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Lampiran 1. Persetujuan Etik



REKOMENDASI PERSETUJUAN ETIK

Nomor : 277/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 13 Juni 2022

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

| | | | |
|---------------------------------------|--|--|---------------------------|
| No Protokol | UH22040201 | No Sponsor Protokol | |
| Peneliti Utama | dr. Yunianingsih Selanno | Sponsor | |
| Judul Peneliti | Hubungan Kadar Glypican-3 (GC3) dan Alpha-Fetoprotein (AFP) pada Pasien Hepatocellular Carcinoma (HCC) | | |
| No Versi Protokol | 2 | Tanggal Versi | 12 Juni 2022 |
| No Versi PSP | 2 | Tanggal Versi | 12 Juni 2022 |
| Tempat Penelitian | RS Universitas Hasanuddin dan RSUP Dr. Wahidin Sudirohusodo Makassar | | |
| Jenis Review | <input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal | Masa Berlaku 13 Juni 2022 sampai 13 Juni 2023 | Frekuensi review lanjutan |
| Ketua KEP Universitas Hasanuddin | Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K) | Tanda tangan | |
| Sekretaris KEP Universitas Hasanuddin | Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K) |   | |

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

Lampiran 2. Naskah Penjelasan untuk Mendapat Persetujuan dari Subyek Penelitian

**NASKAH PENJELASAN UNTUK MENDAPAT PERSETUJUAN
DARI SUBYEK PENELITIAN**

Judul penelitian: Analisis Kadar Glypican 3 (GPC3) dan Alpha-fetoprotein (AFP) pada pasien Hepatocellular Carcinoma (HCC)

Penjelasan kepada subyek penelitian :

Selamat pagi Bapak / Ibu / saudara (i), kami dokter yang akan melakukan penelitian mengenai komponen pada darah pasien kanker hati yaitu Alpha-Fetoprotein dan Glypican 3. Kanker hati adalah tumor ganas hati primer yang berasal dari sel hati. Kanker hati dapat menyebabkan komplikasi seperti perdarahan hebat, koma, syok sampai pada kematian. Alpha-Fetoprotein dan Glypican 3 diharapkan dapat mendeteksi kanker hati lebih cepat, tidak invasif dengan harga yang terjangkau bagi penderita kanker hati agar penanganan penyakit ini dapat lebih cepat dan tepat. Besar harapan kami agar penelitian ini dapat memberikan sumbangsih ilmu pengetahuan dalam penanganan terbaik bagi pasien kanker hati seperti yang Bapak / Ibu / saudara (i) alami.

Adapun penelitian ini tidak memaksa keikutsertaan Bapak / Ibu / saudara (i) dan jika Bapak / Ibu / saudara (i) bersedia menandatangani formulir kesediaan ikut serta dalam penelitian dengan sukarela. Bapak / Ibu / saudara (i) tidak perlu khawatir ketidaksertaan anda dalam penelitian ini tidak mengurangi pelayanan kesehatan yang akan diperoleh dari pihak rumah sakit.

Bila Bapak/Ibu bersedia untuk menjadi responden dalam penelitian ini, maka prosedur yang kami lakukan adalah mengumpulkan sisa sampel darah vena yang telah diambil untuk keperluan pemeriksaan laboratorium sesuai permintaan dokter yang merawat Bapak / Ibu / saudara (i) dengan diagnosa kanker hati. Kami tidak melakukan pengambilan darah khusus

untuk penelitian ini tetapi hanya menambahkan parameter pemeriksaan sehingga kami jamin tidak ada efek samping yang timbul dalam penelitian ini.

Dalam penelitian ini kami tidak memberikan kompensasi. Segala biaya tambahan dalam pemeriksaan ini sepenuhnya akan ditanggung oleh pihak peneliti sehingga Bapak / Ibu / saudara (i) tidak perlu khawatir.

Kami menjamin keamanan dan kerahasiaan semua data pada penelitian ini. Data akan disimpan dengan baik dan aman, sehingga hanya bisa dilihat oleh yang berkepentingan saja. Data pribadi disamarkan pada semua catatan dan pada pelaporan baik lisan ataupun tertulis tidak akan menggunakan data pribadi.

Bila bapak/ibu merasa masih ada hal yang belum jelas atau belum dimengerti dengan baik, maka ibu dapat menanyakan atau minta penjelasan pada kami dr. Yunianingsih Selanno (082113228327)

Penanggung jawab Penelitian

Nama : dr. Yunianingsih Selanno

Alamat : Jln. Daeng Sirua Lrg 1, No.4

Telepon : 082113228327

Lampiran 3. Formulir *Informed Consent*

FORMULIR PERSETUJUAN MENGIKUTI PENELITIAN

Judul penelitian: Analisis Kadar Glypican 3 (GPC3) dan Alpha-fetoprotein (AFP) pada pasien Hepatocellular Carcinoma (HCC)

Saya yang bertanda tangan dibawah ini

Nama :
Jenis kelamin :
Umur :
Alamat :

Setelah mendengar dan mengerti penjelasan yang diberikan mengenai tujuan penelitian, dengan ini saya menyatakan bersedia secara sukarela tanpa paksaan dari pihak manapun untuk berpartisipasi dalam penelitian ini dan saya yakin hasilnya bersifat rahasia hanya peneliti utama dan tim komite etik yang mengetahuinya.

