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KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN KESEHATAN
RSPTN UNIVERSITAS HASANUDDIN

RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR

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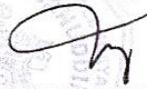
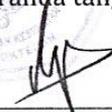


REKOMENDASI PERSETUJUAN ETIK

Nomor : 164/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 10 Maret 2021

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

No Protokol	UH20110678	No Sponsor Protokol	
Peneliti Utama	dr. Jerry Sampebuntu	Sponsor	
Judul Peneliti	Hubungan Antara Kadar Serum 25-Hydroxyvitamin D3 Dengan Aktivitas Penyakit Pada Pasien Lupus Eritematosus Sistemik di Makassar		
No Versi Protokol	2	Tanggal Versi	3 Maret 2021
No Versi PSP	2	Tanggal Versi	3 Maret 2021
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo dan RS Jejaring di Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 10 Maret 2021 sampai 10 Maret 2022	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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan