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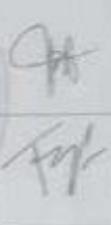


REKOMENDASI PERSETUJUAN ETIK

Nomor: 057/UN4.6.4.5.31/PP36/2023

Tanggal: 13 Nopember 2023

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

| | | | |
|---------------------------------------|---|--|---|
| No Protokol | UH23100742 | No Sponsor | |
| Peneliti Utama | dr. Andi Ayu Lestari | Sponsor | |
| Judul Penelitian | PENGARUH VITAMIN D3 ORAL (DF CHOLICALCIFEROL) TERHADAP KADAR SERUM VITAMIN D3 TEAR FILM DAN TINGKAT KEPARAHAN PENYAKIT PADA PASIEN GRAVES OPHTHALMOPATHY DENGAN MENGGUNAKAN NONINVASIVE OCULAR SURFACE ANALYZER | | |
| No Versi Protokol | 2 | Tanggal Versi | 9 Nopember 2023 |
| No Versi PSP | 2 | Tanggal Versi | 9 Nopember 2023 |
| Tempat Penelitian | RSUP Dr Wahidin Sudirohusodo Makassar | | |
| Jenis Review | <input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 25 Oktober 2023 | Masa Berlaku 13 Nopember 2023 sampai 13 Nopember 2024 | Frekuensi review lanjutan |
| Ketua KEP Universitas Hasanuddin | Nama Prof. dr. Muh Nasrum Massi, PhD, SpMK, Subsp. Bakt(K) | Tanda tangan |  |
| Sekretaris KEP Universitas Hasanuddin | Nama dr. Firdaus Hamid, PhD, SpMK(K) | Tanda tangan |  |

Kewajiban Peneliti Utama:

- Membuatkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Mempersiapkan Laporan SAE ke Komisi Etik dalam 24 jam dan dilengkapi dalam 7 hari dan Lapor SUSAR dalam 72 jam setelah Peneliti Utama menerima laporan
- Mempersiapkan Laporan Kemanan (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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan