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LAMPIRAN

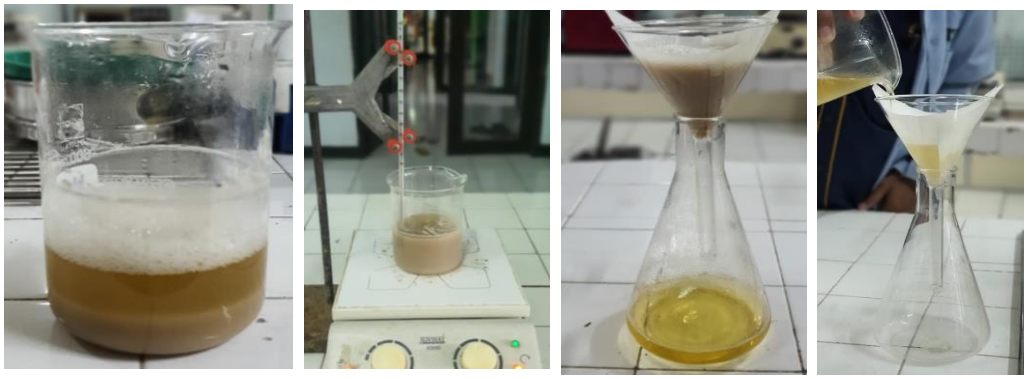
1. Preparasi sampel sisik ikan bandeng

Ikan bandeng diperoleh dari Kabupaten Pangkep, Sulawesi Selatan. Sisik ikan bandeng kemudian dibersihkan dengan air mengalir. Berat total sisik ikan yang diperoleh sebanyak 533 gram. (19 April 2021)

2. Proses pengeringan dan penghalusan sisik bandeng

Sisik ikan bandeng dibungkus dalam aluminium foil untuk pengeringan merata, dikeringkan dalam oven pada suhu 50-55^{0}C selama 7 hari, kemudian dihaluskan dengan blender dan diayak hingga diperoleh serbuk sisik ikan sebanyak 59 gram.
(19-26 April 2021)

3. Proses deproteinase



Serbuk sisik bandeng dicampurkan dengan larutan NaOH 3,5 N dan dipanaskan pada suhu 90°C selama 1 jam sambil dilakukan pengadukan 50 rpm, kemudian disaring. Padatan yang diperoleh dibilas dengan akuades. **(**20 Mei 2021)

4. Proses demineralisasi

Padatan hasil deproteinase dilarutkan dalam HCl 1,5 N dan dipanaskan pada suhu 90°C selama 1 jam dengan pengadukan 50 rpm, kemudian dibilas dengan akuades. (21 Mei 2021)

5. Proses deasitilasi


Kitin yang diperoleh dari demineralisasi dilarutkan dalam NaOH 40% dan dipanaskan pada suhu 90°C selama 1,5 jam dengan pengadukan 50 rpm, kemudian dibilas dengan akuades. (22 Mei 2021)

6. Hasil kitosan


Gel kitosan 2% dan gel plasebo. (7 Juni 2021)

7. Pemeliharaan hewan coba


Adaptasi marmut selama 7 hari (30 Mei 2021)

8. Pelaksanaan implantasi bahan pada hewan coba

Marmut dianestesi di daerah femur dengan injeksi ketamine 0,2 ml/50gr BB, kemudian gigi insisivus kanan mandibula dicabut menggunakan needle holder. Kemudian soket diisi dengan bahan sesuai dengan perlakuan dan disuturing dengan benang *resorbable* 6-0. (14 Juni 2021)

9. Pelaksanaan *sacrifice* hewan coba

Marmut dikorbankan pada hari ke-7 (21 Juni 2021), hari 14 (28 Juni 2021), hari 28 (12 Juli 2021), dilakukan pengambilan jaringan pada rahang mandibula dan difiksasi menggunakan larutan buffer formalin 10% sebagai sampel penelitian

10. Preparat jaringan

Sampel penelitian akan dilakukan permeriksaan sel osteoblas

Explore

Notes

Output Created		01-OCT-2021 11:01:03
Comments		
Input	Data	C:\Users\Panasonic\Documents\SHERLY HE.sav
	Active Dataset	DataSet2
	Filter	<none>
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	Split File	<none>
	N of Rows in Working Data File	27
Missing Value Handling	Definition of Missing	User-defined missing values for dependent variables are treated as missing.
	Cases Used	Statistics are based on cases with no missing values for any dependent variable or factor used.
Syntax		EXAMINE VARIABLES=Oc Ob Wb BY KELOMPOK /PLOT NPPLOT /STATISTICS DESCRIPTIVES /CINTERVAL 95 /MISSING LISTWISE /NOTOTAL.
Resources	Processor Time	00:00:19,39
	Elapsed Time	00:00:17,57

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[DataSet2] C:\Users\Panasonic\Documents\SHERLY HE.sav
```

KELOMPOK

Case Processing Summary

	KELOMPOK	Cases					
		Valid		Missing		Total	
		N	Percent	N	Percent	N	Percent
Ob	P (7)	3	100,0%	0	0,0%	3	100,0%
	P (14)	3	100,0%	0	0,0%	3	100,0%

	P (28)	3	100,0%	0	0,0%	3	100,0%
	B (7)	3	100,0%	0	0,0%	3	100,0%
	B (14)	3	100,0%	0	0,0%	3	100,0%
	B (28)	3	100,0%	0	0,0%	3	100,0%
	KB (7)	3	100,0%	0	0,0%	3	100,0%
	KB (14)	3	100,0%	0	0,0%	3	100,0%
	KB (28)	3	100,0%	0	0,0%	3	100,0%

Descriptives

	KELOMPOK			Statistic	Std. Error
Ob	P (7)	Mean		6,33	1,453
		95% Confidence Interval for Mean	Lower Bound	,08	
			Upper Bound	12,58	
		5% Trimmed Mean		.	
		Median		6,00	
		Variance		6,333	
		Std. Deviation		2,517	
		Minimum		4	
		Maximum		9	
		Range		5	
		Interquartile Range		.	
		Skewness		,586	1,225
		Kurtosis		.	.
	P (14)	Mean		7,67	1,764
		95% Confidence Interval for Mean	Lower Bound	,08	
			Upper Bound	15,26	
		5% Trimmed Mean		.	
		Median		7,00	
		Variance		9,333	
		Std. Deviation		3,055	
		Minimum		5	
		Maximum		11	
		Range		6	
		Interquartile Range		.	
		Skewness		,935	1,225
		Kurtosis		.	.
	P (28)	Mean		8,00	1,155
		95% Confidence Interval for	Lower Bound	3,03	

	Mean	Upper Bound	12,97	
	5% Trimmed Mean		.	
	Median		8,00	
	Variance		4,000	
	Std. Deviation		2,000	
	Minimum		6	
	Maximum		10	
	Range		4	
	Interquartile Range		.	
	Skewness		,000	1,225
	Kurtosis		.	.
	Mean		10,33	,882
	95% Confidence Interval for	Lower Bound	6,54	
	Mean	Upper Bound	14,13	
	5% Trimmed Mean		.	
	Median		10,00	
	Variance		2,333	
B (7)	Std. Deviation		1,528	
	Minimum		9	
	Maximum		12	
	Range		3	
	Interquartile Range		.	
	Skewness		,935	1,225
	Kurtosis		.	.
	Mean		10,33	1,453
	95% Confidence Interval for	Lower Bound	4,08	
	Mean	Upper Bound	16,58	
	5% Trimmed Mean		.	
	Median		10,00	
	Variance		6,333	
B (14)	Std. Deviation		2,517	
	Minimum		8	
	Maximum		13	
	Range		5	
	Interquartile Range		.	
	Skewness		,586	1,225
	Kurtosis		.	.
	Mean		11,00	1,155
B (28)	95% Confidence Interval for	Lower Bound	6,03	
	Mean	Upper Bound	15,97	

		5% Trimmed Mean	.	
		Median	11,00	
		Variance	4,000	
		Std. Deviation	2,000	
		Minimum	9	
		Maximum	13	
		Range	4	
		Interquartile Range	.	
		Skewness	,000	1,225
		Kurtosis	.	.
	KB (7)	Mean	12,67	,882
		95% Confidence Interval for Mean	Lower Bound 8,87	
			Upper Bound 16,46	
		5% Trimmed Mean	.	
		Median	13,00	
		Variance	2,333	
		Std. Deviation	1,528	
		Minimum	11	
		Maximum	14	
		Range	3	
		Interquartile Range	.	
		Skewness	-,935	1,225
		Kurtosis	.	.
	KB (14)	Mean	13,67	1,856
		95% Confidence Interval for Mean	Lower Bound 5,68	
			Upper Bound 21,65	
		5% Trimmed Mean	.	
		Median	15,00	
		Variance	10,333	
		Std. Deviation	3,215	
		Minimum	10	
		Maximum	16	
		Range	6	
		Interquartile Range	.	
		Skewness	-1,545	1,225
		Kurtosis	.	.
	KB (28)	Mean	14,67	1,202
		95% Confidence Interval for Mean	Lower Bound 9,50	
			Upper Bound 19,84	
		5% Trimmed Mean	.	

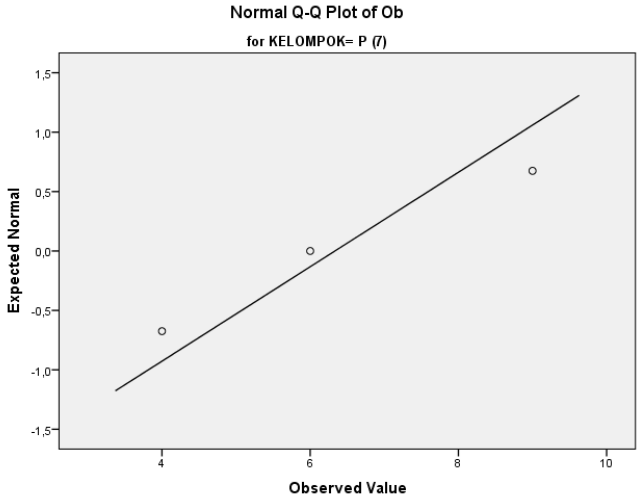
	Median	14,00	
	Variance	4,333	
	Std. Deviation	2,082	
	Minimum	13	
	Maximum	17	
	Range	4	
	Interquartile Range	.	
	Skewness	1,293	1,225
	Kurtosis	.	.

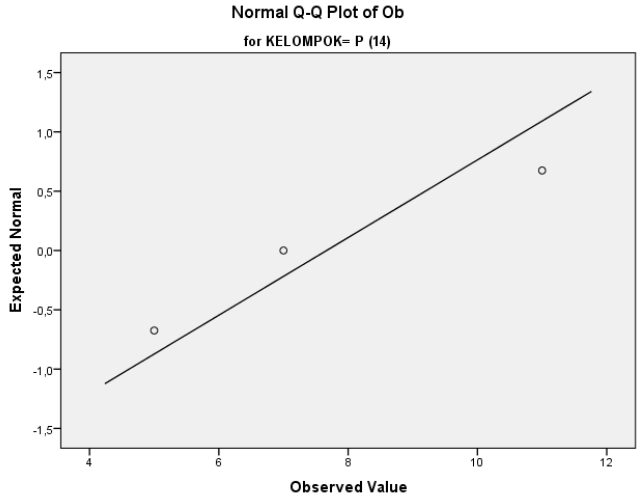
Tests of Normality

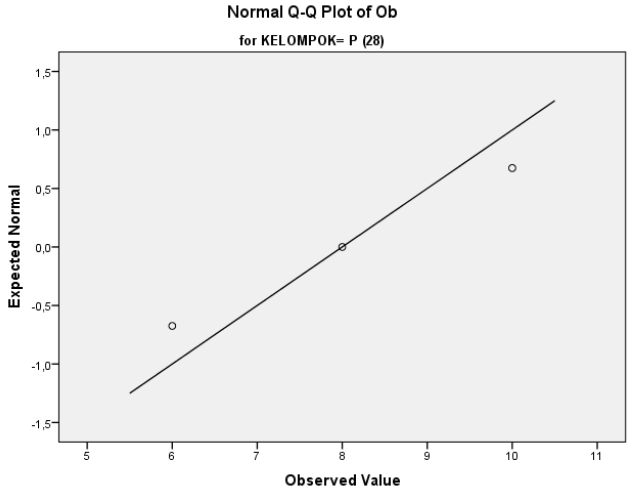
	KELOMPOK	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Ob	P (7)	,219	3	.	,987	3	,780
	P (14)	,253	3	.	,964	3	,637
	P (28)	,175	3	.	1,000	3	1,000
	B (7)	,253	3	.	,964	3	,637
	B (14)	,219	3	.	,987	3	,780
	B (28)	,175	3	.	1,000	3	1,000
	KB (7)	,253	3	.	,964	3	,637
	KB (14)	,328	3	.	,871	3	,298
	KB (28)	,292	3	.	,923	3	,463

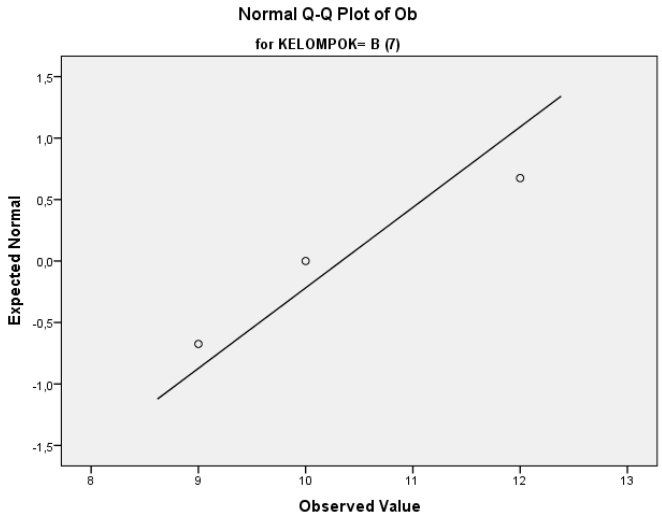
a. Lilliefors Significance Correction

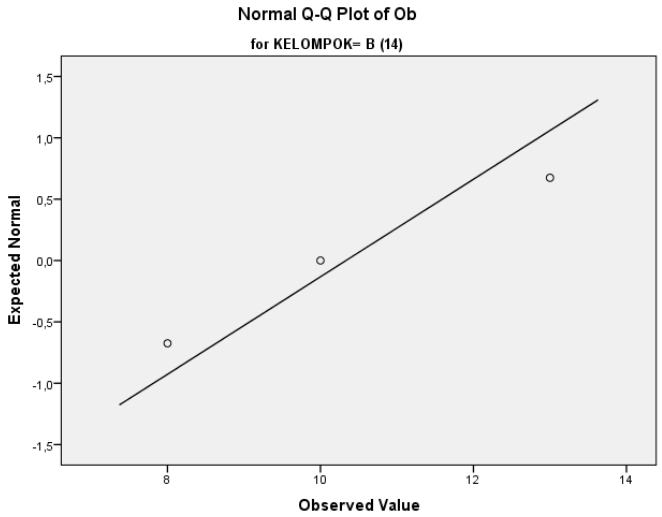
Ob
Normal Q-Q Plots

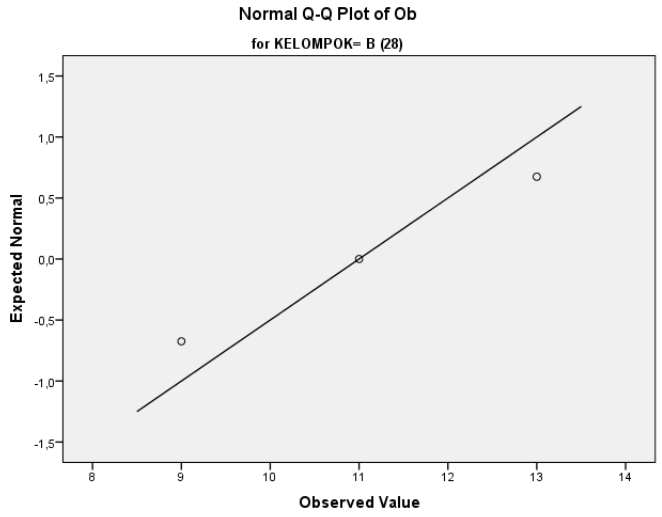


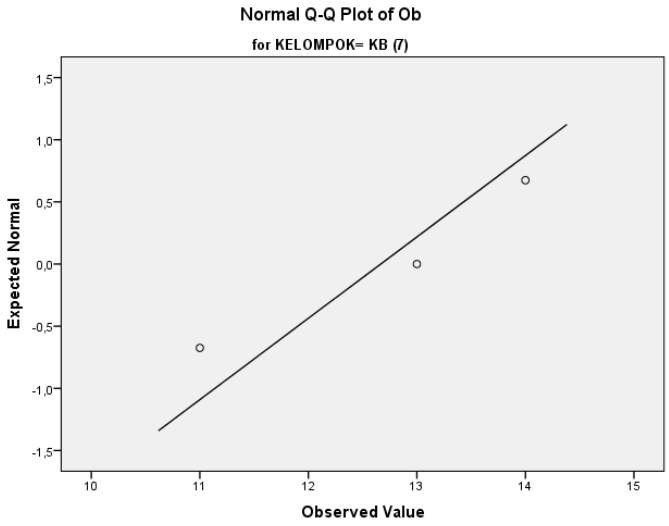


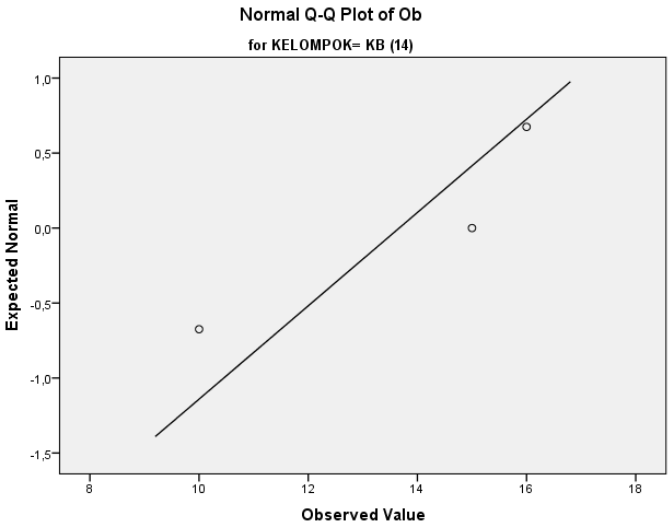


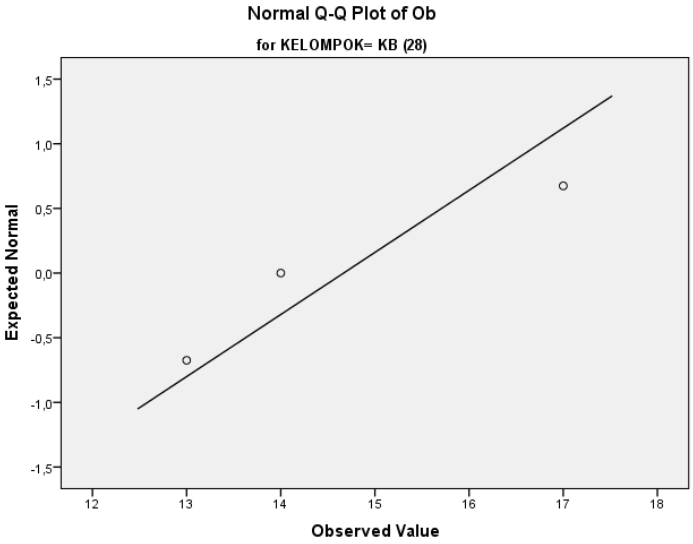

Normal Q-Q Plot of Ob
for KELOMPOK= B (7)
Expected Normal
Observed Value
1,5
1,0
0,5
0,0
-0,5
-1,0
-1,5
8
9
10
11
12
13


Normal Q-Q Plot of Ob
for KELOMPOK= B (14)
Expected Normal
Observed Value
1,5
1,0
0,5
0,0
-0,5
-1,0
-1,5
8
10
12
14

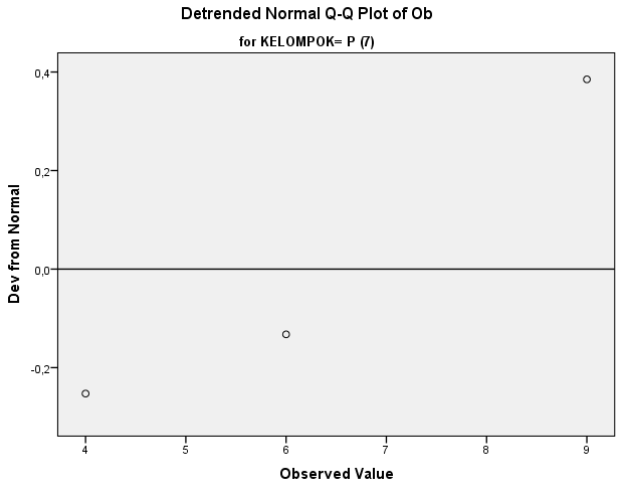

Normal Q-Q Plot of Ob
for KELOMPOK= B (28)
Expected Normal
Observed Value
1,5
1,0
0,5
0,0
-0,5
-1,0
-1,5
8
9
10
11
12
13
14

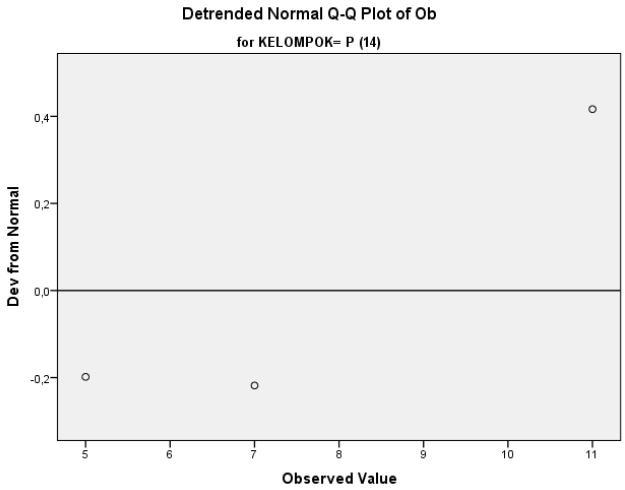

Normal Q-Q Plot of Ob
for KELOMPOK= KB (7)
Expected Normal
Observed Value
1,5
1,0
0,5
0,0
-0,5
-1,0
-1,5
10
11
12
13
14
15

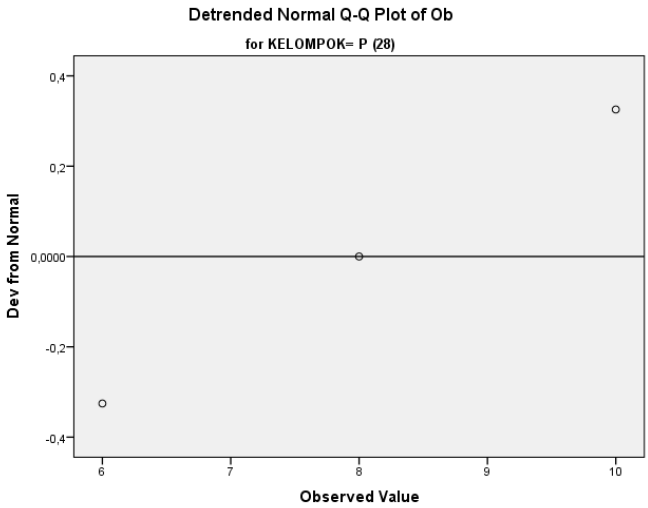

Normal Q-Q Plot of Ob
for KELOMPOK= KB (14)
Expected Normal
Observed Value
1,0
0,5
0,0
-0,5
-1,0
-1,5
8
10
12
14
16
18

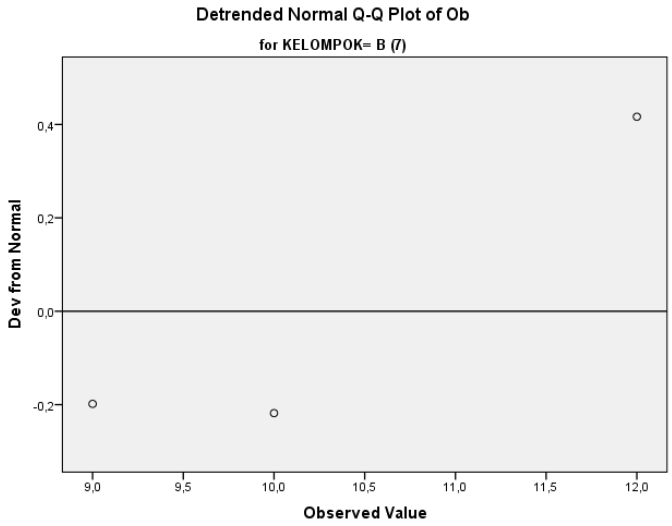

Normal Q-Q Plot of Ob
for KELOMPOK= KB (28)
Expected Normal
Observed Value
1,5
1,0
0,5
0,0
-0,5
-1,0
-1,5
12
13
14
15
16
17
18

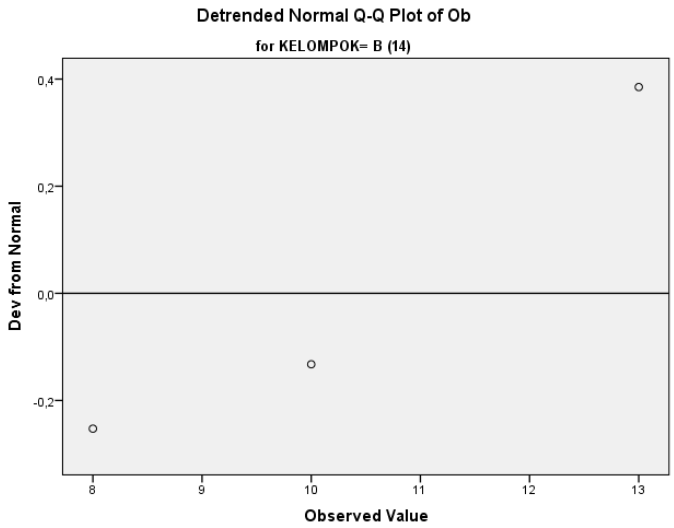
Detrended Normal Q-Q Plots

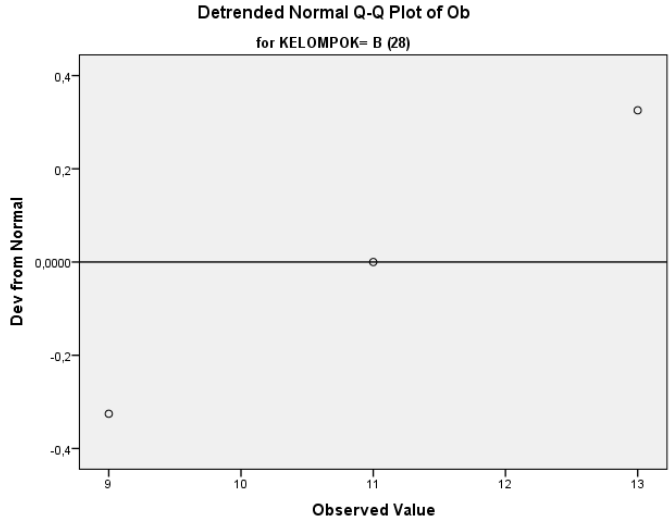


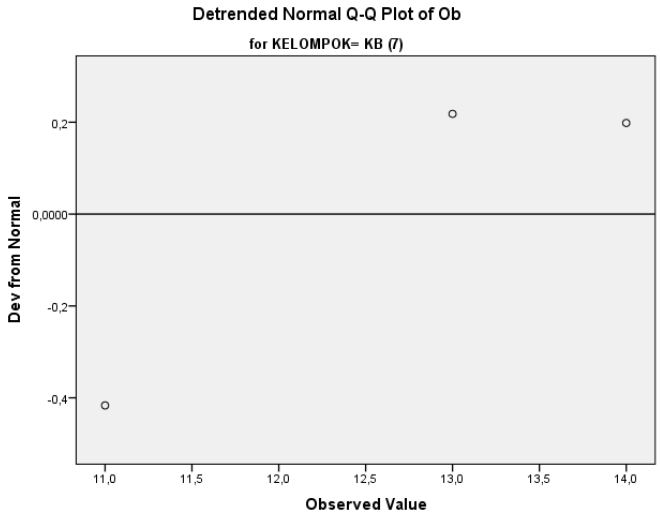


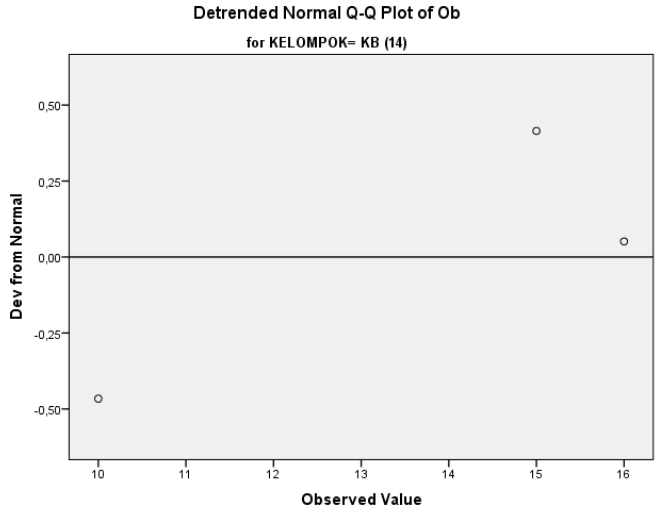


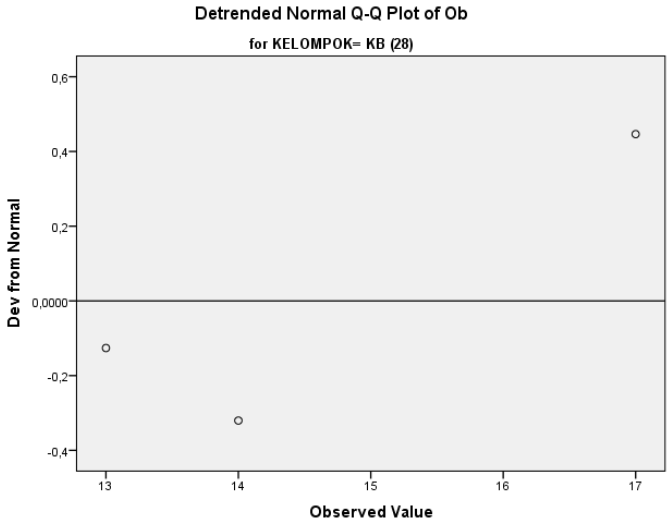

Detrended Normal Q-Q Plot of Ob
for KELOMPOK= B (7)
Dev from Normal
0,4
0,2
0,0
-0,2
9,0
9,5
10,0
10,5
11,0
11,5
12,0
Observed Value


Detrended Normal Q-Q Plot of Ob
for KELOMPOK= B (14)
Dev from Normal
0,4
0,2
0,0
-0,2
8
9
10
11
12
13
Observed Value


Detrended Normal Q-Q Plot of Ob
for KELOMPOK= B (28)
Dev from Normal
0,4
0,2
0,0000
-0,2
-0,4
9
10
11
12
13
Observed Value


Detrended Normal Q-Q Plot of Ob
for KELOMPOK= KB (7)
Dev from Normal
0,2
0,0000
-0,2
-0,4
11,0
11,5
12,0
12,5
13,0
13,5
14,0
Observed Value


Detrended Normal Q-Q Plot of Ob
for KELOMPOK= KB (14)
Dev from Normal
0,50
0,25
0,00
-0,25
-0,50
10
11
12
13
14
15
16
Observed Value


Detrended Normal Q-Q Plot of Ob
for KELOMPOK= KB (28)
Dev from Normal
0,6
0,4
0,2
0,0000
-0,2
-0,4
13
14
15
16
17
Observed Value

