



AMENDMENT APPROVAL

The Ethical Committee of Research in Medical Health, Faculty of Medicine University of Gadjah Mada, with regards of the protection of human rights and welfare in medical research and operates according to ICH-GCP guideline and the applicable laws and regulations has carefully reviewed the proposal entitled:

Penerapan Modul Konseling "Motivational Interviewing Apoteker-Pasien (MIAPA)" pada Pengobatan Diabetes Melitus Tipe 2

Ethical Approval : KE/FK/576/EC 25 Mei 2015
Name of Principal Investigator : Retno Wahyuningrum
Name of Institution : Pharmacy Faculty Universitas Gadjah Mada

And approved the submitted amendment of document :

Name of supervisor : 1. Prof. Dr. Djoko Wahyono, SU, Apt
2. Prof. Dr. Mustofa, M.Kes, Apt
3. Dra. Yayi Suryo Prabandari, M.Si, PhD

Institution(s)/place(s) of research : RSUD Sleman, RSUD Panembahan Senopati Bantul,
RSUD Wates Kulon Progo, RS Panti Rapih, RS Bethesda

Yogyakarta **07 OCT 2015**

Prof. dr. Mohammad Hakimi, Sp.OG(K)., Ph.D
Chairman



CONTINUING REVIEW APPROVAL OF APPROVAL

Ref: KE/FK/576/EC/2015

Ref : KE/FK/ 596 /EC

Title of the Research Protocol : Penerapan Modul Konseling "*Motivational Interviewing* Apoteker-Pasien (MIAPA)" pada Pengobatan Diabetes Melitus Tipe 2

Documents Approved : 1. Study Protocol versi 07 Oct 2015
2. Information for Subjects versi 07 Oct 2015
3. Informed consent form versi 07 Oct 2015

Principle Investigator : Retno Wahyuningrum

Name of supervisor : 1. Prof. Dr. Djoko Wahyono, SU., Apt
2. Prof. Dr. Mustofa, M.Kes., Apt
3. Dra. Yayi Suryo Prabandari, M.Si., Ph.D

Date of Approval : **06 JUN 2016**
(Valid for one year beginning from the date of approval)

Institution(s)/place(s) of research : Poli Penyakit Dalam di RSUD Sleman, RSUD Panembahan Senopati Bantul, RS Jogja, RS Panti Rapih, RS Bethesda, RS PKU Muhammadiyah Yogyakarta dan RSUD Wates Kulon Progo

The Medical and Health Research Ethics Committee (MHREC) states that the above protocol meets the ethical principle outlined in the Declaration of Helsinki 2008 and therefore can be carried out.

The Medical and Health Research Ethics Committee (MHREC) has the right to monitor the research activities at any time.

The investigator(s) is/are obliged to submit:

- Progress report as a continuing review : Annually
- Report of any serious adverse events (SAE)
- Final report upon the completion of the study

Prof. dr. Mohammad Hakimi, Sp.OG(K)., Ph.D
Chairperson

dr. Endy Paryanto, MPH., Sp.A(K)
Secretary

Attachments:

- Continuing review submission form (AF 4.3.01-014.2013-03)
- Serious adverse events (SAE) report form (AF 6.1.01- 019.2013-03)