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REKOMENDASI PERSETUJUAN ETIK

Nomor : 121/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 15 Maret 2022

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

No Protokol	UH22010029	No Sponsor Protokol	
Peneliti Utama	dr. Hafiz Idul Fitranul	Sponsor	
Judul Peneliti	Lebar Distribusi Sel Darah Merah Sebagai Prediktor Major Adverse Cardiac Events (MACE) Jangka Menengah pada Penderita Sindrom Koroner Akut		
No Versi Protokol	2	Tanggal Versi	15 Maret 2022
No Versi PSP	2	Tanggal Versi	15 Maret 2022
Tempat Penelitian	RS Universitas Hasanuddin RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 15 Maret 2022 sampai 15 Maret 2023	Frekuensi review lanjutan
Ketua KEPK FKUH RSUH dan RSWs	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan 	
Sekretaris KEPK FKUH RSUH dan RSWs	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 Lapor 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