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Lampiran 1. Lembar informed consent.

FORMULIR PERSETUJUAN SETELAH PENJELASAN

Yang bertanda tangan dibawah ini :
    Nama   :
    Umur   :
    Jenis Kelamin   :
    Alamat   :
    Pekerjaan   :

Setelah mendapatkan penjelasan dari peneliti dengan ini saya menyatakan bersedia secara sukarela tanpa paksaan untuk mengikuti penelitian ini dan mentaati semua prosedur yang akan dilakukan pada penelitian ini.

Saya tahu bahwa saya berhak untuk bertanya apabila masih ada hal-hal yang saya tidak mengerti.

Saya mengerti bahwa prosedur pengambilan jaringan tumor nasofaring untuk pemeriksaan Programmed Death Ligand 1 terhadap diri sayaberlangsung kurang lebih 15 menit dan dapat menyebabkan hal-hal yang merugikan, namun saya percaya bahwa akan dilakukan tindakan-tindakan kewaspadaan untuk mencegah hal-hal tersebut. Saya mengerti bahwa resiko yang mungkin terjadi dalam pengambilan jaringan tumor nasofaring adalah rasa tidak nyaman dan nyeri dan saya juga mengerti bahwa resiko pengambilan jaringan tumor nasofaring di ruang operasi adalah resiko terjadinya perdarahan. Saya juga telah mengerti bahwa resiko ini dapat diantisipasi dengan cara pengambilan jaringan tumor nasofaring secara legeartis dan anestesi lokal dan umum, serta adanya tampon hidung dan obat obatan anti nyeri dan anti perdarahan. Saya juga telah mengerti bahwahasil pemeriksaan yang didapatkan akan dijamin kerahasiaannya dan semua biaya pemeriksaan adalah tanggungan sepenuhnya dari peneliti.

Saya juga tahu bahwa saya berhak mendapat penanganan atau kompensasi biaya dari peneliti bila terjadi efek samping dari pemeriksaan yang dilakukan.

Saya juga berhak menolak untuk tidak ikut dalam penelitian ini tanpa kehilangan hak saya untuk mendapat pelayanan kesehatan dari dokter.

                                                                    Makassar

        Nama Saksi

    1. (......................................)
        Nama jelas/Tanda tangan

    2. (......................................)   (..)
        Nama jelas/Tanda tangan   Nama jelas/Tanda tangan

Peneliti Utama : **dr. Mila Habibasari**
Komplek Graha Sari Blok C/2, Makassar / Telpon : 082291590001
Dokter Penanggung jawab medis : **Prof. Dr.dr. Abdul Kadir, Ph. D, Sp.T.H.T.K.L(K),M.Kes**
Hertasning Blok E14/11, Makassar/Telepon: 0816 253 509

Lampiran 2. Data Dasar Penelitian

DATA SAMPEL PENELITIAN

NO	NAMA	UMUR (THN)	JK (L/P)	HASIL BIOPSI	DIAGNOSA KLINIS	PD-L1
1.	Tn.GD	40	L	Squamous Cell Carcinoma tidak berkeratin tidak berdiferensiasi	KNF Stadium IVB (T4N0M0)	LOW
2.	Ny.NM		P	Squamous Cell Carcinoma tidak berkeratin tidak berdiferensiasi	KNF Stadium IVC (T4N3M1)	LOW
3.	Ny.R		P	Squamous Cell Carcinoma	KNF Stadium III (T3N1M0)	LOW
4.	Tn.ZB		L	Squamous Cell Carcinoma, WHO tipe II	KNF Stadium II (T2N0M0)	NEG/0
5.	Tn.A		L	Squamous Cell Carcinoma	KNF Stadium II (T2N0M0)	LOW
6.	Tn.OL		L	Squamous Cell Carcinoma, WHO tipe II	KNF Stadium II (T2N0M0)	NEG/0
7.	Ny.BW		P	Squamous Cell Carcinoma	KNF Stadium IVA (T4N0M0)	HIGH
8.	Ny.M		P	Squamous Cell Carcinoma tidak berkeratin tidak berdiferensiasi	KNF Stadium III (T3N1M0)	LOW
9.	Tn.RA		L	Squamous Cell Carcinoma	KNF Stadium II (T2N0M0)	LOW
10.	Tn.SP		L	Squamous Cell Carcinoma	KNF Stadium IVA (T4N3M0)	LOW
11.	Tn.DM		L	Squamous Cell Carcinoma	KNF Stadium IVB (T4N3M1)	HIGH
12.	Tn.TW		L	Squamous Cell Carcinoma, WHO tipe II	KNF Stadium II (T2N0M0)	LOW

No.	Kode		L/P	Diagnosis	Stadium	Ekspresi
13.	Tn.OLH		L	Squamous Cell Carcinoma tidak berkeratin	KNF Stadium II (T2N0M0)	NEG/0
14.	Tn.SM		L	Squamous Cell Carcinoma	KNF Stadium IVB (T4N2M1)	HIGH
15.	Ny.MS		P	Squamous Cell Carcinoma	KNF Stadium IVA (T4N0M0)	HIGH
16.	Nn.ML		P	Squamous Cell Carcinoma	KNF Stadium IVA (T4N0M0)	HIGH
17.	Tn.TL		L	Squamous Cell Carcinoma	KNF Stadium III (T3N0M0)	LOW
18.	Tn.MYN		L	Squamous Cell Carcinoma	KNF Stadium IVA (T3N1M0)	HIGH
19.	Tn.YSF		L	Squamous Cell Carcinoma	KNF Stadium IVA (T3N1M0)	HIGH
20.	Tn.IW		L	Squamous Cell Carcinoma	KNF Stadium III (T3N0M0)	LOW
21.	Tn.WH		L	Squamous Cell Carcinoma	KNF Stadium III (T3N1M0)	HIGH
22.	Tn.SK		L	Squamous Cell Carcinoma	KNF Stadium III (T3N1M0)	LOW
23.	Tn.MR		L	Squamous Cell Carcinoma	KNF Stadium II (T2N0M0)	LOW
24.	Tn.LM		L	Squamous Cell Carcinoma	KNF Stadium IVA (T4N1M0)	HIGH
25	Tn.NM		L	Squamous Cell Carcinoma	KNF Stadium IVA (T4N1M0)	HIGH

	no	jk	umur	stadium	stadium	pdl1	VAR000	VAR000
1	1	1	40	IVB	1	1	1	3
2	2	2	34	IVC	1	1	1	3
3	3	2	39	III	1	1	1	3
4	4	1	35	II	2	0	2	3
5	5	1	37	II	2	1	1	3
6	6	1	41	II	2	0	2	3
7	7	2	41	IVA	1	2	1	2
8	8	2	48	III	1	1	1	3
9	9	1	56	II	2	1	1	3
10	10	2	51	IVA	1	1	1	3
11	11	1	61	IVB	1	2	1	2
12	12	1	58	II	2	1	1	3
13	13	1	49	II	2	0	2	3
14	14	1	49	IVB	1	2	1	2
15	15	2	30	IVA	1	2	1	2
16	16	2	24	IVA	1	2	1	2
17	17	1	45	III	1	1	1	3
18	18	1	45	IVA	1	2	1	2
19	19	1	51	IVA	1	2	1	2
20	20	1	45	III	1	1	1	3
21	21	2	54	III	1	2	1	2
22	22	1	54	III	1	1	1	3
23	23	1	26	II	2	1	1	3
24	24	1	46	IVA	1	2	1	2
25	25	1	46	IVA	1	2	1	2

Frequencies

Statistics

		Jenis Kelamin	Stadium Kanker	Stadium Kanker	PD-L1
N	Valid	25	25	25	25
	Missing	0	0	0	0

Frequency Table

Jenis Kelamin

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Laki-laki	17	68.0	68.0	68.0
	Perempuan	8	32.0	32.0	100.0
	Total	25	100.0	100.0	

Stadium Kanker

				Valid	Cumulative
Valid	II III	7	28.0	28.0	28.0
	IVA	6	24.0	24.0	52.0
	IVB				
	IVC	8	32.0	32.0	84.0
	Total	3	12.0	12.0	96.0

Stadium Kanker

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Lanjut (III/IV)	18	72.0	72.0	72.0
	Dini (I/II)	7	28.0	28.0	100.0
	Total	25	100.0	100.0	

PD-L1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Negative	3	12.0	12.0	12.0
	Low	12	48.0	48.0	60.0
	High	10	40.0	40.0	100.0
	Total	25	100.0	100.0	

Means

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
Umur (Tahun) * Stadium Kanker	25	100.0%	0	0.0%	25	100.0%

Report

Umur (Tahun)

Stadium Kanker	Mean	N	Std. Deviation	Median	Minimum	Maximum
Lanjut (III/IV)	44.61	18	9.004	45.50	24	61
Dini (I/II)	43.14	7	11.711	41.00	26	58
Total	44.20	25	9.600	45.00	24	61

T-Test

Group Statistics

	Stadium Kanker	N	Mean	Std. Deviation	Std. Error Mean
Umur (Tahun)	Lanjut (III/IV)	18	44.61	9.004	2.122
	Dini (I/II)	7	43.14	11.711	4.426

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
Umur (Tahun)	Equal variances assumed	1.328	.261	.337	23	.739
	Equal variances not assumed			.299	8.910	.772

Independent Samples Test

								t-test for Equality of Means			
		C a								95% Confidence Interval of the Difference	
		V a		Miss ing		T o		Mean Difference	Std. Error Difference		
		N	Per cent	N	Per cen	N	Perc ent			Lower	Upper
Jenis Kelamin * Stadium Kanker		25	100.0%		0.0	2 5	100.0%				
Umur (Tahun)	Equal variances assumed							1.468	4.358	-7.546	10.483
	Equal variances not assumed							1.468	4.909	-9.653	12.590

Crosstabs

Case Processing Summary

Jenis Kelamin * Stadium Kanker Crosstabulation

			Stadium Kanker		
			Lanjut (III/IV)	Dini (I/II)	
Jenis Kelamin	Laki-laki	Count	10	7	17
		% within Jenis Kelamin	58.8%	41.2%	100.0%
		% within Stadium Kanker	55.6%	100.0%	68.0%
	Perempuan	Count	8	0	8
		% within Jenis Kelamin	100.0%	0.0%	100.0%
		% within Stadium Kanker	44.4%	0.0%	32.0%
Total		Count	18	7	25
		% within Jenis Kelamin	72.0%	28.0%	100.0%
		% within Stadium Kanker	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.575[a]	1	.032		
Continuity Correction[b]					
Likelihood Ratio Fisher's Exact Test	2.761	1	.097		
Linear-by-Linear Association	6.613	1	.010		
N of Valid Cases				.057	.040

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.24.

b. Computed only for a 2x2 table

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
PD-L1 * Stadium Kanker	25	100.0%	0	0.0%	25	100.0%

PD-L1 * Stadium Kanker Crosstabulation

			Stadium Kanker		
			Lanjut		
PD-L1	Negative	Count	0	3	3
		% within PD-L1	0.0%	100.0%	100.0%

Low	Count		8	4	12
	% within PD-L1		66.7%	33.3%	100.0%
High	Count		10	0	10
	% within PD-L1		100.0%	0.0%	100.0%
Total	Count		18	7	25
	% within PD-L1		72.0%	28.0%	100.0%

Chi-Square Tests

			Asymp. Sig. (2-sided)
Pearson Chi-Square	11.772[a]	2	.003
Likelihood Ratio	14.371	2	.001
Linear-by-Linear Association	10.611	1	.001

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is .84.

NPar Tests

Kruskal-Wallis Test

Ranks

Stadium Kanker	N	Mean Rank
PD-L1 Lanjut (III/IV) Dini (I/II)	18	15.61
Total	7	6.29
	25	

Test Statistics[a,b]

	PD-L1
Chi-Square df	9.808
Asymp. Sig.	1

a. Kruskal Wallis Test

b. Grouping Variable: Stadium Kanker

ROC Curve

Case Processing Summary

	Valid N (listwise)
Positive[a]	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is Lanjut (III/IV).

ROC Curve
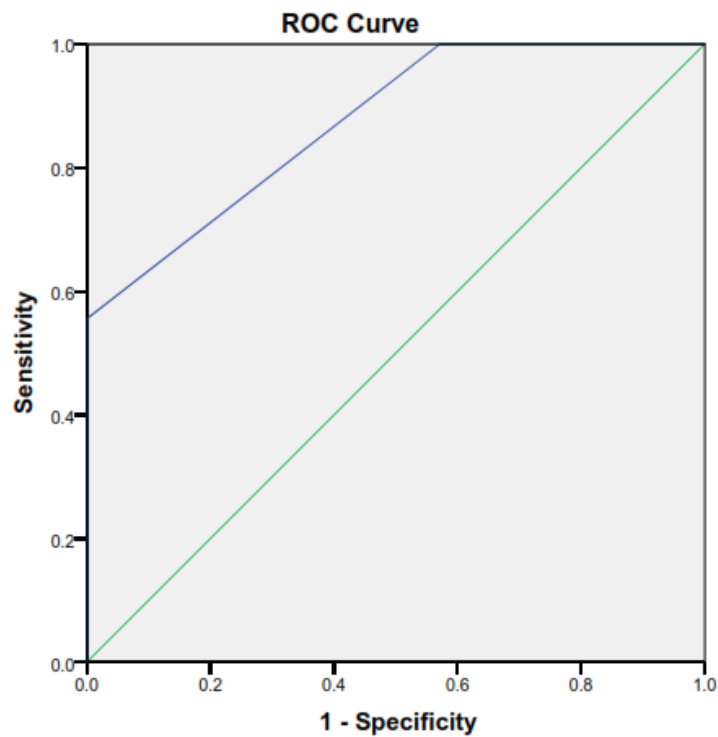
Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s): PD-L1

		Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.873	.073	.004	.730	1.000

The test result variable(s): PD-L1 has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): PD-L1

Positive if Greater Than or Equal To[a]		
-1.00	1.000	1.000
.50	1.000	.571

The test result variable(s): PD-L1 has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is

the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

Crosstab

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
PD-L1 * Stadium Kanker	25	100.0%	0	0.0%	25	100.0%
PD-L1 * Stadium Kanker	25	100.0%	0	0.0%	25	100.0%

PD-L1 * Stadium Kanker

Crosstab

			Stadium Kanker		
			Lanjut (III/IV)	Dini (I/II)	Total
PD-L1	Low/High	Count	18	4	22
		% within PD-L1	81.8%	18.2%	100.0%
		% within Stadium Kanker	100.0%	57.1%	88.0%
	Negative	Count	0	3	3
		% within PD-L1	0.0%	100.0%	100.0%
		% within Stadium Kanker	0.0%	42.9%	12.0%
Total		Count	18	7	25
		% within PD-L1	72.0%	28.0%	100.0%
		% within Stadium Kanker	100.0%	100.0%	100.0%

Chi-Square Tests

			Asymp. Sig. (2-sided)	Exact Sig.	Exact Sig.
Pearson Chi-Square	8.766[a]	1	.003		
Continuity Correction[b]					
Likelihood Ratio	5.178	1	.023		
Fisher's Exact Test					
Linear-by-Linear Association	8.786	1	.003		

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .84.

b. Computed only for a 2x2 table

PD-L1 Stadium Kanker

Crosstab

			Stadium Kanker		
			Lanjut (III/IV)	Dini (I/II)	
PD-L1	High	Count	10	0	10
		% within PD-L1	100.0%	0.0%	100.0%
		% within Stadium Kanker	55.6%	0.0%	40.0%
	Negative/Low	Count	8	7	15
		% within PD-L1	53.3%	46.7%	100.0%
		% within Stadium Kanker	44.4%	100.0%	60.0%
Total		Count	18	7	25
		% within PD-L1	72.0%	28.0%	100.0%
		% within Stadium Kanker	100.0%	100.0%	100.0%

Chi-Square Tests

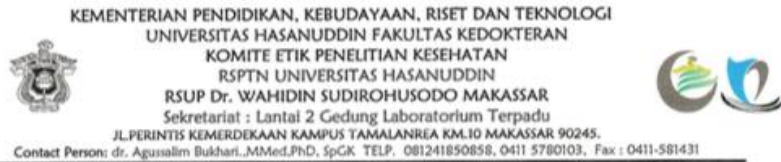|			Asymp. Sig. (2-sided)	Exact Sig.	Exact Sig.
Pearson Chi-Square	6.481[a]	1	.011		
Continuity Correction[b]					
Likelihood Ratio	4.373	1	.037		
Fisher's Exact Test					
Linear-by-Linear Association	8.920	1	.003		

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 2.80.

b. Computed only for a 2x2 table

Graph

Stadium Kanker

Lanjut (III/IV)   **Dini (I/II)**

Count

PD-L1
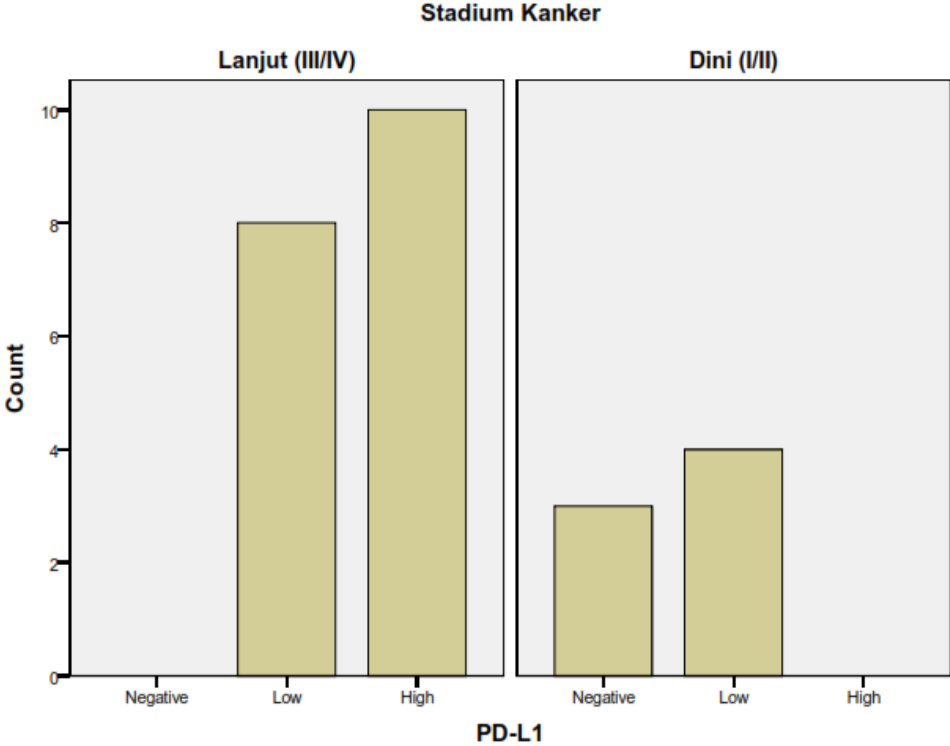
Lampiran 3. Rekomendasi Persetujuan Etik

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

REKOMENDASI PERSETUJUAN ETIK
Nomor : 450/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 12 Juli 2021

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

No Protokol	UH21030118	No Sponsor Protokol	
Peneliti Utama	**dr. Mila Habibasari**	Sponsor	
Judul Peneliti	Ekspresi kadar PD-L1 sebagai penanda prognosis pada pasien karsinoma nasofaring		
No Versi Protokol	**2**	Tanggal Versi	**6 Juli 2021**
No Versi PSP	**2**	Tanggal Versi	**6 Juli 2021**
Tempat Penelitian	RS Dr. Wahidin Sudirohusodo Makassar		
Jenis Review	☐ Exempted ☒ Expedited ☐ Fullboard Tanggal	Masa Berlaku **12 Juli 2021** sampai **12 Juli 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 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 prokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan

Lampiran 5. Dokumentasi Penelitian