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REKOMENDASI PERSETUJUAN ETIK

Nomor : 128/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 26 Februari 2021

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

No Protokol	UH21020104	No Sponsor	
Peneliti Utama	dr. Olivia Desty Sabunga	Protokol	
Judul Peneliti	EKSPRESI MARKER CANCER STEM CELL CD133 PADA ASTROSITOMA YANG IDH-MUTANT DAN IDH-WILDTYPE (ISOCITRATE DEHYDROGENASE)		
No Versi Protokol	1	Tanggal Versi	19 Februari 2021
No Versi PSP		Tanggal Versi	
Tempat Penelitian	Laboratorium Patologi Anatomi Fakultas Kedokteran Universitas Hasanuddin Makassar		
Jenis Review	<input checked="" type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input type="checkbox"/> Fullboard Tanggal	Masa Berlaku 26 Februari 2021 sampai 26 Februari 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

LAMPIRAN

Lampiran 1. Daftar Sampel Penelitian

No.	No. Sediaan	Diagnosa	Jenis Kelamin	Umur	Lokasi massa	Coding	Scoring IDH1		Coding	Scoring CD133		H-score
							Mutant/ Positif	Wild/ Negatif		Intensitas	Extensivity (%)	
1.	HUH.20.488	1	1	22 thn	Fossa Posterior	2		2%	2	1	20	20
2.	P18.4138	1	1	16 thn	Intracranial	1	>10%		1	3	30	90
3.	P17.0452	1	1	65 thn	Intracranial	1		1%	2	0	0	0
4.	P18.0642	1	1	42 thn	Otak	1	>10%		1	3	25	75
5.	P17.1046	1	1	35 thn	Intrakranial	1		1%	2	1	10	10
6.	P20.024	1	1	56 thn	Vertebra T1-T2	2		5%	2	1	15	15
7.	P17.2171	1	1	6 thn	Cerebellum	2	>10%		1	3	15	45
8.	P18.4536	1	1	67 thn	Cerebellum	2		1%	2	0	0	0
9.	P20.1763	1	1	70 thn	Cerebellum	2		5%	2	0	0	0
10.	P18.2140	1	1	5 thn	Cerebellum	2	>10%		1	3	30	90
11.	P19.4513	1	1	32 thn	Frontal Sin	1		1%	2	2	10	20
12.	P17.2376	1	1	36 thn	Temporal	1	>10%		1	1	5	5
13.	P17.1038	1	1	43 thn	Parietal	1	>10%		1	3	10	30
14.	P19.865	1	2	30 thn	Cerebellum	2		1%	2	1	30	30
15.	29662	1	2	44 thn	Parietal	1		1%	2	1	10	10
16.	P19.1215	1	2	28 thn	Hipofise	1	>10%		1	2	80	160
17.	P17.3894	1	2	30 thn	Intradura intrameduller	2	>10%		1	1	10	10
18.	P17.0872	1	2	21 thn	Fossa Posterior	2		1%	2	1	10	10

19.	P20.944	1	2	30 thn	Temporal	1		0%	2	2	50	100
20.	P20.251	1	2	42 thn	Intrakranial	1	>10%		1	3	80	240
21.	P18.4488	1	2	42 thn	Otak	1		2%	2	0	0	0
22.	P15.2365	1	2	32 thn	Occipital	1	>10%		1	3	90	270
23.	35585	2	1	67 thn	Intracranial		>10%		1	3	80	240
24.	P18.3766	2	1	34 thn	Parietal	1	>10%		1	2	10	20
25.	P18.0785	2	1	20 thn	Otak	1	>10%		1	2	30	60
26.	P17.2907	2	1	22 thn	Cortex cerebri	1	>10%		1	3	60	180
27.	P17.1853	2	1	63 thn	Vertebra L5-S1	2	>10%		1	1	5	5
28.	P21.1601	2	1	47 thn	Parietal	1	>10%		1	3	90	270
29.	9659	2	2	43 thn	Cerebellum	2	>10%		1	3	45	135
30.	P18.4374	2	2	57 thn	Temporal	1	>10%		1	2	5	10
31.	P19.1357	2	2	7 thn	Temporoparietal	1	>10%		1	2	5	10
32.	P17.2597	2	2	38 thn	Intracerebri	1	>10%		1	1	50	50
33.	P17.4120	2	2	42 thn	Frontotemporal	1	>10%		1	3	40	120
34.	P19.2516	2	2	58 thn	Intracerebri	1		5%	2	1	10	10
35.	48444	2	2	42 thn	Parietal	1	>10%		1	3	90	270
36.	8751	2	2	43 thn	Cerebellum	2	>10%		1	0	0	0
37.	834	2	2	50 thn	Intracerebri	1	>10%		1	3	90	270
38.	P19.013	3	1	53 thn	Frontotemporal	1	>10%		1	3	80	240
39.	37536	3	1	53 thn	Intracerebri	1	>10%		1	3	85	255
40.	35671	3	1	63 thn	Intracranial	1	>10%		1	3	80	240
41.	P20.1010	3	1	17 thn	Intrakranial	1	>10%		1	3	80	240
42.	SWG.79A	3	1	49 thn	Intracerebri	1	>10%		1	3	90	270

43.	37781	3	1	43 thn	Intracranial	1	>10%		1	3	70	210
44.	P17.2882	3	1	70 thn	Intracerebri	1	>10%		1	3	60	180
45.	P17.4517	3	1	26 thn	tumor otak	1		1%	2	1	5	5
46.	P17.2943	3	1	65 thn	tumor otak	1	>10%		1	3	50	150
47.	P16.2098	3	1	39 thn	Frontal	1		5%	2	3	10	30
48.	P19.1376	3	1	62 thn	Intracerebri	1	>10%		1	2	20	40
49.	P17.1972	3	1	46 thn	Hemisfer	1	>10%		1	3	80	240
50.	P17.3595	3	1	29 thn	Otak	1		3%	2	2	50	100
51.	P17.4114	3	1	7 thn	Intracranial	1		1%	2	3	5	15
52.	P17.4467	3	1	37 thn	Intracranial	1	>10%		1	1	2	2
53.	19.2056	3	1	58 thn	Intracranial	1	>10%		1	3	70	210
54.	P15.2931	3	1	14 thn	Frontal	1	>10%		1	3	50	150
55.	19.2416	3	1	62 thn	Occipital	1	>10%		1	3	80	240
56.	P21.690	3	1	52 thn	Parieto-occipital	1		8%	2	2	10	20
57.	HUH21.298	3	1	29 thn	Parietal	1	>10%		1	3	80	240
58.	HUH21.303	3	1	21 thn	Temporal	1	>10%		1	3	80	240
59.	HUH21.378	3	2	9 thn	Temporoparietal	1	>10%		1	3	90	270
60.	SWG 20.001	3	2	39 thn	Intracerebri	1	>10%		1	3	90	270
61.	P19.057	3	2	45 thn	Temporoparietal	1		8%	2	2	50	100
62.	P18.3275	3	2	48 thn	Otak	1		5%	2	0	0	0
63.	P17.4390	3	2	20 thn	Intracerebri	1		2%	2	0	0	0
64.	P19.609	3	2	8 thn	Intracerebri	1	>10%		1	3	90	270
65.	17.1222	3	2	37 thn	Intracranial	1	>10%		1	3	70	210
66.	49177	3	2	49 thn	Frontal	1	>10%		1	3	90	270
67.	P21.1099	3	2	59 thn	Frontoparietal	1	>10%		1	3	50	150

KETERANGAN:

DIAGNOSA HISTOPATOLOGI

1= Diffuse Astrocytoma

2= Anaplastik Astrocytoma

3= Glioblastoma

JENIS KELAMIN

1 = Laki-laki
2 = Perempuan

1= Supratentorial

2= Infratentorial

LOKASI TUMOR

SCORING IDH1-R132H

1= IDH-*mutant* (Ekspresi IDH1 \geq 10% terwarnai pada sitoplasma dan inti sel tumor)

2= IDH-*wildtype* (Ekspresi IDH1 <10% terwarnai pada sitoplasma dan inti sel tumor)

SCORING CD133

Intensitas

0= Tidak terwarnai

1= *Weak* (terlihat pada objektif 400x)

2= *Moderate* (terlihat pada objektif 100x)

3= *Strong* (terlihat pada objektif 40x)

Untuk Hscore

Descriptives

		Statistic	Std. Error
HScore	Mean	115.4776	12.90100
	95% Confidence Interval for Mean		
	Lower Bound	89.7199	
	Upper Bound	141.2353	
	5% Trimmed Mean	113.3085	
	Median	90.0000	
	Variance	11151.193	
	Std. Deviation	105.59921	
	Minimum	.00	
	Maximum	270.00	
	Range	270.00	
	Interquartile Range	230.00	
	Skewness	.310	.293
	Kurtosis	-1.611	.578

Untuk tabel deskriptif

Diagnosa

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Diffuse Astrocytoma	22	32.8	32.8	32.8
	Anaplastik Astrocytoma	15	22.4	22.4	55.2
	Glioblastoma	30	44.8	44.8	100.0
	Total	67	100.0	100.0	

Jenis Kelamin

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Laki-Laki	40	59.7	59.7	59.7
	Perempuan	27	40.3	40.3	100.0
	Total	67	100.0	100.0	

Usia

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0-19 Tahun	9	13.4	13.4	13.4
	20-39 Tahun	24	35.8	35.8	49.3
	40-59 Tahun	24	35.8	35.8	85.1
	>59 Tahun	10	14.9	14.9	100.0
	Total	67	100.0	100.0	

Lokasi

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Supratentorial	55	82.1	82.1	82.1
	Infratentorial	12	17.9	17.9	100.0
	Total	67	100.0	100.0	

IDH1

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<10%	21	31.3	31.3	31.3
	>10%	46	68.7	68.7	100.0
	Total	67	100.0	100.0	

HScore

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Low	34	50.7	50.7	50.7
	High	33	49.3	49.3	100.0
	Total	67	100.0	100.0	

Hubungan antara usia dengan diagnosa

Usia * Diagnosa Crosstabulation

		Diagnosa			Total	
		Diffuse Astrocytoma	Anaplastik Astrocytoma	Glioblastoma		
Usia	0-19 Tahun	Count	3	1	5	9
		% within Usia	33.3%	11.1%	55.6%	100.0%
	20-39 Tahun	Count	10	5	9	24
		% within Usia	41.7%	20.8%	37.5%	100.0%
	40-59 Tahun	Count	6	7	11	24
		% within Usia	25.0%	29.2%	45.8%	100.0%
	>59 Tahun	Count	3	2	5	10
		% within Usia	30.0%	20.0%	50.0%	100.0%
Total		Count	22	15	30	67
		% within Usia	32.8%	22.4%	44.8%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	2.683 ^a	6	.847	.861		
Likelihood Ratio	2.753	6	.839	.863		
Fisher's Exact Test	2.681			.870		
Linear-by-Linear Association	.188 ^b	1	.665	.703	.362	.056
N of Valid Cases	67					

a. 6 cells (50.0%) have expected count less than 5. The minimum expected count is 2.01.

b. The standardized statistic is .434.

Hubungan usia dengan IDH

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Usia * IDH1	67	100.0%	0	0.0%	67	100.0%

Usia * IDH1 Crosstabulation

			IDH1		Total
			<10%	>10%	
Usia	0-19 Tahun	Count	1	8	9
		% within Usia	11.1%	88.9%	100.0%
	20-39 Tahun	Count	10	14	24
		% within Usia	41.7%	58.3%	100.0%
	40-59 Tahun	Count	7	17	24
		% within Usia	29.2%	70.8%	100.0%
	>59 Tahun	Count	3	7	10
		% within Usia	30.0%	70.0%	100.0%
Total		Count	21	46	67
		% within Usia	31.3%	68.7%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)	Point Probability
Pearson Chi-Square	2.962 ^a	3	.398	.426		
Likelihood Ratio	3.252	3	.354	.401		
Fisher's Exact Test	2.796			.441		
Linear-by-Linear Association	.089 ^b	1	.766	.776	.440	.110
N of Valid Cases	67					

a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is 2.82.

b. The standardized statistic is -.298.

Hubungan usia dengan CD133

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Usia * IDH1	67	100.0%	0	0.0%	67	100.0%

Usia * IDH1 Crosstabulation

			IDH1		Total
			<10%	>10%	
Usia	0-19 Tahun	Count	1	8	9
		% within Usia	11.1%	88.9%	100.0%
	20-39 Tahun	Count	10	14	24
		% within Usia	41.7%	58.3%	100.0%
	40-59 Tahun	Count	7	17	24
		% within Usia	29.2%	70.8%	100.0%
	>59 Tahun	Count	3	7	10
		% within Usia	30.0%	70.0%	100.0%
Total		Count	21	46	67
		% within Usia	31.3%	68.7%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	2.962 ^a	3	.398	.426		
Likelihood Ratio	3.252	3	.354	.401		
Fisher's Exact Test	2.796			.441		
Linear-by-Linear Association	.089 ^b	1	.766	.776	.440	.110
N of Valid Cases	67					

a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is 2.82.

b. The standardized statistic is -.298.

Hubungan Diagnosa dengan IDH

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Diagnosa * IDH1	67	100.0%	0	0.0%	67	100.0%

Diagnosa * IDH1 Crosstabulation

			IDH1		Total
			<10%	>10%	
Diagnosa	Diffuse Astrocytoma	Count	12	10	22
		% within Diagnosa	54.5%	45.5%	100.0%
	Anaplastik Astrocytoma	Count	1	14	15
		% within Diagnosa	6.7%	93.3%	100.0%
	Glioblastoma	Count	8	22	30
		% within Diagnosa	26.7%	73.3%	100.0%
Total		Count	21	46	67
		% within Diagnosa	31.3%	68.7%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	10.053 ^a	2	.007	.006		
Likelihood Ratio	10.865	2	.004	.006		
Fisher's Exact Test	9.869			.007		
Linear-by-Linear Association	3.798 ^b	1	.051	.053	.036	.018
N of Valid Cases	67					

a. 1 cells (16.7%) have expected count less than 5. The minimum expected count is 4.70.

b. The standardized statistic is 1.949.

Hubungan Diagnosa dengan CD133

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Diagnosa * HScore	67	100.0%	0	0.0%	67	100.0%

Diagnosa * HScore Crosstabulation

			Ekspresi CD133		Total
			Low	High	
Diagnosa	Diffuse Astrocytoma	Count	18	4	22
		% within Diagnosa	81.8%	18.2%	100.0%
	Anaplastik Astrocytoma	Count	8	7	15
		% within Diagnosa	53.3%	46.7%	100.0%
	Glioblastoma	Count	8	22	30
		% within Diagnosa	26.7%	73.3%	100.0%
Total		Count	34	33	67
		% within Diagnosa	50.7%	49.3%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	15.498 ^a	2	.000	.000		
Likelihood Ratio	16.482	2	.000	.000		
Fisher's Exact Test	15.806			.000		
Linear-by-Linear Association	15.263 ^b	1	.000	.000	.000	.000
N of Valid Cases	67					

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.39.

b. The standardized statistic is 3.907.

Hubungan IDH dengan CD133

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
IDH1 * HScore	67	100.0%	0	0.0%	67	100.0%

IDH1 * HScore Crosstabulation

			HScore		Total
			Low	High	
IDH1	<10%	Count	18	3	21
		% within IDH1	85.7%	14.3%	100.0%
	>10%	Count	16	30	46
		% within IDH1	34.8%	65.2%	100.0%
Total		Count	34	33	67
		% within IDH1	50.7%	49.3%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	14.964 ^a	1	.000	.000	.000	
Continuity Correction ^b	12.995	1	.000			
Likelihood Ratio	16.202	1	.000	.000	.000	
Fisher's Exact Test				.000	.000	
Linear-by-Linear Association	14.740 ^c	1	.000	.000	.000	.000
N of Valid Cases	67					

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 10.34.

b. Computed only for a 2x2 table

c. The standardized statistic is 3.839.

Hubungan Lokasi dengan diagnosa

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Diagnosa * Lokasi	67	100.0%	0	.0%	67	100.0%

Diagnosa * Lokasi Crosstabulation

			Lokasi		Total
			Supratentorial	Infratentorial	
Diagnosa	Diffuse Astrocytoma	Count	13	9	22
		% within Diagnosa	59.1%	40.9%	100.0%
	Anaplastik Astrocytoma	Count	12	3	15
		% within Diagnosa	80.0%	20.0%	100.0%
	Glioblastoma	Count	30	0	30
		% within Diagnosa	100.0%	.0%	100.0%
Total		Count	55	12	67
		% within Diagnosa	82.1%	17.9%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.505 ^a	2	.001
Likelihood Ratio	18.205	2	.000
Linear-by-Linear Association	14.287	1	.000
N of Valid Cases	67		

a. 2 cells (33,3%) have expected count less than 5. The minimum expected count is 2,69.

Jenis kelamin dengan diagnosa

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Jenis_Kelamin * Diagnosa	67	100.0%	0	0.0%	67	100.0%

Jenis_Kelamin * Diagnosa Crosstabulation

			Diagnosa			Total
			Diffuse Astrocytoma	Anaplastik Astrocytoma	Glioblastoma	
Jenis_Kelamin	Laki-Laki	Count	13	6	21	40
		% within Jenis_Kelamin	32.5%	15.0%	52.5%	100.0%
Perempuan	Perempuan	Count	9	9	9	27
		% within Jenis_Kelamin	33.3%	33.3%	33.3%	100.0%
Total	Total	Count	22	15	30	67
		% within Jenis_Kelamin	32.8%	22.4%	44.8%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)	Point Probability
Pearson Chi-Square	3.746 ^a	2	.154	.171		
Likelihood Ratio	3.734	2	.155	.181		
Fisher's Exact Test	3.672			.171		
Linear-by-Linear Association	.834 ^b	1	.361	.397	.220	.074
N of Valid Cases	67					

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 6.04.

b. The standardized statistic is -.913.