

## DAFTAR PUSTAKA

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**REKOMENDASI PERSETUJUAN ETIK**

Nomor : 546/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 30 Agustus 2021

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

No Protokol	UH21080487	No Sponsor Protokol	
Peneliti Utama	<b>dr. Andi Fithrani Neilufar,S.Ked</b>	Sponsor	
Judul Peneliti	Hubungan Derajat Gastroesofageal Valve Flap dengan Kejadian Gastroesofageal Refluks Disease Yang Dinilai Berdasarkan Skor GerdQ Dan Gambaran Endoskopi		
No Versi Protokol	<b>1</b>	Tanggal Versi	<b>16 Agustus 2021</b>
No Versi PSP		Tanggal Versi	
Tempat Penelitian	<b>RS Dr. Wahidin Sudirohusodo Makassar</b>		
Jenis Review	<input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku <b>30 Agustus 2021</b> sampai <b>30 Agustus 2022</b>	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian Kesehatan FKUH	Nama <b>Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)</b>	Tanda tangan	
Sekretaris Komisi Etik Penelitian Kesehatan FKUH	Nama <b>dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)</b>	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