

Jawatankuasa Etika Penyelidikan Manusia UniSA | UniSA Human Research Ethics Committee (UHREC)

Our Ref : UniSA.C/2/UHREC/628-2(85)
Date : 8th April 2019

Mr Sulistyo Andarmoyo
Postgraduate Candidate
Faculty of Medicine
UniSA, Medical Campus

Dear Madam Yusrizarni,

THE APPROVAL OF HUMAN RESEARCH ETHICS

It is my pleasure to inform you that your study protocol has been reviewed and is hereby granted an ethical approval by Universiti Sultan Zainal Abidin Human Research Ethics Committee (UHREC). This study has been assigned with a study protocol code (UniSA/UHREC/2018/46) which should be used for all communications with UHREC related to this study.

Title	The Effectiveness of Psychospiritual ' Tazkiyatun-Nafs' Intervention Among Type 2 Diabetes Mellitus Patients in Ponorogo East Java, Indonesia		
Protocol No.	-	Principle Investigator	Mr Sulistyo Andarmoyo
UHREC Code	UniSA/UHREC/2018/46		
Date of Approval • Protocol received • Reviewed by Committee • Received Amended Protocol	1 st Oct 2018 11 th Oct 2018 12 th Feb 2019	Co-investigator (s)	<ul style="list-style-type: none"> • Prof. Dr. Harmy bin Mohamd Yusoff (supervisor) • Assoc. Prof. Dr. Berhanudin bin Abdullah • Dr. Yuzana binti Mohd Yusop
Study Site	Primary Health Care, Ponorogo, East Java, Indonesia	Duration of Study	6 months
Financial Support	-	Validity of Ethical Clearance	until 31 st December 2019

The following items (✓) were received and reviewed in the process of approval.

- (✓) Research proposal
- (✓) Research information sheet (English & Malay)
- (✓) Informed consent form (English & Malay)
- (✓) Approval letter from faculty/ Institute research committee
- (✓) Curriculum Vitae (CV) of researchers

Investigator(s) are required to :-

- a) follow instructions, guidelines and requirements of the UniSA Human Research Ethics Committee (UHREC)
- b) report any protocol deviations/amendments to UniSA Human Research Ethics Committee (UHREC)
- c) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP)
- d) note that UniSA Human Research Ethics Committee (UHREC) may audit the approved study

Thank you.

Yours truly,



PROF. DR. NYI NYI NAING @ SYED HATIM NOOR
Chairperson
UniSA Human Research Ethics Committee