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LAMPIRAN



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
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KOMITE ETIK PENELITIAN KESEHATAN
RSPTN UNIVERSITAS HASANUDDIN
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REKOMENDASI PERSETUJUAN ETIK

Nomor : 1162/UN4.6.4.5.31/ PP36/ 2019

Tanggal: 2 Desember 2019

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

| | | | |
|--|--|--|---------------------------|
| No Protokol | UH19111006 | No Sponsor Protokol | |
| Peneliti Utama | dr. Elanda Putri Madyaningtias | Sponsor | |
| Judul Peneliti | Hubungan Hb A1c Terhadap Proses Penyembuhan Tulang Pasca Operasi Pada Pasien Diabetes Melitus | | |
| No Versi Protokol | 1 | Tanggal Versi | 21 Nopember 2019 |
| No Versi PSP | | Tanggal Versi | |
| Tempat Penelitian | RSUP dr. Wahidin Sudirohusodo dan RS Jejaring di Makassar | | |
| Jenis Review | <input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal | Masa Berlaku 2 Desember 2019 sampai 2 Desember 2020 | Frekuensi review lanjutan |
| Ketua Komisi Etik Penelitian Kesehatan FKUH | Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K) | Tanda tangan | |
| Sekretaris Komisi Etik Penelitian Kesehatan FKUH | Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K) | Tanda tangan | |

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan