



MEDICAL AND HEALTH RESEARCH ETHICS COMMITTEE (MHREC)
FACULTY OF MEDICINE GADJAH MADA UNIVERSITY
– DR. SARDJITO GENERAL HOSPITAL



ETHICS COMMITTEE APPROVAL

Ref : KE/FK/0234 /EC/2018

- Title of the Research Protocol : Pengembangan Herbamon® Sebagai Fitofarmaka Untuk Hipertensi Melalui Studi Preklinik dan Klinik : (Kajian Uji Kemanfaatan Dalam Klinik, Uji Klinik Fase-2 dan Fase-3)
- Documents Approved : 1. Study Protocol versi 01 2018
2. Information for Subjects ver1/17.1.2018
3. Informed consent form ver1/17.1.2018
4. Case Report Form ver1/17.1.2018
5. Lembar Rekrutmen Subyek ver1/17.1.2018
6. Catatan Harian ver1/17.1.2018
- Principle Investigator : Prof. dr. Ngatidjan, M.Sc., Sp.FK(K)
- Participating Investigator(s) : 1. Prof. Dr. Mustofa, Apt., M.Kes
2. Dr. dr. Eti Nurwening Sholikah, M.Kes., M.Med.Ed
3. dr. Dwi Aris Agung N., M.Sc., Ph.D
4. Dr. dr. Woro Rukmi Pratiwi, M.Kes., Sp.PD
- Name of medically Responsible Physician : Dr. dr. Woro Rukmi Pratiwi, M.Kes., Sp.PD
- Date of Approval : **22 MAR 2018**
(Valid for one year beginning from the date of approval)
- Institution(s)/place(s) of research : Departemen Farmakologi dan Terapi FK-UGM dan Rumah Sakit Condong Catur

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. Rizka Humardewayanti Asdie, Sp.PD-KPTI
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)