



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



ETHICS COMMITTEE APPROVAL

Ref: KE/FK/147/EC/2016

Title of the Research Protocol : Kajian Peresepan Obat Off-Label pada Anak di Apotek Dan Poliklinik Anak Daerah Istimewa Yogyakarta

Documents Approved : Study Protocol versi 02 2015

Principle Investigator : Ndaru Setyaningrum, M.Sc., Apt

Participating Investigator(s) : 1. Suci Gartina
2. Haudatul Khamsani
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6. Yossi Indriani
7. Wartu Lestari
8. Atry Ratnasari
9. Moch Andriawan M
10. Ika Octavia Widianingrum
11. Febri Ariyanto
12. Aya Shaufia Itsnayain
13. Rizki Akbar
14. Mukti Karyanawati
15. Ninik Wahyuningsih
16. Silviana Trisna Setia Putri

Date of Approval : 17 FEB 2016
(Valid for one year beginning from the date of approval)

Institution(s)/place(s) of research : Apotek di Kota Yogyakarta

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. Ngatidjan, M.Sc., Sp.FK(K)
Chairperson

dr. Rizka Humardewyanti 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)

Recognized by Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP)
12-Feb-16