



**MINISTRY OF EDUCATION AND CULTURE  
FACULTY OF MEDICINE GADJAH MADA UNIVERSITY  
MEDICAL AND HEALTH RESEARCH ETHICS COMMITTEE (MHREC)**

**ETHICS COMMITTEE APPROVAL**

Ref : KE/FK/ 1132 /EC

Title of the Research Protocol : Aplikasi Sistem Perancah CHA-gelatin sheet, Fibrin dan Kitosan pada Viabilitas Sel Punca Mesenkin dan Ekspresi Gen Diferensiasi Osteogenik RunX2/Cbfa1, Osterix dan Osteocalcin

Documents Approved : 1. Study Protocol versi 01 2013  
2. Information for Subjects versi 03 2013  
3. Informed consent form versi 03 2013

Principle Investigator : Rizal Aziz  
Participating Investigator(s) : 1. Fransiscus F.A. Kerans  
2. Rio Hermantara

Name of supervisor : 1. dr. E. Henny Herningtyas, M.Si, PhD  
2. dr. Lutfan Lazuardi, PhD

Date of Approval : **27 DEC 2013**  
(Valid for one year beginning from the date of approval)

Institution(s)/place(s) of research : Laboratorium Patologi Klinis Fakultas Kedokteran UGM

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. dr. Eti Nurwening Sholikhah, M.Kes  
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)