Approval for data collection is for 1 calendar year from date of receipt of above mentioned acknowledgement.
- 3. The submission of an annual progress report by the PRP on the data collection activities of the study (form RECH-004 available on Research Ethics Committee (Human) portal) by 15 November this year for studies approved/extended in the period October of the previous year up to and including September of this year, or 15 November next year for studies approved/extended after September this year.
- 4. In the event of a requirement to extend the period of data collection (i.e. for a period in excess of 1 calendar year from date of approval), completion of an extension request is required (form RECH-005 available on Research Ethics Committee (Human) portal)
- In the event of any changes made to the study (excluding extension of the study), completion of an amendments form is required (form RECH-006 available on Research Ethics Committee (Human) portal).
 Immediate submission (and possible discontinuation of the study in the case of serious events) of the
- Immediate submission (and possible discontinuation of the study in the case of serious events) of the relevant report to RECH (form RECH-007 available on Research Ethics Committee (Human) portal) in the event of any unanticipated problems, serious incidents or adverse events observed during the course of the study.
- Immediate submission of a Study Termination Report to RECH (form RECH-008 available on Research Ethics Committee (Human) portal) upon expected or unexpected closure/termination of study.
 Immediate submission of a Study Exception Report of RECH (form RECH-009 available on Research
- Ethics Committee (Human) portal) in the event of any study deviations, violations and/or exceptions.
- Acknowledgement that the study could be subjected to passive and/or active monitoring without prior notice at the discretion of Research Ethics Committee (Human).

20

2

Please quote the ethics clearance reference number in all correspondence and enquiries related to the study. For speedy processing of email queries (to be directed to https://www.lmti.com/mandela.ac.za), it is recommended that the ethics clearance reference number together with an indication of the query appear in the subject line of the email.

We wish you well with the study.

Yours sincerely

P

Dr \$ Govender Chairperson: Research Ethics Committee (Human)

Cc: Department of Research Development Faculty Manager: Health Sciences

Appendix 1; Acknowledgement of conditions for ethical approval

21

FACULTY OF HEALTH SCIENCES		
POSTGRADUATE EDUCATION, TRAINING, RESEARCH AND ETHICS UNIT		
		HUMAN RESEARCH COMMITTEE CLEARANCE CERTIFICATE
	PROTOCOL NUMBER	: 067/2017
	PROJECT	: PREVALENCE OF CATATONIA IN TWO MENTAL HEALTH UNITS IN URBAN AND RURAL SOUTH AFRICA
	INVESTIGATOR(S)	: PROF Z ZINGELA
	DEPARTMENT	: PSYCHIATRY & BEHAVIOURAL SCIENCES
	DECISION OF THE COMMITTEE	: APPROVED
	DATE OF APPROVAL	: 07 MAY 2020
	DURATION	: 1 YEAR (07 MAY 2020 – 07 MAY 2021)
	CONDITIONS	: NONE
	6 months. The committee expects	e committee with a progress or outcome report of the research after every a report on any changes in the protocol as well as any untoward events that tudy not later than 7 days of knowing as the investigator/s.

WALTER SISULU UNIVERSITY

DR EJ NDEBIA CHAIRPERSON ACADEMIC HEALTH SERVICE COMPLEX OF THE EASTERN CAPE POSTGRADUATE EDUCATION AND TRAINING FACULTY OF HEALTH SCIENCES WALTER SISULU UNIVERSITY P/BAG X 1, WSU, 5117, E.C TEL: (047) 502 2100 / FAX: (047) 502 2101

07.05.2020 DATE

DECLARATION OF INVESTIGATOR(S) (To be completed in duplicate and one copy returned to the Research Officer at BOG GF 03 Administration Building, Sisson Street Campus, Fort Gale, Mthatha, WSU)

/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 Research Ethics Committee. I/We agree to a completion of a 6-monthly/ yearly progress report. The committee reserves the right to withdraw approval in the event that there are serious ethical violations.

(Date)