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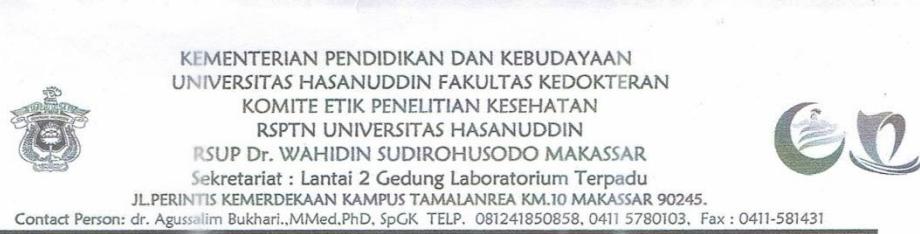
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LAMPIRAN



REKOMENDASI PERSETUJUAN ETIK

Nomor : 505/UN4.6.4.5.31 / PP36 / 2020

Tanggal: 3 September 2020

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

No Protokol	UH20080391	No Sponsor Protokol	
Peneliti Utama	dr. Arman Mikael Singara	Sponsor	
Judul Peneliti	Status Kesehatan Gigi dan Mulut pada Pasien Penyakit Ginjal Kronik.		
No Versi Protokol	1	Tanggal Versi	19 Agustus 2020
No Versi PSP	1	Tanggal Versi	19 Agustus 2020
Tempat Penelitian	RSUP 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 3 September 2020 sampai 3 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. 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