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LAMPIRAN



KEMENTERIAN PENDIDIKAN DAN KEBUDAYAAN
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 KOMITE ETIK PENELITIAN KESEHATAN
 RSPTN UNIVERSITAS HASANUDDIN
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REKOMENDASI PERSETUJUAN ETIK Nomor : 359/UN4.6.4.5.31/PP36/2020

Dengan Ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol
 berikut ini telah mendapatkan Persetujuan Etik : Tanggal: 8 Juli 2020

No Protokol	UH20010041	No Sponsor Protokol	
Peneliti Utama	dr Martin Saputro Wardoyo	Sponsor	
Judul Peneliti	Hubungan Manitol 20% Dengan Dosis Berbeda Terhadap Osmolaritas Darah, Gula Darah Serum dan Faktor Koagulasi Pasien Cedera Otak Sedang Dengan Peningkatan Tekanan Intrakranial		
No Versi Protokol	2	Tanggal Versi	3 Juli 2020
No Versi PSP	2	Tanggal Versi	3 Juli 2020
Tempat Penelitian	RSUP Dr Wahidin Sudirohusodo dan RS Jejaring		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard 5 Februari 2020	Masa Berlaku 8 Juli 2020 Sampai 8 Juli 2021	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FK UH	Nama Prof.Dr.dr.Suryani As'ad.,MSc,Sp.GK (K)	Tanda tangan	Tanggal
Sekretaris Komisi Etik Penelitian Kesehatan FK UH	Nama dr. Agussalim Bukhari, M.Med, PhD, Sp.GK (K)	Tanda tangan	Tanggal

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