

KEPUSTAKAAN

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REKOMENDASI PERSETUJUAN ETIK

Nomor : 687 / H4.8.4.5.31 / PP36-KOMETIK / 2018

Tanggal: 21 September 2018

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

No Protokol	UH18020088	No Sponsor Protokol	
Peneliti Utama	dr. A. Dewi Chandra Kirana	Sponsor	Pribadi
Judul Peneliti	Efek Glutation Oral (Vitamin C, Asam Alfa Lipoat, dan Zink) terhadap Perubahan Manifestasi Klinis Kecerahan Kulit (Analisa dengan Kromameter		
No Versi Protokol	2	Tanggal Versi	19 September 2018
No Versi PSP	2	Tanggal Versi	19 September 2018
Tempat Penelitian	RSUP dr. Wahidin Sudirohusodo, RS Universitas Hasanuddin, RS Jeja di Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 7 Februari 2018	Masa Berlaku	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan	
Sekretaris Komisi Etik Penelitian	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 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 prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan