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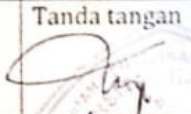



**REKOMENDASI PERSETUJUAN ETIK**

Nomor : 813/UN4.6.4.5.31/PP36/2020

Tanggal: 18 Desember 2020

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

|  |  |   |                              |
|--|--|---|------------------------------|
| No Protokol                                      | UH20120700   | No Sponsor<br>Protokol  |                              |
| Peneliti Utama                                   | <b>dr. Glendy</b>  | Sponsor   |                              |
| Judul Peneliti                                   | Perbandingan Kadar Sitokin Interleukin 10 Pada Penderita Hirschprung Disease Yang Mengalami Hirschsprung-Associated Enterocolitis (HAEC) Berdasarkan Grade Histopatologi Kolon |   |                              |
| No Versi Protokol                                | 1  | Tanggal Versi   | 7 Desember 2020              |
| No Versi PSP                                     | 1  | Tanggal Versi   | 7 Desember 2020              |
| Tempat Penelitian                                | RSUP Dr. Wahidin Sudirohusodo Makassar   |   |                              |
| Jenis Review                                     | <input type="checkbox"/> Exempted<br><input checked="" type="checkbox"/> Expedited<br><input type="checkbox"/> Fullboard Tanggal   | Masa Berlaku<br>18 Desember 2020<br>sampai<br>18 Desember 2021  | Frekuensi review<br>lanjutan |
| Ketua Komisi Etik Penelitian Kesehatan FKUH      | Nama<br><b>Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)</b>  | Tanda tangan<br> |                              |
| Sekretaris Komisi Etik Penelitian Kesehatan FKUH | Nama<br><b>dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)</b>   | Tanda tangan<br> |                              |

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

