



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



ETHICS COMMITTEE APPROVAL

Ref : KE/FK/0312 /EC

Substitute for

Ref: KE/FK/ 484 /EC (2012)

Title of the Research Protocol : Uji Klinik Perbandingan Pengaruh Kontrasepsi Pil KB mengandung Lynestrenol dengan Levonorgestrel terhadap Kualitas Air Susu Ibu

Documents Approved : Study Protocol 2007

Principle Investigator : Prof. dr. Siswanto Agus Wilopo, S.U., M.Sc., Sc.D

Date of Approval : **06 APR 2018**
(Valid for one year beginning from the date of approval)

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

Dr. dr. Eti Nurwening Sholikhah, M.Kes., M.Med.Ed
Vice Chairperson

dr. Rizka Humardewayanti A., 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)