



Komite Etik Penelitian
Research Ethics Committee

Surat Layak Etik
Research Ethics Approval



No:003713/KEP STIKes Medistra Indonesia/2024

Peneliti Utama : Hainun Nisa
Principal Investigator

Peneliti Anggota : Puri Kresna Wati
Member Investigator
Lenny Irmawaty Sirait
Linda k Telaumbanua

Nama Lembaga : STIKes Medistra Indonesia
Name of The Institution

Judul : Perbandingan pijat Oksitosin dan Pijat Oketani terhadap Produksi ASI pada Ibu Postpartum di
Title
TPMB Hj. Ida Royani Kabupaten Karawang
Comparison of Oxytocin Massage and Oketani Massage on Breast Milk Production in Postpartum Mothers at the Hj. Ida Royani TPMB, Karawang Regency

Atas nama Komite Etik Penelitian (KEP), dengan ini diberikan surat layak etik terhadap usulan protokol penelitian, yang didasarkan pada 7 (tujuh) Standar dan Pedoman WHO 2011, dengan mengacu pada pemenuhan Pedoman CIOMS 2016 (lihat lampiran). *On behalf of the Research Ethics Committee (REC), I hereby give ethical approval in respect of the undertakings contained in the above mention research protocol. The approval is based on 7 (seven) WHO 2011 Standard and Guidance part III, namely Ethical Basis for Decision-making with reference to the fulfilment of 2016 CIOMS Guideline (see enclosed).*

Kelayakan etik ini berlaku satu tahun efektif sejak tanggal penerbitan, dan usulan perpanjangan diajukan kembali jika penelitian tidak dapat diselesaikan sesuai masa berlaku surat kelayakan etik. Perkembangan kemajuan dan selesainya penelitian, agar dilaporkan. *The validity of this ethical clearance is one year effective from the approval date. You will be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance. You will be expected to provide mid progress and final reports upon completion of your study. It is your responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.*

Setiap perubahan dan alasannya, termasuk indikasi implikasi etis (jika ada), kejadian tidak diinginkan serius (KTD/KTDS) pada partisipan dan tindakan yang diambil untuk mengatasi efek tersebut; kejadian tak terduga lainnya atau perkembangan tak terduga yang perlu diberitahukan; ketidakmampuan untuk perubahan lain dalam personel penelitian yang terlibat dalam proyek, wajib dilaporkan. *You require to notify of any significant change and the reason for that change, including an indication of ethical implications (if any); serious adverse effects on participants and the action taken to address those effects; any other unforeseen events or unexpected developments that merit notification; the inability to any other change in research personnel involved in the project.*

Masa berlaku:
02 Maret 2024 - 02 April 2025

02 Maret 2024

Chair

Person

apt.Feri Setiadi, S.Farm., M.Farm