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REKOMENDASI PERSETUJUAN ETIK

Nomor : 1144/UN4.6.4.5.31/ PP36/ 2019

Tanggal: 29 Nopember 2019

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

No Protokol	UH19100853	No Sponsor Protokol	
Peneliti Utama	dr. Bobby Saunders	Sponsor	
Judul Peneliti	Faktor Yang Mempengaruhi Reperfusion Delay dan Dampaknya Terhadap Luaran Pada Pasien Dengan ST Elevasi Miokard Infark di Pusat Jantung Terpadu RSUP Dr Wahidin Sudirohusodo Makassar		
No Versi Protokol	2	Tanggal Versi	21 Nopember 2019
No Versi PSP	2	Tanggal Versi	21 Nopember 2019
Tempat Penelitian	RSUP dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 29 Nopember 2019 sampai 29 Nopember 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 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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

