



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



CONTINUING REVIEW APPROVAL OF APPROVAL

Ref: KE/FK/194/EC Year 2013

Ref : KE/FK/ *536* /EC

Title of the Research Protocol : Exploration of Immune Response and Host Genetic Variation on Hepatitis Infection in Indonesia

Documents Approved : 1. Study Protocol versi 2012  
2. Information for Subjects versi 2012  
3. Informed consent form versi 2012

Principle Investigator : Widya Wasityastuti

Name of supervisor : 1. Prof. Yoshitake Hayashi, MD, PhD  
2. Yoshihiko Yano, MD, PhD  
3. Neneng Ratnasari, MD, M.Sc  
4. Didik Setyo Heriyanto, MD, PhD  
5. Teguh Triyono, MD, M.Sc  
6. Nungki Anggorowati, MD, PhD

Date of Approval : **12 MAY 2014**  
(Valid for one year beginning from the date of approval)

Institution(s)/place(s) of research : Dr. Sardjito Hospital Yogyakarta, dr. Sutomo Hospital Surabaya and dr. Cipto Mangunkusumo Hospital Jakarta

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  
Chairman

dr. Madarina Julia, Sp.A(K), MPH., Ph.D  
Secretary

Attachments:

- Continuing review submission form (AF 4.3.01-014.2012-02)
- Serious adverse events (SAE) report form (AF 6.1.01- 019.2012-02)