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**KEMENTERIAN RISET, TEKNOLOGI DAN PERGURUAN TINGGI
UNIVERSITAS HASANUDDIN
FAKULTAS KEDOKTERAN**



KOMITE ETIK PENELITIAN KESEHATAN

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LAMPIRAN 1

**NASKAH PENJELASAN UNTUK MENDAPAT PERSETUJUAN DARI
KELUARGA/SUBJEK PENELITIAN**

**INSULIN LIKE GROWTH FACTOR BINDING PROTEIN 7 (IGFBP7)
URIN SEBAGAI PREDIKTOR GANGGUAN GINJAL AKUT
PADA PASIEN SEPSIS**

Bapak/Ibu yang terhormat, saya dr. Fitriyani Hamzah dari Bagian Ilmu Kesehatan Anak RS Dr. Wahidin Sudirohusodo bermaksud mengadakan penelitian untuk menilai kadar Insulin Like Growth Factor Binding Protein 7 (IGFBP7) Urin pada anak sepsis.

Sepsis merupakan salah satu penyebab morbiditas dan mortalitas anak yang dirawat di ruang rawat inap dan ruang rawat intensif dan menjadi penyebab tersering Gangguan Ginjal Akut (GgGA). Anak-anak dengan GgGA dan sepsis berat mempunyai kemungkinan kematian/kecacatan lebih dari dua kali lipat dibandingkan dengan anak-anak dengan GgGA tanpa sepsis atau sepsis ringan.

Salah satu parameter penilaian GgGA yang sering digunakan adalah kreatinin serum. Namun, kreatinin ini bukan merupakan penanda

cedera ginjal yang sensitif kerana kadarnya meningkat hingga 72 jam setelah cedera. pemeriksaan kreatinin membutuhkan pengambilan sampel darah vena yang bersifat invasif dan seringkali sulit dilakukan. Oleh karenanya, GgGA pada anak lebih sulit dideteksi secara dini bahkan dapat terjadi keterlambatan diagnosis yang selanjutnya menghasilkan luaran yang buruk.

Salah satu parameter yang dapat digunakan untuk memprediksi terjadinya gangguan ginjal akut pada pasien anak yang mengalami sepsis adalah Insulin Like Growth Factor Binding Protein 7 (IGFBP7) Urin. Hasil pemeriksaan ini berguna untuk memprediksi lebih dini terjadinya gangguan ginjal akut pada anak yang mengalami sepsis sehingga dengan penanganan yang tepat bisa mencegah memburuknya kondisi pasien.

Kami akan menanyakan dan mencatat identitas anak ibu/bapak (nama, alamat, tanggal lahir, jenis kelamin), menghitung status gizi anak. Selanjutnya akan dilakukan Insulin Like Growth Factor Binding Protein 7 (IGFBP7). Pemeriksaan ini dilakukan dengan mengambil urin penderita sebanyak 5 cc dan dilakukan pemeriksaan laboratorium. Pemeriksaan ini akan dilakukan oleh dokter dan dibantu oleh analis laboratorium.

Penelitian ini bersifat sukarela tanpa paksaan, sehingga ibu/bapak dapat menolak ikut atau berhenti terlibat dalam penelitian ini tanpa takut akan kehilangan hak untuk mendapat pelayanan kesehatan yang dibutuhkan oleh anak ibu/bapak.

Semua data dari penelitian ini akan dicatat dan dipublikasikan tanpa membuka data pribadi anak ibu/bapak. Data pada penelitian ini akan dikumpulkan dan disimpan dalam file manual maupun elektronik, diaudit dan diproses serta dipresentasikan pada:

- Forum ilmiah Program Pendidikan Dokter Spesialis Terpadu Fakultas Kedokteran Universitas Hasanuddin.
- Publikasi pada jurnal ilmiah dalam Negeri

Setelah membaca dan mengerti atas penjelasan yang kami berikan mengenai pentingnya menilai kadar Insulin Like Growth Factor Binding Protein 7 (IGFBP7) pada anak sepsis sehingga dapat diberikan penanganan yang lebih cepat dan tepat, maka kami mengharapkan bapak/ibu untuk menandatangani surat persetujuan mengikuti penelitian. Atas kesediaan dan kerja samanya, saya mengucapkan terima kasih.