Saya mengerti bahwa pada proses pengambilan darah sudah tercakup saat saya menjalani tindakan flebotomi tadi. Saya mengetahui bahwa saya berhak untuk menolak atau berhenti dari penelitian ini. Biaya pemeriksaan Glypican 3 dalam penelitian ini ditanggung oleh peneliti.

Bila masih ada hal yang belum saya mengerti atau saya ingin mendapatkan penjelasan lebih lanjut, saya bisa mendapatkannya dari dokter peneliti sebagai *contact person* (alamat dan nomor telepon tertera di bawah).

Makassar, Juni 2022

.....
Nama subyek

.....
Dokter penanggung jawab klinis

No. Nama Saksi

Tanda tangan

1.

2.

Lampiran 4. Data Penelitian

| No. | NAMA | JK | UMUR | SIROSIS | GPC3 | AFP | BCLC |
|-----|----------------|----|------|---------|-------|--------|------|
| 1 | hartati | p | 53 | | 0.01 | 1.37 | B |
| 2 | yermias | I | 57 | | 0.01 | >400 | C |
| 3 | aco logha | I | 42 | | 0.01 | 351.26 | B |
| 4 | suhraeri | I | 57 | ✓ | 0.01 | 79.47 | B |
| 5 | muchlis hi | I | 42 | ✓ | 0.01 | >400 | C |
| 6 | abd halil | I | 58 | | 0.01 | >400 | B |
| 7 | rustan | I | 49 | ✓ | 0.01 | >400 | C |
| 8 | rahman andi | I | 53 | | 0.01 | >400 | A |
| 9 | syahrir arifin | I | 65 | | 2.8 | 46.14 | C |
| 10 | jufri | I | 56 | | 1.169 | >400 | B |
| 11 | agus p | I | 46 | | 0.407 | >400 | B |
| 12 | p.erni | p | 45 | | 0.778 | 0.78 | A |
| 13 | dentaufa | p | 51 | ✓ | 0.59 | 13.25 | A |
| 14 | grace dengen | p | 77 | ✓ | 0.99 | 12.06 | B |
| 15 | kasiono | I | 59 | | 0.581 | >400 | A |
| 16 | dahlan | I | 46 | ✓ | 0.01 | >400 | B |
| 17 | mudjiono | I | 77 | ✓ | 0.438 | >400 | A |
| 18 | Benjamin k | I | 59 | | 0.46 | >400 | A |
| 19 | Idham | I | 63 | ✓ | 0.01 | 669.51 | B |
| 20 | Lasakka | I | 63 | | 0.623 | 0.76 | A |
| 21 | Dody Bahrun | I | 43 | ✓ | 0.01 | >400 | B |
| 22 | Amri | I | 49 | ✓ | 0.01 | >400 | C |
| 23 | Muh.Alim | I | 56 | | 0.702 | >400 | A |
| 24 | La mania | I | 57 | ✓ | 0.01 | 1.64 | B |
| 25 | azis | I | 46 | | 0.01 | >400 | B |
| 26 | Idarmi | p | 54 | | 0.612 | 1.38 | A |
| 27 | Abd. Rahim | I | 52 | ✓ | 0.01 | 10.92 | D |
| 28 | Dannu | I | 56 | | 0.01 | >400 | A |
| 29 | Rustam | I | 50 | | 0.01 | >400 | B |
| 30 | Jumrana | p | 52 | | 0.01 | 222.22 | B |
| 31 | baharuddin | I | 52 | | 0.01 | >400 | C |
| 32 | m. agus saad | I | 53 | | 0.84 | >400 | B |
| 33 | latoro | I | 53 | | 0.01 | >400 | A |
| 34 | harianto | I | 50 | | 0.01 | >400 | A |
| 35 | hasanuddin | I | 60 | | 0.623 | >400 | C |
| 36 | gassing | I | 59 | | 0.01 | >400 | C |
| 37 | anwar t | I | 36 | | 0.01 | >400 | B |
| 38 | amran | I | 54 | ✓ | 0.01 | >400 | A |
| 39 | mardiana | p | 43 | | 0.01 | 313.38 | C |
| 40 | jama ali | I | 79 | ✓ | 0.01 | 84.51 | B |

