ETHICS COMMITTEE APPROVAL

Ref: KE/FK/47/EC/2016

Title of the Research Protocol: Kajian Persepsi Obat Off-Label pada Anak di Apotek Daerah Intimewa Yogyakarta

Documents Approved: Study Protocol versi 02 2015

Principal Investigator: Niara Setyaningrum, M.Sc., Apt

Participating Investigator(s):
1. Suci Garima
2. Haudatul Khansani
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12. Aya Shafria Inmayain
13. Rizki Akbar
14. Mukt Karyanawati
15. Nimik Wahyurangsih
16. Silviana Trisna Setia Putri

Date of Approval: 17 Feb 2016

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

Prodi dan N. S. M., Sp. FK(II)
Chairperson

Dr. Risya Humardewiyanti, Asdie, Sp. PD-KPTI
Secretary

Attachments:
- Continuing review submission form (AF 4.3.01-04 2011-03)
- Serious adverse events (SAE) report form (AF 6.1.01-09.2013-03)

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