



**ETHICS COMMITTEE APPROVAL**

Ref : KE/FK/1116 /EC/2018

Title of the Research Protocol : Hubungan Penggunaan Obat Psikoaktif terhadap Risiko Jatuh pada Pasien Geriatri

Documents Approved : 1. Study Protocol versi 01 2018  
2. Information for Subjects versi 01 2018  
3. Informed consent form versi 01 2018

Principle Investigator : Dr. Fita Rahmawati, Sp.FRS., Apt

Participating Investigator(s) : 1. Lily Annisa, S.Farm., Apt  
2. Nasikhatul Mustafidah, S.Farm., Apt

Date of Approval : 19 OCT 2018  
(Valid for one year beginning from the date of approval)

Institution(s)/place(s) of research : RSUD dr. Soedono Madiun dan RSUD "Sogaten"

The Medical and Health Research Ethics Committee (MIIREC) states that the above protocol meets the ethical principle outlined in the Declaration of Helsinki 2013 and therefore can be carried out.

The Medical and Health Research Ethics Committee (MIIREC) 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. Tri Wibawa, Ph.D., Sp.MK(K)  
Chairperson

dr. Yana Supriatna, Sp.Rad(K), Ph.D  
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)