



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL PELAYANAN KESEHATAN

RSUP Dr. HASAN SADIKIN BANDUNG

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No. Reg. 08.22.250

PERSETUJUAN ETIK
ETHICAL APPROVAL

NOMOR :LB.02.01/X.6.5/250/2022

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 throughly reviewed the proposal entitled:

"Subtle tuberculous arthritis of ankle joint: the role of Technetium-99m-Ethambutol scintigraphy"

Nama Peneliti Utama : Dr. Andri Primadhi, dr., SpOT(K)
Principal Researcher

Pembimbing/Peneliti Lain : -
Supervisor/Other Researcher

Nama Institusi : Departemen/KSM Orthopaedi dan Traumatologi
Institution Fakultas Kedokteran Universitas Padjadjaran
RSUP Dr. Hasan Sadikin Bandung

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

- a. Penelitian dapat dilaksanakan setelah mendapatkan Surat Izin Penelitian dari RSUP Dr. Hasan Sadikin Bandung atau dari institusi dimana penelitian dilaksanakan.
- b. 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).
- a. **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.**
- b. **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 : 10 Agustus 2022
Date



Ketua
Chairman,
RSUP Dr. HASAN SADIKIN
BANDUNG
Dr. Ina Rosalina, dr., Sp.A(K), M.Kes., MH.Kes.
NIP. 196010251987032001

***Ethical approval berlaku satu tahun dari tanggal persetujuan**

****Peneliti berkewajiban :**

1. Menjaga kerahasiaan identitas subjek penelitian
Keep the subject's confidential

2. Memberitahukan status penelitian apabila :

- a. Setelah masa berlakunya keterangan lolos kaji etik, penelitian masih belum selesai, dalam hal ini *ethical approval* dan surat izin penelitian harus diperpanjang
- b. Penelitian berhenti ditengah jalan

Notify of the research status:

- a. *There after of period of passing Ethical Approval, a research still not completed, this matter ethical approval and research permit have to*