The Government of the Republic of the Union of Myanmar
Ministry of Health and Sports
Department of Medical Research
No. 5, Ziwaka Road, Dagon Township, Yangon 11191
Tel : 95-1-375447, 95-1-375457, 95-1-375459 Fax : 95-1-251514

ERC Number: 000817
Approval Number: Ethics/DMR/2017/049
Date of Approval: 29 March, 2017 (valid up to 28 March, 2018)

Project Title: **Prevalence of peripheral neuropathy and its impact on activities of daily living in the diabetics**

Principal Investigator: Daw Mi Mi Thet Mon Win
University of Nursing

Documents Accepted:

1. Ethical Proposal Form Version Dated 9 March, 2017
2. Full Proposal Protocol Version Dated 9 March, 2017
3. Proposal Summary Version Dated 9 March, 2017
4. Agreement to comply with ethical guideline Dated 9 March, 2017
5. Informed Consent Form (English & Myanmar) Version Dated 9 March, 2017
6. Assessment form (English) Version Dated 9 March, 2017
7. Questionnaires (English & Myanmar) Version Dated 9 March, 2017
8. Request for permission for the study Version Dated 9 March, 2017
9. Approval from the Department of Nursing Ethics Committee of Okayama University Dated 30 November, 2016
10. Approval from Research and Ethical Committee, University of Nursing, Yangon Dated 22 February, 2017
11. Investigators' CV Dated 9 March, 2017

The Ethics Review Committee on Medical Research Involving Human Subjects, Department of Medical Research, Ministry of Health and Sports approves to conduct the proposed research project as it is in full compliance with the Declaration of Helsinki, Council for International Organizations of Medical Sciences guidelines and International Conference on Harmonisation in Good Clinical Practice guidelines.

Prof. Pe Thet Khin
Chairperson
Ethics Review Committee
Department of Medical Research

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Approval is subject to following conditions:

- The principal investigator (PI) must notify immediately to the ERC of any changes or deviation in the conduct of the research activity. Only with the ERC's approval such changes in the study must be pursued. The PI must also make a prompt report to the ERC of any new and significant information that may impact a research subject's safety or willingness to continue in the study and any anticipated problems involving risks to the participants or other.

- PI is responsible for submitting the progress report at least 6 weeks prior to the expiry of the approved date to allow adequate time for the ERC for substantive and meaningful review and for assuring that the research is not conducted beyond the approved date.

- Final report is to be provided to ERC at the end of the study.

- Random site visits may be carried out to ensure that informed consent procedures are appropriate.