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Lampiran I

NASKAH PENJELASAN DAN INFORMASI PENELITIAN KEPADA SUBYEK PENELITIAN

Selamat pagi Bapak / Ibu /Saudara(i), saya dr.Santiwati Anda, bermaksud untuk melakukan penelitian dengan cara mengambil sampel darah sesuai standar protokol RSJ untuk mengetahui polimorfisme Cathecol-O-Methyltransferase (COMT) Val158Met Pada Etnis Toraja

Kami sangat mengharapkan kehadiran Bapak/Ibu/Saudara(i) untuk dapat bergabung dalam penelitian ini. Bapak/Ibu/Saudara(i) tidak perlu khawatir karena kami akan menjamin kerahasiaan dalam penelitian ini. Jika Bapak/ibu/Saudara(i) bersedia diharapkan dapat memberikan persetujuan secara tertulis, penelitian ini bersifat sukarela tanpa paksaan, sehingga Saudara(i) dapat menolak atau mengundurkan diri tanpa resiko kehilangan hak untuk mendapatkan pelayanan kesehatan di Rumah Sakit ini. Bila menyetujui untuk berpartisipasi, maka kami akan menanyakan beberapa hal mengenai data pribadi dan riwayat kesehatan saudara dan akan melakukan pengambilan sampel darah sebanyak 3 cc atau sekitar 2 sendok makan yang dilakukan oleh tenaga laboran. Pengambilan darah ini tidak menimbulkan rasa sakit, tetapi mungkin akan terasa sedikit tidak nyaman, tindakan pemeriksaan ini dilakukan secara steril dan dengan penuh kehati-hatian oleh dokter peneliti sendiri. Efek samping yang terjadi pada saat pengambilan darah tidak ada. Kami pihak peneliti akan memberikan kompensasi berupa biaya pemeriksaan yang ada hubungannya dengan penelitian ini. Kami akan menjamin keamanan dan kerahasiaan semua data penelitian ini.

Manfaat penelitian ini bagi subyek adalah ini adalah mendapatkan informasi tambahan mengenai Gangguan Skizofrenia dan akan memberikan sumbangsih pada Ilmu Pengetahuan di Bidang Kedokteran. Penelitian ini akan dipublikasikan di Jurnal Internasional.

Jika Bapak/Ibu/Saudara(i) setuju untuk berpartisipasi, maka diharapkan menandatangani surat persetujuan keikutsertaan dalam penelitian ini. Atas kesediaan dan kerjasamanya diucapkan terima kasih.

Identitas Peneliti

Nama : dr. Santiwati Anda

Alamat : Taman Sudiang Indah Blok F3 No 1, Makassar

Lampiran 2

FORMULIR PERSETUJUAN MENGIKUTI PENELITIAN SETELAH MENDAPAT PENJELASAN

Setelah membaca informasi penelitian serta mendengar penjelasan dan menyadari pentingnya penelitian :

Polimorfisme Cathecol-O-Methyltransferase (COMT) Val158Met pada Pasien
Skizofrenia Etnis Toraja

Maka saya yang bertanda tangan dibawah ini/ wakil/ keluarga :

Nama :
Umur :
Jenis Kelamin :
Pekerjaan :
Alamat :

Saya bersedia untuk dilakukan pengambilan sampel darah. Saya mengerti sepenuhnya bahwa jumlah darah yang diambil tidak akan mempengaruhi kondisi kesehatan saya dan hal ini semata – mata dilakukan untuk kepentingan penelitian. Saya mengetahui bahwa saya berhak untuk menolak ikut serta dalam penelitian ini tanpa kehilangan hak saya untuk mendapatkan pelayanan kesehatan yang seharusnya saya peroleh.

Semua biaya pemeriksaan dan biaya pengobatan bila terjadi keluhan apapun sehubungan dengan penelitian ini, ditanggung oleh peneliti.

Bila masih ada hal yang masih belum saya mengerti atau saya ingin mendapatkan penjelasan lebih lanjut, saya bisa mendapatkannya dari dokter peneliti. Demikian persetujuan ini saya buat dengan penuh kesadaran tanpa paksaan.

| | Nama | Tanda Tangan |
|-------------|-------|--------------|
| Tgl/Bln/Thn | | |
| Klien | | |
| Saksi 1 | | |
| Saksi 2 | | |
| | | |

Lampiran 3. Skala PANSS

THE POSITIVE AND NEGATIVE SYNDROME SCALE (PANSS)

Umur :

Tanggal :

Penilai :

Nama :

Keterangan :

Nilai 1 : ***Tidak ada gejala.***

Nilai 2 : ***Gejala minimal***, gejalanya masih diragukan keberadaannya,
Atau masih cenderung tampak normal.

Nilai 3 : ***Gejala ringan***, keberadaan gejala yang jelas, tetapi
Tidak terlalu berpengaruh pada fungsi keseharian.

Nilai 4 : ***Gejala sedang***, adanya gejala yang menimbulkan masalah
serius sehingga kadang-kadang cukup mengganggu aktivitas
keseharian.

Nilai 5 : ***Gejala agak berat***, manifestasi gejala bermakna yang
mempengaruhi fungsi seseorang, tetapi tidak keseluruhan
hidup, dan masih dapat diatasi.

Nilai 6 : ***Gejala berat***, psikopatologi yang berat dan frekuensinya
sering, sangat mengganggu kehidupan seseorang dan
selalu membutuhkan pengawasan langsung.

Nilai 7 : ***Gejala sangat berat***, merujuk pada psikopatologi dengan
level serius, sangat mempengaruhi hampir seluruh fungsi
kehidupan sehingga membutuhkan pengawasan ketat.

Gejala Positif (P)

| Gejala | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|-----------------------------|---|---|---|---|---|---|---|
| P1. Waham | | | | | | | |
| P2. Kekacauan proses piker | | | | | | | |
| P3. Halusinasi | | | | | | | |
| P4. Gaduh gelisah | | | | | | | |
| P5. Waham kebesaran | | | | | | | |
| P6. Kecurigaan atau kejaran | | | | | | | |
| P7. Permusuhan | | | | | | | |

Gejala Negatif (N)

| Gejala | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---------------------------------------|---|---|---|---|---|---|---|
| N1. Afek tumpul | | | | | | | |
| N2. Penarikan emosi | | | | | | | |
| N3. Kemiskinan <i>rapport</i> | | | | | | | |
| N4. Penarikan diri | | | | | | | |
| N5. Pemikiran abstrak | | | | | | | |
| N6. . Spontanitas dan arus Percakapan | | | | | | | |
| N7. Pemikiran stereotipik | | | | | | | |

Skala Psikopatologi Umum (G)

| Gejala | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---------------------------------------|---|---|---|---|---|---|---|
| G1.Kekhawatiran Somatic | | | | | | | |
| G2. Ansietas | | | | | | | |
| G3. Rasa bersalah | | | | | | | |
| G4.Ketegangan | | | | | | | |
| G5. Manerisme dan sikap tubuh | | | | | | | |
| G6. Depresi | | | | | | | |
| G7. Retardasi motoric | | | | | | | |
| G8. Ketidakkoperatipan | | | | | | | |
| G9. Isi pikiran yang tidak biasa | | | | | | | |
| G10. Disorientasi | | | | | | | |
| G11.Perhatian Buruk | | | | | | | |
| G12.Kurangnya daya nilai dan tilikan | | | | | | | |
| G13.Gangguan dorongan kehendak | | | | | | | |
| G14. Pengendalian impuls yang buruk | | | | | | | |
| G15. Preokupasi | | | | | | | |
| G16. Penghindaran sosial secara aktif | | | | | | | |

Lampiran 4 Kuisisioner

Nama :

Umur :

Alamat :

Tanggal :

Penilai :

Soal

Jawaban

7. Apakah anda mempunyai masalah keluarga sebelumnya?

ya

tidak

Jika ya apa masalahnya:.....
.....
.....

8. Apakah Anda mempunyai masalah dengan lingkungan sosial?

ya

tidak

Jika Ya apa masalahnya:.....
.....
.....

9. Apakah Anda mempunyai masalah dengan pendidikan?

ya

tidak

Jika Ya apa masalahnya :
.....
.....

10. Apakah Anda mempunyai masalah dengan pekerjaan ?

ya

tidak

Jika Ya apa masalahnya :
.....
.....

11. Apakah Anda mempunyai masalah dengan perumahan?

ya

tidak

Jika Ya apa masalahnya:.....

.....
.....

12. Apakah Anda mempunyai masalah dengan ekonomi? ya tidak

Jika Ya apa masalahnya:.....
.....
.....

13. Apakah Anda mempunyai masalah dengan hukum.? ya tidak

Jika Ya apa masalahnya:.....
.....
.....

14. Apakah Anda mempunyai masalah psikososial lain? ya tidak

Jika Ya apa masalahnya:.....
.....
.....

15. Apakah Anda mempunyai utang pesta adat berupa kerbau ? ya tidak

Jika ya, berapa ekor
.....
.....

16. Apakah utang ini menjadi beban pemikiran anda ? ya tidak

Jika iya, mengapa :.....
.....
.....

17. Apakah anda bekerja? ya tidak

Jika iya, berapa kira – kira penghasilan anda.....
.....
.....



KOMITE ETIK PENELITIAN KESEHATAN
RSPTN UNIVERSITAS HASANUDDIN
RSUP Dr. WAHIDIN SUDIROHUSODO MAKASSAR
Sekretariat : Lantai 2 Gedung Laboratorium Terpadu
JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM 10 MAKASSAR 90245.



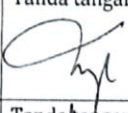

Contact Person: dr. Agussalim Bukhari, MMed, PhD, SpCK TELP. 081241850858, 0411 5780103, Fax : 0411-581431

REKOMENDASI PERSETUJUAN ETIK

Nomor : 449/UN4.6.4.5.31/PP36/2020

Tanggal: 19 Agustus 2020

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

| | | | |
|--|--|--|---------------------------------|
| No Protokol | UH20060242 | No Sponsor Protokol | |
| Peneliti Utama | dr. Santiwati Anda | Sponsor | |
| Judul Peneliti | Polimorfisme Cathecol-O-Methyl Transferase (COMT) Val 158 Met Pada Pasien Skizofrenia Etnis Toraja | | |
| No Versi Protokol | 2 | Tanggal Versi | 23 Juli 2020 |
| No Versi PSP | 2 | Tanggal Versi | 23 Juli 2020 |
| Tempat Penelitian | RS Universitas Hasanuddin Dan Jejaring nya di Makassar | | |
| Jenis Review | <input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard Tanggal 1 Juli 2020 | Masa Berlaku 19 Agustus 2020 sampai 19 Agustus 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 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