

**PERSETUJUAN ETIK
ETHICAL APPROVAL**
NOMOR : DP.04.03/D.XIV.6.5/73/2024

Komite Etik Penelitian RSUP Dr. Hasan Sadikin Bandung, dalam upaya melindungi hak asasi dan kesejahteraan subjek penelitian serta menjamin bahwa penelitian yang menggunakan formulir survei/registrasi/surveilans/Bahan Biologi Tersimpan dan non klinis lainnya berjalan dengan memperhatikan implikasi etik, sosial dan non klinis lainnya yang berlaku, telah mengkaji dengan teliti proposal penelitian berjudul :

The Research Ethics Committee of Dr. Hasan Sadikin General Hospital Bandung, in order to protect the right and welfare of the research subject and to guaranty that the research using survey questionnaire/registry/surveillance/archived biological materials/other non clinical materials, will carried out according to ethical, legal social implications and other applicable regulations, has been thoughtfully reviewed the proposal entitled:

"Korelasi Transcranial Doppler Pulsatility Index dengan Durasi Ventilasi Mekanik pada Pasien Pasca Operasi Bedah Otak"

Nama Peneliti Utama
Principal Researcher : Dr. Raka Jati Prasetya, dr., MKed.An, SpAn

Pembimbing/Peneliti Lain
Supervisor/Other Researcher : Dr. Tinni T. Maskoen, dr., Sp.An-TI, Subsp.T.I.(K), Subsp.M.N.(K), FIPM
Osmond Muftilov Pison, dr., Sp.An-TI, Subsp.T.I.(K), M.Kes

Nama Institusi
Institution : Departemen/KSM Anestesiologi dan Terapi Intensif
Fakultas Kedokteran Universitas Padjadjaran
RSUP Dr. Hasan Sadikin Bandung

proposal tersebut dapat disetujui pelaksanaannya.
herby declare that the proposal approved

- Penelitian dapat dilaksanakan setelah mendapatkan Surat Izin Penelitian dari RSUP Dr. Hasan Sadikin Bandung atau dari institusi dimana penelitian dilaksanakan.
- Pada akhir penelitian laporan pelaksanaan penelitian harus diserahkan kepada Komite Etik Penelitian RSUP Dr. Hasan Sadikin Bandung.
Jika ada perubahan protokol dan/atau perpanjangan penelitian, harus mengajukan Kembali permohonan kajian etik penelitian (amandemen protokol).
- Research can be carried out after obtaining a research permit from Dr. Hasan Sadikin General Hospital Bandung or from the institution where the research is carried out.**
- At the end of research, a report of reseach implementation must be submitted to Health Research Ethics Committee of Dr. Hasan Sadikin General Hospital Bandung.**
If there's a change of protocol and/or a research extension, the principal investigator is required to resubmit the protocol for approval (protocol amendment).

Ditetapkan di : Bandung
Issued in
Tanggal : 15 Maret 2024
Date



Dr. Ina Rosalina, dr., Sp.A(K), M.Kes., MH.Kes.
NIP. 196010251987032001

*Ethical approval berlaku satu tahun dari tanggal persetujuan

**Peneliti berkewajiban :

- Menjaga kerahasiaan identitas subjek penelitian
Keep the subject's confidential
Membertahukan status penelitian apabila :
 - Setelah masa berlakunya keterangan lolos kaji etik, penelitian masih belum selesai, dalam hal ini *ethical approval* dan surat izin penelitian harus diperpanjang
 - Penelitian berhenti ditengah jalan

Notify of the research status:

- There after of period of passing Ethical Approval, a research still not completed, this matter ethical approval and research permit have to be extended
- Study ended midway

2. Melaporkan kejadian serius yang tidak diinginkan (*serious adverse events*)
Report a undesirable serious event (serious adverse events)

- Melaporkan pelaksanaan penelitian secara berkala
Report a study on periodically