



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



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23 November 2021

HREC REF: 710/2021

Prof E Jonas

Division of Surgical Gastroenterology Unit

E-23, NGSH

Email: eduard.jonas@uct.ac.za

Student: jei.krige@uct.ac.za

Dear Prof Jonas

PROJECT TITLE: A THREE-PART ANALYSIS OF FACTORS INFLUENCING MORTALITY AFTER SALVAGE TIPS IN CIRRHOTIC PATIENTS WITH RECALCITRANT VARICEAL BLEEDING FOLLOWING FAILED ENDOSCOPIC INTERVENTION (I) ASSESSMENT OF IN-HOSPITAL MORTALITY PROGNOSTIC FACTORS, (II) IDENTIFICATION OF OPTIMAL SCORING SYSTEMS PREDICTING IN-HOSPITAL MORTALITY (III) LONG-TERM OUTCOME AFTER SALVAGE TIPS (MPHIL DEGREE - PROFESSOR JAKE KRIGE)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020; 06 July 2020 & 01 July 2021.

Approval is granted for one year until the 30 November 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Prof Jake Krige will also be involved in this study.

Please quote the HREC REF 710/2021 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal Investigator **must** obtain appropriate Institutional approval, where necessary, before the research may occur.

Yours sincerely



PROFESSOR M. BLOCKMAN

CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938

NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.