Identitas peneliti :

Nama : dr. Fitrayani Hamzah

Alamat : Rusunawa 1 Unhas Blok D406 Makassar

Telepon : 085299281708

Wassalam

Peneliti,

dr. Fitrayani Hamzah

**KEMENTERIAN RISET, TEKNOLOGI DAN PERGURUAN TINGGI
UNIVERSITAS HASANUDDIN
FAKULTAS KEDOKTERAN**



KOMITE ETIK PENELITIAN KESEHATAN

Sekretariat : Lantai 2 Gedung Laboratorium Terpadu

JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10, Makassar.

Telp.0411-5044671, Fax (0411) 586297.

Contact person **dr. Agus Salim Buchari,M.Med,PhD,SpGK** (HP. 081241850858)

Lampiran 2

**FORMULIR PERSETUJUAN ORANG TUA
MENGIKUTI PENELITIAN SETELAH MENDAPAT PENJELASAN**

Maka saya yang bertanda tangan di bawah ini, orang tua/ wali :

Nama :

Pekerjaan :

Alamat :

Setelah mendengar dan mengerti penjelasan yang diberikan oleh dr. Fitrayani Hamzah tentang penelitian yang akan dilakukannya, bersama ini secara sukarela mengizinkan anak saya :

Nama :

Jenis kelamin : Laki-laki / Perempuan

untuk diikutkan dalam penelitian ini.

Saya tahu bahwa saya mempunyai hak untuk menanyakan pada dr. Rusmelani Sain apabila masih ada hal-hal yang belum jelas. Saya juga tahu bahwa saya tidak perlu merasa terpaksa mengikutkan anak saya dalam penelitian ini karena penolakan saya tidak akan mempengaruhi hak saya dan keluarga untuk mendapatkan pelayanan kesehatan.

Saya juga mengerti bahwa saya tidak perlu membayar semua biaya pemeriksaan yang ada hubungannya dengan penelitian ini, dan semua biaya perawatan dan pengobatan bila terjadi hal-hal yang tidak diinginkan akan dibiayai oleh peneliti, jika terjadi perselisihan/beda pendapat akan diselesaikan secara musyawarah (kekeluargaan).

Makassar,.....

NO.	NAMA	TANDA TANGAN
1.	ORANG TUA/WALI
2.	SAKSI I
3.	SAKSI II

Penanggung Jawab Penelitian :

Nama : dr. Fitrayani Hamzah
Alamat : Rusunawa 1 Unhas Blok D406
Makassar
Telepon : 085299281708

Penanggung Jawab

Nama : Dr. dr. Idham Jaya Ganda, Sp. A(K)
Alamat : Jl. Mapala A III/1
Makassar
Telepon : 081342660437

Lampiran 3. Rekomendasi Etik



REKOMENDASI PERSETUJUAN ETIK
Nomor : 311/UNA.6.4.5.31/PP.16/2021

Tanggal : 19 Mei 2021

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

No Protokol	UH21040211	No Sponsor Protokol	
Peneliti Utama	dr. Fitriyani Hamzah	Sponsor	
Judul Peneliti	INSULIN LIKE GROWTH FACTOR BINDING PROTEIN 7 (IGFBP7) URIN SEBAGAI PREDIKTOR GANGGUAN GINJAL AKUT PADA PASIEN ANAK YANG MENGALAMI SEPSIS		
No Versi Protokol	2	Tanggal Versi	27 April 2021
No Versi PSP	2	Tanggal Versi	27 April 2021
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 21 April 2021	Masa Berlaku 19 Mei 2021 sampai 19 Mei 2022	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 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