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## Lampiran 1. Rekomendasi Persetujuan Etik



KEMENTERIAN PENDIDIKAN, KEBUDAYAAN, RISET DAN TEKNOLOGI  
UNIVERSITAS HASANUDDIN FAKULTAS KEDOKTERAN  
KOMITE ETIK PENELITIAN UNIVERSITAS HASANUDDIN  
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, SpGK TELP. 081241850858, 0411 5780103, Fax : 0411-581431



### REKOMENDASI PERSETUJUAN ETIK

Nomor : 87/UN4.6.4.5.31/ PP36/ 2022

Tanggal: 3 Februari 2023

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

No Protokol	UH23010044	No Sponsor Protokol	
Peneliti Utama	<b>dr. Fidya Putri</b>	Sponsor	
Judul Peneliti	Hubungan Antara Ankle Brachial Index (ABI) Dengan Derajat Keparahan Neuropati Diabetik Pada Pasien Diabetes Melitus Tipe 2		
No Versi Protokol	2	Tanggal Versi	2 Februari 2023
No Versi PSP	2	Tanggal Versi	2 Februari 2023
Tempat Penelitian	RSUP Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 3 Februari 2023 sampai 3 Februari 2024	Frekuensi review lanjutan
Ketua KEP Universitas Hasanuddin	Nama <b>Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)</b>	Tanda tangan	
Sekretaris KEP Universitas Hasanuddin	Nama <b>dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)</b>	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



## Lampiran 2. FORMULIR PERSETUJUAN SETELAH PENJELASAN

Saya yang bertandatangan di bawah ini:

Nama : .....  
Umur : .....  
Alamat : .....  
No. HP : .....

Telah mendengar/membaca dan mengerti penjelasan yang diberikan mengenai tujuan, manfaat, dan prosedur pada penelitian dengan judul Hubungan Antara Ankle Brachial index (ABI) dengan Derajat Keparahan Neuropati Diabetik pada pasien diabetes melitus. Saya menyatakan setuju untuk ikut dalam penelitian ini secara sukarela tanpa paksaan.

Saya tahu bahwa keikutsertaan saya ini bersifat sukarela tanpa paksaan, sehingga saya bisa menolak ikut atau mengundurkan diri dari penelitian ini. Saya berhak bertanya atau meminta penjelasan pada peneliti bila masih ada hal yang belum jelas atau masih ada hal yang ingin saya ketahui tentang penelitian ini.

Saya juga mengerti bahwa semua biaya yang dikeluarkan sehubungan dengan penelitian ini akan ditanggung oleh peneliti. Saya percaya bahwa keamanan dan kerahasiaan data penelitian terjamin dan dengan ini menyetujui semua data yang dihasilkan pada penelitian ini untuk disajikan dalam bentuk lisan maupun tulisan.

Dengan membubuhkan tanda tangan saya di bawah ini, saya menegaskan keikutsertaan saya secara sukarela dalam studi penelitian ini.

	<b>Nama</b>	<b>Tanda tangan</b>	<b>Tgl/Bln/Thn</b>
Responden	.....	.....	.....
Saksi 1	.....	.....	.....
Saksi 2	.....	.....	.....

Penanggung jawab penelitian :

Nama : dr. Fiddy Putri  
Alamat : Nusa Tamalanrea Indah Jl. Akasia Blok C1, Makassar  
Telepon (HP) : 081255010575

Penanggungjawab medis :

Nama : Dr. dr. Audry Devisanty Wuysang, Sp.S (K), M.Si  
Alamat (RS) : Jl. G. Salahutu No. 24, Makassar  
Telepon(HP) : 08152529593

**Lampiran 3. FORMULIR PASIEN PENELITIAN**  
NO. ....

Tgl Pemeriksaan	Pemeriksa	Jam
<b>Identitas Pasien</b>		
Nomor Rekam Medis	RS	
Nama		
Umur/ Tanggal lahir	tahun/ - - (dd - mm - yyyy)	
Alamat / No telepon		
Jenis kelamin	L/P	Pendidikan terakhir
Biometrik	TB = cm; BB = kg; IMT = kg/m <sup>2</sup>	
Pekerjaan		
Tipe DM	1/2	
Durasi DM	tahun	
Berobat DM teratur	Ya/Tidak	
Tatalaksana DM	OAD/insulin/OAD + insulin	
Hipertensi	Ya/Tidak	
Dislipidemia	Ya/Tidak	
Riw merokok 1 thn terakhir	Ya/Tidak	
HbA1c		
<b>Kriteria Inklusi</b>		
Pertanyaan	Ya	Tdk
1. Pasien dengan diagnosis DM sesuai kriteria <i>American Diabetes Association</i>		
2. Pasien berusia antara 25-65 tahun		
3. Pasien kooperatif, bersedia diikutsertakan dalam penelitian ini dan menandatangani informed consent.		
<b>Kriteria Eksklusi</b>		
Pertanyaan	Ya	Tdk
1. Pasien dengan gangguan kesadaran, penyakit cerebrovascular dan kanker		
2. Penderita penyakit ginjal kronis, penyakit hati kronis, penyakit keganasan dan HIV		
3. Pasien yang sedang menjalani kemoterapi atau radioterapi		

#### Lampiran 4. FORMULIR NCS (*NERVE CONDUCTION STUDIES*)

Indikator	Kanan	Kiri	Nilai Normal
Tibialis (motorik)			
Latensi distal (ms)			≤5,8
Amplitudo (mV)			≥4,0
NCV* (m/s)			≥41
Peroneus (motorik)			
Latensi distal (ms)			≤6,5
Amplitudo (mV)			≥2,0
NCV* (m/s)			≥44
Suralis (sensorik)			
Latensi puncak (ms)			≤4,4
Amplitudo (μV)			≥6
NCV* (m/s)			≥40
Peroneus superficialis (sensorik)			
Latensi puncak (ms)			≤4,4
Amplitudo (μV)			≥6
NCV* (m/s)			≥40

\*NCV: *Nerve Conduction Velocity*

#### Kategori

Tipe neuropati berdasarkan jenis saraf : Motorik/sensorik/sensorimotor  
 Tipe neuropati berdasarkan patogenesis : Demielinasi/aksonal/campuran  
 BDC : 0/1/2/3/4

## Lampiran 5. FORMULIR ABI (ANKLE BRACHIAL INDEX)

Tekanan Darah	Kanan	Kiri
<b>Tangan</b>		
Sistole		
Diastole		
<b>Kaki</b>		
Sistole		
Diastole		
Nilai ABI		
<b>Kategori</b>		

### Interpretasi

- a. Kalsifikasi =  $>1,3$
- b. Normal =  $0,91 - 1,3$
- c. Oklusi ringan =  $0,70 - 0,90$
- d. Oklusi sedang =  $0,40 - 0,69$
- e. Oklusi berat =  $< 0,40$

## Lampiran 6. Raw Data Penelitian

No	Nama	Tgl Lahir	Umur	Jenis Kelamin	Pend Terakhir	TB	BB	IMT	Terapi DM	HT	Dislipid	Merokok	HbA1c	BDC	ABI Kanan	ABI Kiri	ABI Kanan	ABI Kiri
1	St	25/05/65	57	Perempuan	D3	149	63	28,38	Insulin	Ya	Ya	Tidak	14	Normal	1	1	Boderline	Boderline
2	Ha	31-Dec-64	57	Perempuan	S1	153,00	52,60	22,47	OAD + insulin	Tidak	Ya	Tidak	11,3	Sedang	0,9	0,8	Oklusi ringan	Oklusi ringan
3	Sy	1-Jan-65	57	Laki-laki	SMA	160	49	19,14	OAD + insulin	Tidak	Tidak	Tidak	6,7	Ringan	0,9	1	Oklusi ringan	Boderline
4	In	13/11/66	56	Perempuan	SMA	160	56	21,88	OAD	Ya	Ya	Tidak	6,1	Normal	1,2	1,1	Normal	Normal
5	Ik	19-Aug-84	38	Laki-laki	S1	168,00	70,00	24,80	OAD	Ya	Ya	Tidak	8,2	Normal	1	1	Boderline	Boderline
6	Ka	11-Jan-78	44	Perempuan	SMA	153	65	27,77	OAD	Ya	Ya	Tidak	8,2	Normal	1	1,1	Boderline	Normal
7	An	31-Dec-60	61	Laki-laki	S2	169,00	67,00	23,46	OAD	Tidak	Tidak	Tidak	10,8	Ringan	0,9	1	Oklusi ringan	Boderline
8	Mu	26/11/64	58	Perempuan	S3	155	67	27,89	OAD	Ya	Ya	Tidak	10,4	Sedang	1	1	Boderline	Boderline
9	Da	7-Sep-69	53	Laki-laki	SLTP	162,50	61,50	23,29	OAD	Tidak	Tidak	Ya	7,9	Sedang	1	1	Boderline	Boderline
10	Ma	18/03/75	47	Perempuan	SMA	158	57	22,83	OAD	Tidak	Tidak	Tidak	7,8	Ringan	0,9	1	Oklusi ringan	Boderline
11	Moe	4-Feb-55	64	Laki-laki	S1	157,00	71,00	28,80	OAD	Ya	Ya	Ya	7,9	Ringan	0,8	1	Oklusi ringan	Boderline
12	Her	10/10/65	57	Perempuan	S1	160,00	60,00	23,44	OAD	Tidak	Ya	Tidak	12	Normal	0,8	0,8	Oklusi ringan	Oklusi ringan
13	Na	31/12/68	53	Perempuan	S1	149,00	37,00	16,67	OAD	Ya	Tidak	Tidak	7,3	Normal	1	1,1	Boderline	Normal
14	Muh	26-May-75	47	Laki-laki	S2	166,50	72,50	26,15	Insulin	Tidak	Ya	Tidak	14,3	Sedang	1	1	Boderline	Boderline
15	Ra	18-Jun-56	66	Laki-laki	S2	162,50	55,50	21,02	Insulin	Tidak	Tidak	Ya	10,5	Ringan	1,2	1	Normal	Boderline
16	HS	2-Aug-68	54	Perempuan	SLTA	160,00	65,00	25,39	Insulin	Ya	Tidak	Tidak	9,7	Sedang	0,8	0,9	Oklusi ringan	Oklusi ringan
17	AS	15/08/63	59	Laki-laki	SLTA	176,00	56,00	18,08	Insulin	Tidak	Tidak	Tidak	9,8	Normal	1	1	Boderline	Boderline
18	Hu	25/05/61	61	Laki-laki	SLTA	156,00	76,00	31,23	OAD	Ya	Tidak	ya	11,28	Sedang	0,7	0,6	Oklusi ringan	Oklusi ringan
19	FM	24/12/60	62	Perempuan	SD	160,00	75,00	29,30	OAD	Ya	Tidak	Tidak	11,5	Sedang	1	1	Boderline	Boderline
20	Hw	04/04/63	59	Perempuan	SLTA	154,00	60,00	25,30	OAD	Tidak	Tidak	Tidak	8,2	Normal	1	1	Boderline	Boderline
21	Naz	18/03/58	64	Laki-laki	SLTA	160,00	65,00	25,39	OAD	Ya	Tidak	Tidak	8	Normal	0,9	0,8	Oklusi ringan	Oklusi ringan
22	Mah	17-Jun-69	53	Laki-laki	S1	162,00	52,00	19,81	Insulin	Tidak	Ya	Tidak	7,2	Sedang	1	1	Boderline	Boderline
23	Has	15/04/78	44	Perempuan	SD	143,50	55,50	26,95	OAD	Tidak	Tidak	Tidak	7,8	Normal	0,9	1	Oklusi ringan	Boderline
24	RS	30/04/69	53	Perempuan	S1	139,00	39,00	20,19	Insulin	Ya	Ya	Tidak	13	Ringan	1	1	Boderline	Boderline
25	Si	22/11/65	57	Laki-laki	SLTA	170,00	74,00	25,61	OAD	Tidak	Ya	Tidak	6,6	Normal	0,9	0,8	Oklusi ringan	Oklusi ringan
26	Hf	05/05/59	64	Laki-laki	S2	170,00	73,00	25,26	Insulin	Ya	Ya	Tidak	6,5	Sedang	1,1	1,1	Normal	Normal
27	FR	05/01/00	53	Perempuan	S2	160,00	56,00	21,88	Insulin + OAD	Tidak	Tidak	Tidak	10,1	Berat	1,4	1,4	Kalsifikasi	Kalsifikasi
28	RA	20-Dec-71	51	Laki-laki	S1	164,00	68,00	25,28	OAD + insulin	Ya	Ya	Ya	7,5	Sedang	1	1	Boderline	Boderline
29	Ts	20-Jun-73	49	Laki-laki	SLTA	150,00	41,00	18,22	OAD	Tidak	Tidak	Tidak	11,3	Berat	1,4	1,4	Kalsifikasi	Kalsifikasi

30	HMY	16-Dec-64	58	Laki-laki	S2	164,50	63,00	23,28	Insulin	Ya	Tidak	Ya	9,5	Berat	1	1	Boderline	Boderline
31	Ro	29-Jan-61	62	Perempuan	SLTA	155,50	66,00	27,30	OAD + insulin	Ya	Ya	Tidak	10,0	Sedang	0,8	0,9	Oklusi ringan	Oklusi ringan
32	Be	17-Sep-79	43	Perempuan	S1	159,50	72,00	28,30	Insulin	Tidak	Ya	Tidak	11,5	Sedang	0,8	0,9	Oklusi ringan	Oklusi ringan
33	Mmp	26-Mar-70	53	Perempuan	S1	151,00	48,00	21,05	Insulin	Tidak	Ya	Tidak	6,7	Sedang	0,8	0,9	Oklusi ringan	Oklusi ringan
34	Asf	20-Sep-75	47	Perempuan	S1	155,50	56,50	23,37	OAD	Tidak	Tidak	Tidak	10,6	Normal	1	1	Boderline	Boderline
35	DI	7-Sep-69	53	Laki-laki	SLTP	162,50	61,50	23,29	OAD	Tidak	Tidak	Ya	7,9	Sedang	1	1	Boderline	Boderline
36	Wnh	28-Feb-66	57	Laki-laki	S3	160,00	70,00	27,34	Insulin	Tidak	Ya	Tidak	9,2	Sedang	1	1	Boderline	Boderline

## Lampiran 7. Hasil Analisis Data Statistik

### Case Processing Summary

	Valid		Cases Missing		Total	
	N	Percent	N	Percent	N	Percent
ABI_Kanan * BDC	36	100.0%	0	0.0%	36	100.0%

### ABI\_Kanan \* BDC Crosstabulation

Count

		BDC				Total
		Normal	Ringan	Sedang	Berat	
ABI_Kanan	Oklusi ringan	3	0	6	0	9
	Borderline	6	6	8	1	21
	Normal	3	0	1	0	4
	Kalsifikasi	0	0	0	2	2
Total		12	6	15	3	36

### Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	31.264 <sup>a</sup>	9	.000
Likelihood Ratio	21.489	9	.011
Linear-by-Linear Association	.480	1	.489
N of Valid Cases	36		

a. 14 cells (87.5%) have expected count less than 5. The minimum expected count is .17.

### Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.682	.000
N of Valid Cases		36	

### Case Processing Summary

	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
ABI_Kiri * BDC	36	100.0%	0	0.0%	36	100.0%

### ABI\_Kiri \* BDC Crosstabulation

Count

		BDC				Total
		Normal	Ringan	Sedang	Berat	
ABI_Kiri	Oklusi ringan	4	4	6	0	14
	Borderline	7	1	8	1	17
	Normal	1	1	1	0	3
	Kalsifikasi	0	0	0	2	2
Total		12	6	15	3	36

### Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	26.998 <sup>a</sup>	9	.001
Likelihood Ratio	16.422	9	.059
Linear-by-Linear Association	2.420	1	.120
N of Valid Cases	36		

a. 13 cells (81.3%) have expected count less than 5. The minimum expected count is .17.



### Symmetric Measures

		Value	Approximate Significance
Nominal by Nominal	Contingency Coefficient	.655	.001
N of Valid Cases		36	