



SEKRETARIAT ETIKA PENYELIDIKAN UKM • UKM RESEARCH ETHICS COMMITTEE

Reference : UKM PPI/111/8

Date : 11 July 2024

Dr. Nor Azura Binti Azmi
Center for Rehabilitation and Special Needs Studies (ICaRehab)
Faculty of Health Sciences
The National University of Malaysia

Dear Professor/Datuk/Dato'/Datin/Sir/Madam,

ETHICAL APPROVAL TO CONDUCT RESEARCH IN THE NATIONAL UNIVERSITY OF MALAYSIA

Research title : A Randomised Controlled Trial Investigating the Effect of The Soft Robotic Assisted Hand Training on Upper Limb Function, Lung Function and Quality of Life in Stroke Survivors Undergoing Rehabilitation

Ethics Ref. No. : JEP-2024-261

Approval period : 09 July 2024 – 08 July 2026

Study Site : **Phase 1:** Rumah Rehab Al-Hilmi, Seremban
Phase 2: Dewan Community Desa Mentari PJS 6 in Petaling Jaya, Selangor

Sample Size : **Phase 1:**
24 participants (12 physiotherapists and 12 stroke survivors)

Phase 2:
44 participants of the main RCT
10 participants of stroke survivors for pilot RCT (intervention=5; control =5)

With reference to the above.

2. The Research Ethics Committee, The National University of Malaysia (RECUKM) has provided ethical approval for above study. Please be reminded permission from the Deputy Dean of research of the faculty or Director of Institute/Centre and all relevant heads of departments / units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations.

3. Please note that the investigator's responsibility is to ensure that:

- i. All Adverse Events should be reported to RECUKM as soon as possible.
- ii. Progress report should be submitted every **6 Months**.
- iii. All changes / amendments to the study documents / study sites / study team must be notified to the RECUKM. All changes must be approved by RECUKM before continuation of the study.
- iv. Application for renewal of the approval has to be submitted to RECUKM within one month (1 month) prior to the expiry of ethical approval.
- v. Final Report should be provided to RECUKM when the project is complete.
- vi. Please take note that all records and data are to be kept strictly CONFIDENTIAL and can only be used for the purpose of this study. All precautions are to be taken to maintain data confidentiality.



UNIVERSITI KEBANGSAAN MALAYSIA
The National University of Malaysia

SEKRETARIAT ETIKA PENYELIDIKAN UKM • **UKM RESEARCH ETHICS COMMITTEE**

Required forms can be obtained from the The Research Ethics Committee, The National University of Malaysia (RECUKM) website: <https://www.ukm.my/jepukm>

Thank you.

Yours sincerely,

PROFESSOR DR. MOHD SHAHRIR MOHAMED SAID

Chairman

Research Ethics Committee

The National University of Malaysia

- c.c. - **Deputy Dean (Research & Innovation)**
Faculty of Health Sciences
National University Of Malaysia
- **Chairperson of Center for Rehabilitation and Special Needs Studies (ICaRehab)**
Faculty of Health Sciences
National University Of Malaysia
- **Associate Professor Dr. Nor Azlin Binti Mohd Nordin**
- **Dr. Mohd Azzuan Bin Ahmad**
- **Nik Intan Shakina Binti Ramli (P120057)**
Center for Rehabilitation and Special Needs Studies (ICaRehab)
Faculty of Health Sciences
National University of Malaysia
- Approval letter File 2024

Sekretariat Etika Penyelidikan Universiti Kebangsaan Malaysia

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SEKRETARIAT ETIKA PENYELIDIKAN UKM • UKM RESEARCH ETHICS COMMITTEE

NAME OF ETHICS COMMITTEE/IRB: Research Ethics Committee, The National University of Malaysia	ETHICS COMMITTEE/IRB REF NO: JEP-2024-261
PROTOCOL TITLE: A Randomised Controlled Trial Investigating the Effect of The Soft Robotic Assisted Hand Training on Upper Limb Function, Lung Function and Quality of Life in Stroke Survivors Undergoing Rehabilitation	
PRINCIPAL INVESTIGATOR: Dr. Nor Azura Binti Azmi Center for Rehabilitation and Special Needs Studies (ICaRehab) Faculty of Health Sciences The National University of Malaysia	

The following items have been received and reviewed in connection with the above study to be conducted by the above investigator.

Documents

Research Application Form (UKM-JEP-BO01)
 Review Form (UKM-JEP-BO02)
 Non-Disclosure Agreement (UKM-JEP-BO03)
 Conflict Of Interest Form
 Research Proposal / Protocol
 Participant Information Sheet:
 Malay English Others :
 Participant Consent Form:
 Malay English Others :
 Questionnaire:
 Malay English Others :
 Case report Form:
 Malay English Others :
 Curriculum Vitae of Researchers:
 Principal Co-researcher Student
 Good Clinical Practice Certificate (GCP)
 Project Agreement

The Research Ethics Committee, The National University of Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any): -----

Date of Approval: 09 July 2024

PROFESSOR DR. MOHD SHAHRIR MOHAMED SAID
 Chairman
 Research Ethics Committee
 The National University of Malaysia

