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REKOMENDASI PERSETUJUAN ETIK

Nomor : 602/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 29 September 2020

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

No Protokol	UH20080423	No Sponsor	
Peneliti Utama	dr. Andy Hakim	Protokol	
Judul Peneliti	HUBUNGAN KADAR Antibodi IgA Anti-dsDNA DENGAN NEFRITIS LUPUS DI RUMAH SAKIT MAKASSAR		
No Versi Protokol	2	Tanggal Versi	28 September 2020
No Versi PSP	2	Tanggal Versi	28 September 2020
Tempat Penelitian	RSUP Dr.Wahidin Sudirohusodo dan RS Jejangin di Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 29 September 2020 sampai 29 September 2021	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. Agusssalim 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