| | | | | | | | |
|----|-----------------|---|----|---|-------|---------|---|
| 41 | mustang | | 42 | v | 3.253 | >400 | B |
| 42 | sidral | | 60 | v | 0.467 | >400 | C |
| 43 | rafiuddin | | 55 | | 0.171 | 115.82 | C |
| 44 | s.affandy | | 39 | | 4.545 | 2.37 | C |
| 45 | samiun | | 57 | | 0.823 | >400 | A |
| 46 | hengky yusuf | | 45 | v | 0.01 | >400 | D |
| 47 | tungga | | 59 | v | 0.01 | 74.56 | A |
| 48 | Joni kamban | | 42 | | 0.734 | 1.34 | A |
| 49 | bondo | | 59 | v | 0.01 | >400 | A |
| 50 | marthen | | 63 | | 1.151 | >400 | B |
| 51 | franslint | | 66 | v | 0.01 | 3.12 | A |
| 52 | sofia bara | p | 56 | | 0.53 | >400 | C |
| 53 | sabaruddin | | 54 | v | 0.447 | 47.43 | B |
| 54 | husein m | | 25 | | 0.01 | >400 | B |
| 55 | idham chalik | | 63 | v | 0.01 | >400 | B |
| 56 | zulkifli saidah | | 55 | v | 0.299 | >400 | D |
| 57 | ardin | | 51 | v | 0.01 | >400 | C |
| 58 | daniel | | 49 | | 0.01 | 33.66 | B |
| 59 | riki | | 53 | | 0.01 | 7.68 | B |
| 60 | sunardi | | 63 | v | 0.491 | >400 | C |
| 61 | nasruddin | | 52 | | 0.468 | 1.16 | C |
| 62 | baddu cappa | | 69 | | 0.739 | 1.31 | A |
| 63 | bakri pata | | 54 | v | 0.01 | 169.37 | C |
| 64 | ismail | | 57 | v | 0.01 | 67.23 | C |
| 65 | mariani | p | 47 | | 0.13 | 4322.66 | B |
| 66 | zainal | | 63 | | 0.01 | >400 | B |
| 67 | a bahman | | 69 | v | 0.01 | 16.85 | A |
| 68 | jupri | | 43 | v | 0.49 | 5.25 | B |
| 69 | kamaruddin | | 61 | v | 0.023 | 3.96 | C |
| 70 | petrus maka | | 73 | | 0.111 | 6.57 | C |
| 71 | ambo sakka | | 63 | v | 0.332 | 2.18 | B |
| 72 | sulihajji | | 55 | | 0.901 | 2.01 | B |
| 73 | ahmad roby | | 53 | | 4.525 | 1.38 | B |
| 74 | rusdin | | 56 | | 0.01 | >400 | C |
| 75 | lanto | | 47 | | 0.01 | 63.13 | B |
| 76 | syaharuddin | | 63 | v | 0.01 | 71.87 | A |
| 77 | ahmad tang | | 50 | | 0.01 | >400 | A |
| 78 | judding | | 54 | | 0.875 | 11.12 | B |
| 79 | baharuddin | | 49 | v | 0.01 | 36.65 | A |
| 80 | abd malik | | 51 | | 0.01 | >400 | C |
| 81 | sarijuddin | | 52 | | 0.01 | >400 | A |
| 82 | jabar | | 42 | | 0.01 | 24.57 | D |
| 83 | burhanuddin | | 42 | | 0.01 | >400 | B |

| | | | | | | | |
|----|--------------|---|----|---|-------|------|---|
| 84 | musliani | p | 55 | v | 0.135 | 1.58 | A |
| 85 | adnan unjung | l | 64 | | 0.315 | 1.24 | A |

Lampiran 5. Curriculum Vitae

A. DATA PRIBADI

Nama : dr. Yunianingsih Selanno
 Tempat, tanggal lahir : Ambon, 7 Juni 1981
 Agama : Islam
 Pekerjaan : Mahasiswa PPDS
 Alamat : Jln Daeng Sirua, Lrg 1 No. 4 Makassar

B. RIWAYAT PENDIDIKAN

| NO. | STRATA | INSTITUSI | TEMPAT | TAHUN TAMAT |
|-----|---------------------------------------|--------------------|-------------------|-----------------|
| 1 | SD | SD Negeri 26 Ambon | Maluku | 1993 |
| 2 | SMP | SMP Negeri 6 Ambon | Maluku | 1996 |
| 3 | SMA | SMAN 1 Bau-Bau | Sulawesi Tenggara | 1999 |
| 4. | S1 (Dokter) | UMI | Sulawesi Selatan | 2000 |
| 6 | Spesialis 1 (Sp.1) Patologi Klinik | Unhas | Sulawesi Selatan | 2018 - Sekarang |

C. RIWAYAT PEKERJAAN

| No | Kedudukan | Instansi | Tempat | Periode |
|----|-----------------|-----------|--------------------|-----------------|
| 1 | Dokter Umum PNS | RSUD Piru | Seram Bagian Barat | 2009 - Sekarang |