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LAMPIRAN

Lampiran 1 – Persetujuan Setelah Penjelasan



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN
RSPN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
Sekretariat : Lantai 2 Gedung Laboratorium Terpadu



JL. PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.
Contact Person: dr. Agus Salim Bukhari, MMed, PhD, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

LAMPIRAN 1

FORMULIR PERSETUJUAN SETELAH PENJELASAN (PSP) (INFORMED CONSENT)

Selamat pagi Bapak / Ibu / Saudara(i), saya (tim peneliti) bermaksud untuk melakukan penelitian **Analisa dan Pemetaan Genetik Penyakit Parkinson Bawaan di Sulawesi Selatan: Pendekatan Berfokus pada Keluarga.**

Disini tim peneliti bermaksud untuk mengetahui apa saja mutasi genetik yang dapat ditemukan pada Bapak / Ibu / Saudara(i) dan keluarga, yang terkait dengan gejala penyakit Parkinson yang sedang dialami. Hal ini sangat penting agar ke depan kami dapat lebih memahami kondisi genetik yang bisa mencetuskan penyakit Parkinson, serta memahami pola pewarisan dalam keluarga yang terkena. Terutama di Sulawesi Selatan, dimana penelitian genetik Parkinson masih sangat jarang dilakukan.

Bapak / Ibu / Saudara(i) dan keluarga dipilih untuk mengikuti penelitian ini karena memenuhi kriteria penelitian, yaitu merupakan pasien terdiagnosis Penyakit Parkinson, yang juga memiliki Riwayat keluarga dengan keluhan serupa. Tentunya bahwa partisipasi dalam penelitian ini bersifat sukarela dan dapat mengundurkan diri kapan saja tanpa mengurangi hak mendapatkan pelayanan kesehatan. Dan jika Bapak / Ibu / Saudara(i) dan keluarga, menyetujui untuk ikut maka harus mengikuti protocol penelitian sampai selesai.

Tes genetik dilakukan dengan sampel darah Bapak / Ibu / Saudara(i) dan keluarga. Saat pengambilan sampel darah kemungkinan Bapak / Ibu / Saudara(i) dan keluarga dapat mengalami rasa kurang nyaman, namun kami akan berusaha sebisa mungkin untuk meminimalisir hal tersebut. Darah akan diambil oleh tenaga Kesehatan professional pada daerah lengan, dengan jumlah



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sebanyak 3 ml. Efek samping tindakan pengambilan sampel misalnya nyeri atau perdarahan ringan, namun jika terjadi akan kami tangani secepatnya sesuai protocol. Setelah pengambilan, sampel akan dikirim ke laboratorium penelitian untuk dilakukan pemeriksaan genetik. Pada prosedur ini, tidak ada biaya yang dibebankan kepada pasien dan keluarga. Tentu kami sangat menghargai partisipasi Bapak / Ibu /Saudara(i) dan keluarga, dan jika berkenan akan diberikan uang transport dan cinderamata sebagai kompensasi waktu dan tenaga Bapak / Ibu /Saudara(i) dan keluarga

Segala data pribadi yang diperoleh dalam penelitian ini akan kami jaga kerahasiaannya. Adapun jika hasil penelitian ini dipublikasikan sebagai naskah akademik atau dalam presentasi ilmiah, maka identitas Bapak / Ibu /Saudara(i) dan keluarga akan kami jaga. Jika ada hal yang ingin ditanyakan mengenai penelitian ini dapat menghubungi peneliti dengan alamat dan nomor kontak di bawah ini.

Identitas Peneliti

Nama: dr. Gita Vita Soraya

Alamat: Jl. Bunaken No 48 Bukit Baruga

No Hp: 082346816358



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Lampiran 2 – Rekomendasi Persetujuan Etik



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI
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REKOMENDASI PERSETUJUAN ETIK

Nomor : 248/UN4.6.4.5.31/ PP36/ 2024

Tanggal: 17 April 2024

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

No Protokol	UH24020095		No Sponsor	
Peneliti Utama	dr. Gita Vita Soraya, Ph.D		Sponsor	
Judul Peneliti	Analisis Dasar Genetik Penyakit Parkinson Bawaan di Sulawesi Selatan: Pendekatan Berfokus pada Keluarga			
No Versi Protokol	2	Tanggal Versi	2 April 2024	
No Versi PSP	2	Tanggal Versi	2 April 2024	
Tempat Penelitian	RSUP. Dr. Wahidin Sudirohusodo dan RS Jejangir Makassar			
Jenis Review	☐ Exempted ☒ Expedited ☐ Fullboard Tanggal		Masa Berlaku 17 April 2024 sampai 17 April 2025	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Prof. dr. Muh Nasrum Massi, PhD, SpMK, Subsp. Bakt(K)		Tanda tangan	
Sekretaris KEP Universitas Hasanuddin	dr. Firdaus Hamid, PhD, SpMK(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 protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan



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Daftar Istilah, Singkatan, dan Lambang

Daftar Istilah

Istilah	Arti dan Penjelasan
Motorik	Kemampuan untuk menggerakkan anggota tubuh, seperti tangan, kaki, kepala, dan bibir.
Bradikinesia	Suatu kondisi yang menyebabkan gerakan menjadi lambat
Tremor	Gerakan gemetar yang tidak disengaja dan terjadi berulang kali.
Gait	Gaya berjalan atau berlari seseorang.
Freezing	Posisi diam tanpa bergerak.
Instabilitas Postural	Ketidakmampuan untuk mempertahankan keseimbangan tubuh.
Disabilitas	Keterbatasan atau gangguan pada fungsi tubuh yang memengaruhi mobilitas, ketangkasan, kapasitas fisik, atau stamina.
Kognitif	Proses mental yang berkaitan dengan berpikir, memahami, mengingat, dan memproses informasi.

Daftar Singkatan dan Lambang

APOE	: Apolipoprotein E
BDNF	: <i>brain-derived neurotrophic factor</i>
CI	: <i>confidence interval</i>
COMT	: <i>catechol-o-methyl-transferase</i>
DAT	: <i>dopamine transporter</i>
DRD	: <i>dopamine receptor</i>
FTD	: <i>frontotemporal dementia</i>
FP	: <i>forward primer</i>
HWE	: <i>hardy-weinberg equilibrium</i>
LBD	: <i>lewy body dementia</i>
LID	: <i>levodopa induced dyskinesia</i>
LRRK2	: <i>leucine-rich repeat kinase-2</i>
MAO	: <i>monoamine oxidase</i>
MDS-UPDRS	: <i>movement disorders society – unified parkinson's disease rating scale</i>
MLIC	: <i>motor levodopa induced complication</i>
MMSE	: <i>mini mental state examination</i>



or fluctuation

iple systems atrophy

s ratio

merase chain reaction

PD	: <i>parkinson's disease</i>
PRISMA	: <i>preferred reporting items in systematic reviews and meta-analysis</i>
PSP	: <i>progressive supranuclear palsy</i>
RP	: <i>reverse primer</i>
REM	: <i>random effect model</i>
SLC6	: <i>solute carrier-6</i>
SNP	: <i>single nucleotide polymorphism</i>
SNCA	: <i>alpha-synuclein</i>
SMD	: <i>standardized mean difference</i>

