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## REKOMENDASI PERSETUJUAN ETIK

Nomor : 257/UN4.6.4.5.31/ PP36/ 2020

Tanggal: 4 Mei 2020

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

| | | | |
|---|---|---|---|
| No Protokol | UH20030157 | No Sponsor Protokol | |
| Peneliti Utama | **dr. Ivan Levin Tanamal** | Sponsor | |
| Judul Peneliti | Faktor - Faktor Yang Mempengaruhi Kelainan Elektrokardiografi Pada Pasien Demam Berdarah Dengue | | |
| No Versi Protokol | **2** | Tanggal Versi | **29 April 2020** |
| No Versi PSP | **2** | Tanggal Versi | **29 April 2020** |
| Tempat Penelitian | **RSUP Dr.Wahidin Sudirohusodo dan RS Jejaring di Makassar** | | |
| Jenis Review | ☐ Exempted<br>☒ Expedited<br>☐ Fullboard Tanggal | Masa Berlaku **4 Mei 2020** sampai **4 Mei 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 prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan