

LAMPIRAN 1 KELAIKAN ETIK

**PEMERINTAH PROVINSI JAWA TIMUR
RUMAH SAKIT UMUM DAERAH DOKTER SOETOMO SURABAYA
BIDANG PENELITIAN DAN PENGEMBANGAN
Jl. Prof.Dr. Moestopo No. 6-8 Tlp. 031-5501073,5501164
S U R A B A Y A**

NOTA DINAS

Kepada Yth	: 1. Kepala Poli Onkologi Satu Atap 2. 3. RSUD Dr. Soetomo Surabaya
Dari	: Kepala Bidang Penelitian dan Pengembangan
Nomor	: 070/ 631 / 301.4.2/Litb/ VI /2020
Tanggal	: 16 Juni 2020
Sifat	: Penting
Lampiran	: 1 Explar
Perihal	: Permohonan ijin penelitian

Dengan ini kami mohon ijin penelitian atas nama :

Lintong D.S. Damanik, dr

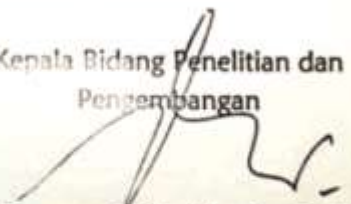
Untuk dapat melaksanakan permohonan ijin penelitian di unit kerja / bagian Saudara dengan judul :

**HUBUNGAN RATIO ALBUMIN-CRP TERHADAP RESPON KLINIS NEOADJUVAN
KEMOTERAPI REGIMEN CAF PADA WANITA DENGAN LOCALLY ADVANCE BREAST
CANCER DI RSUD DR. SOETOMO**

Apabila dapat disetujui kami mengharapkan jawaban Saudara dalam waktu tidak terlalu lama guna proses administrasi lebih lanjut. Sebagai bahan pertimbangan Saudara, bersama ini kami lampirkan foto copy *letter of exemption*.

Atas perhatian dan kerjasamanya kami sampaikan terima kasih.

Kepala Bidang Penelitian dan
Pengembangan


Dr. Damayanti Tinduh, dr., Sp.KFR(K)
Pembina
NIP. 19710112 200604 2 031

Tembusan :Yth
1. Direktur RSUD Dr. Soetomo (sebagai laporan)
2. Direktur Pendidikan Profesi dan Penelitian
3. Arsip

PEMERINTAH PROPINSI JAWA TIMUR
RUMAH SAKIT UMUM DAERAH Dr. SOETOMO
KOMITE ETIK PENELITIAN KESEHATAN
Jl. Mayjen Prof. Dr. Moestopo No. 6-8, Telp. 031-5501071-5501073, Fax. 031-5501164
SURABAYA 60286

SURAT EXEMPTION
(" LETTER OF EXEMPTION ")

Ref. No. : 0030/LOE/301.4.2/VI/2020

Judul Protokol Penelitian : HUBUNGAN RATIO ALBUMIN-CRP TERHADAP RESPON KLINIS
NEOAJUVAN KEMOTERAPI REGIMEN CAF PADA WANITA DENGAN
LOCALLY ADVANCE BREAST CANCER DI RSUD DR. SOETOMO

Dokumen yang disetujui : 0065/106/VI/2020 (versi: 3)

Peneliti Utama : Hantoro Ishardiyanto, dr., Sp.B (K) Onk

Peneliti Lain : 1. Dr. Hartono, dr., Sp.PK (K) MQIH
2. Lintong Darianto S Damanik, dr

Instalasi/Tempat Penelitian : SMF Bedah
RSUD Dr. Soetomo

Komite Etik Penelitian Kesehatan RSUD Dr Soetomo menyatakan bahwa dokumen diatas sesuai dengan The Office for Human Research Protections (OHRP) dibawah persyaratan the U.S. Department of Health and Human Services (HHS) Regulasi 45 CFR bagian 46 untuk **exempt review**.



dr. Tri Wahyu Saputro (K)
Ketua Panel 3

Dr. Laksmi Wulandari dr., SpP(K)
Sekretaris Panel 3

LAMPIRAN 2 DATA STATISTIK**RATIO**

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Rendah	32	88.9	88.9	88.9
Tinggi	4	11.1	11.1	100.0
Total	36	100.0	100.0	

RECIST

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Complete Disease	5	13.9	13.9	13.9
Partial Respons	23	63.9	63.9	77.8
Stable Disease	8	22.2	22.2	100.0
Total	36	100.0	100.0	

RESPON

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Respon (+)	28	77.8	77.8	77.8
Respons (-)	8	22.2	22.2	100.0
Total	36	100.0	100.0	

HASIL PA

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Ductal	32	88.9	88.9	88.9
Non Ductal	4	11.1	11.1	100.0
Total	36	100.0	100.0	

SUBTYPE

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Luminal A	12	33.3	33.3	33.3
	Luminal B (Her-2 Positif)	7	19.4	19.4	52.8
	Luminal B (Her-2 Negatif)	6	16.7	16.7	69.4
	Basal like	6	16.7	16.7	86.1
	Erb-B2 overexpression	5	13.9	13.9	100.0
	Total	36	100.0	100.0	

KATEGORI USIA

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	> 50 tahun	18	50.0	50.0	50.0
	< 50 tahun	18	50.0	50.0	100.0
	Total	36	100.0	100.0	

Crosstab CAR RATIO DENGAN RESPON

			RESPON		Total
			Respon (+)	Respons (-)	
RATIO	Rendah	Count	27	5	32
		% within RESPON	96.4%	62.5%	88.9%
	Tinggi	Count	1	3	4
		% within RESPON	3.6%	37.5%	11.1%
Total		Count	28	8	36
		% within RESPON	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	7.252 ^a	1	.007		
Continuity Correction ^b	4.224	1	.040		
Likelihood Ratio	5.903	1	.015		
Fisher's Exact Test				.028	.028
Linear-by-Linear Association	7.051	1	.008		
N of Valid Cases	36				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is .89.

b. Computed only for a 2x2 table

Crosstab HAIL PA DENGAN RESPON

			RESPON		Total
			Respon (+)	Respon (-)	
HASIL PA	Ductal	Count	25	7	32
		% within RESPON	89.3%	87.5%	88.9%
	Non Ductal	Count	3	1	4
		% within RESPON	10.7%	12.5%	11.1%
Total		Count	28	8	36
		% within RESPON	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	.020 ^a	1	.887		
Continuity Correction ^b	.000	1	1.000		
Likelihood Ratio	.020	1	.889		
Fisher's Exact Test				1.000	.652
Linear-by-Linear Association	.020	1	.889		
N of Valid Cases	36				

Crosstab SUBTIPE DENGAN RESPON

			RESPON		Total
			Respon (+)	Respon (-)	
SUBTYPE	Luminal A	Count	5	7	12
		% within RESPON	17.9%	87.5%	33.3%
	Luminal B (Her-2 Positif)	Count	7	0	7
		% within RESPON	25.0%	0.0%	19.4%
	Luminal B (Her-2 Negatif)	Count	6	0	6
		% within RESPON	21.4%	0.0%	16.7%
	Basal like	Count	5	1	6
		% within RESPON	17.9%	12.5%	16.7%
	Erb-B2 overexpression	Count	5	0	5
		% within RESPON	17.9%	0.0%	13.9%
Total		Count	28	8	36
		% within RESPON	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	14.304 ^a	4	.006
Likelihood Ratio	16.431	4	.002
Linear-by-Linear Association	7.032	1	.008
N of Valid Cases	36		

Crosstab USIA DENGAN RESPON

			RESPON		Total
			Respon (+)	Respons (-)	
KATEGORI USIA	> 50 tahun	Count	14	4	18
		% within RESPON	50.0%	50.0%	50.0%
	< 50 tahun	Count	14	4	18
		% within RESPON	50.0%	50.0%	50.0%
Total		Count	28	8	36
		% within RESPON	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2- sided)	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson Chi-Square	.000 ^a	1	1.000		
Continuity Correction ^b	.000	1	1.000		
Likelihood Ratio	.000	1	1.000		
Fisher's Exact Test				1.000	.655
Linear-by-Linear Association	.000	1	1.000		
N of Valid Cases	36				

Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
							Lower	Upper
Step 1 ^a RATIO	2.785	1.253	4.939	1	.026	16.200	1.389	188.883
Constant	-4.471	1.510	8.763	1	.003	.011		

LAMPIRAN 3

NAMA	USIA	RM	CRP	Albumin	CRP/ALB	RATIO	RECIST	RESPON	DIAGNOSIS	SUBTYPE	KATEGORI USIA	HASIL PA
MU	57	12752210	1.20	3.30	.36	Tinggi	Partial Respons	Respons (+)	Ca Mammae D T4bN1M0	Luminal A	> 50 Tahun	Ductal Carcinoma
MK	60	12776648	.10	3.50	.03	Rendah	Partial Respons	Respons (+)	Ca Mammae S T4bN1M0	Erb-B2 overexpression	> 50 Tahun	Ductal Carcinoma
MS	45	10712616	.10	4.00	.03	Rendah	Complete Disease	Respons (+)	Ca Mammae D T4bN0M0	Erb-B2 overexpression	< 50 Tahun	Ductal Carcinoma
NT	46	12761905	.30	3.50	.09	Rendah	Partial Respons	Respons (+)	Ca Mammae D T4bN1M0	Luminal B-like (HER-2 positif)	< 50 Tahun	Ductal Carcinoma
AI	40	12706110	.20	1.90	.11	Rendah	Partial Respons	Respons (+)	Ca Mammae D T4bN2M0	Luminal B-like (HER-2 positif)	< 50 Tahun	Ductal Carcinoma
RH	60	12772711	.10	3.60	.03	Rendah	Complete Disease	Respons (+)	Ca Mammae D T4bN0M0	Erb-B2 overexpression	> 50 Tahun	Ductal Carcinoma
VK	64	12800306	.30	3.60	.08	Rendah	Partial Respons	Respons (+)	Ca Mammae D T4bN0M0	Erb-B2 overexpression	> 50 Tahun	Non Ductal Carcinoma
ME	58	12802068	.10	3.70	.03	Rendah	Partial Respons	Respons (+)	ca mamma S T4bN1M0	Erb-B2 overexpression	> 50 Tahun	Ductal Carcinoma
SL	56	12548282	.30	3.50	.09	Rendah	Complete	Respons	Ca mammae	Luminal B-	> 50 Tahun	Non Ductal

RI	33	12779653	.30	3.70	.08		Rendah	Partial Respons	Respons (+)	Ca mammae D T4bN1M0	Luminal B- like (HER-2 positif)	< 50 Tahun	Ductal Carcinoma
JT	61	12774330	.20	3.80	.05		Rendah	Partial Respons	Respons (+)	Ca Mammae S T4bN0M0	Basal like	> 50 Tahun	Ductal Carcinoma
RD	50	12419026	.10	3.60	.03		Rendah	Partial Respons	Respons (+)	Ca Mammae D T4bN1M0	Luminal A	< 50 Tahun	Ductal Carcinoma
VVN	41	12780311	.30	3.70	.08		Rendah	Partial Respons	Respons (+)	Ca mammae S T4bN1M0	Luminal B- like (HER-2 negatif)	< 50 Tahun	Ductal Carcinoma
GY	60	12689451	.30	3.80	.08		Rendah	Stable Disease	Respons (-)	Ca mammae D T4b N2 M0	TNBC	> 50 Tahun	Non Ductal Carcinoma
AY	55	12683200	.10	3.60	.03		Rendah	Partial Respons	Respons (+)	Ca mammae D T4cN1M0	Basal like	> 50 Tahun	Non Ductal Carcinoma
HTJ	51	12690748	2.80	3.50	.80		Tinggi	Stable Disease	Respons (-)	Ca mammae S T4bNoMo	TNBC	> 50 Tahun	Non Ductal Carcinoma
MR	41	12711630	.10	3.60	.03		Rendah	Partial Respons	Respons (+)	Ca maamae S T4b N1 M0	Luminal B- like (HER-2 positif)	< 50 Tahun	Ductal Carcinoma
RM	53	12690489	.30	3.40	.09		Rendah	Partial Respons	Respons (+)	Ca mammae S T4dN3M0	Basal like	> 50 Tahun	Ductal Carcinoma

HR	39	12687392	.40	3.20	.13	Rendah	Partial Respons	Respons (+)	Ca mammae S T3N0M0	Luminal B- like (HER-2 negatif)	< 50 Tahun	Ductal Carcinoma
RM	50	12690482	1.00	3.70	.27	Rendah	Stable Disease	Respons (-)	Ca mammae S T4bN1M0	TNBC	< 50 Tahun	Non Ductal Carcinoma
SR	74	11015234	.50	3.70	.14	Rendah	Stable Disease	Respons (-)	Ca mammae D T4cN1M0	TNBC	> 50 Tahun	Ductal Carcinoma
AAR	39	12667698	1.50	3.50	.43	Tinggi	Stable Disease	Respons (-)	Ca mammae D T4cN0M0	TNBC	< 50 Tahun	Ductal Carcinoma
HA	48	12702487	.30	3.50	.09	Rendah	Stable Disease	Respons (-)	Ca mammae D T4N3cM0	TNBC	< 50 Tahun	Ductal Carcinoma
Ny. LS	69	11057460	.20	1.90	.11	Rendah	Stable Disease	Respons (-)	Ca Mammae D T4dN0M0	Luminal A	> 50 Tahun	Ductal Carcinoma
Ny. MR	39	12689714	.10	3.60	.03	Rendah	Partial Respons	Respons (+)	Ca mammae S T4cN1M0	Luminal B- like (HER-2 positif)	< 50 Tahun	Ductal Carcinoma
Ny. MS	42	12708549	.10	4.00	.03	Rendah	Partial Respons	Respons (+)	Ca mammae D T4bN0M0	Basal like	< 50 Tahun	Ductal Carcinoma
Ny. Mi	42	12708549	.10	4.00	.03	Rendah	Partial Respons	Respons (+)	Ca mammae D T4bN0M0	Basal like	< 50 Tahun	Ductal Carcinoma