```
* Chart Builder.
GGRAPH
  /GRAPHDATASET NAME="graphdataset" VARIABLES=KELOMPOK MEANSE(Ob,
1)[name="MEAN_Ob" LOW="MEAN_Ob_LOW" HIGH="MEAN_Ob_HIGH"]
MISSING=LISTWISE REPORTMISSING=NO
  /GRAPHSPEC SOURCE=INLINE.
BEGIN GPL
  SOURCE: s=userSource(id("graphdataset"))
  DATA: KELOMPOK=col(source(s), name("KELOMPOK"), unit.category())
  DATA: MEAN_Ob=col(source(s), name("MEAN_Ob"))
  DATA: LOW=col(source(s), name("MEAN_Ob_LOW"))
  DATA: HIGH=col(source(s), name("MEAN_Ob_HIGH"))
  GUIDE: axis(dim(1), label("KELOMPOK"))
  GUIDE: axis(dim(2), label("Mean Ob"))
  GUIDE: text.footnote(label("Error Bars: +/- 1 SE"))
  SCALE: cat(dim(1), include("2", "3", "4", "6", "7", "8", "14",
"15", "16"))
  SCALE: linear(dim(2), include(0))
  ELEMENT: interval(position(KELOMPOK*MEAN_Ob),
shape.interior(shape.square))
  ELEMENT:
interval(position(region.spread.range(KELOMPOK*(LOW+HIGH))),
shape.interior(shape.ibeam))
END GPL.
```

Ggraph

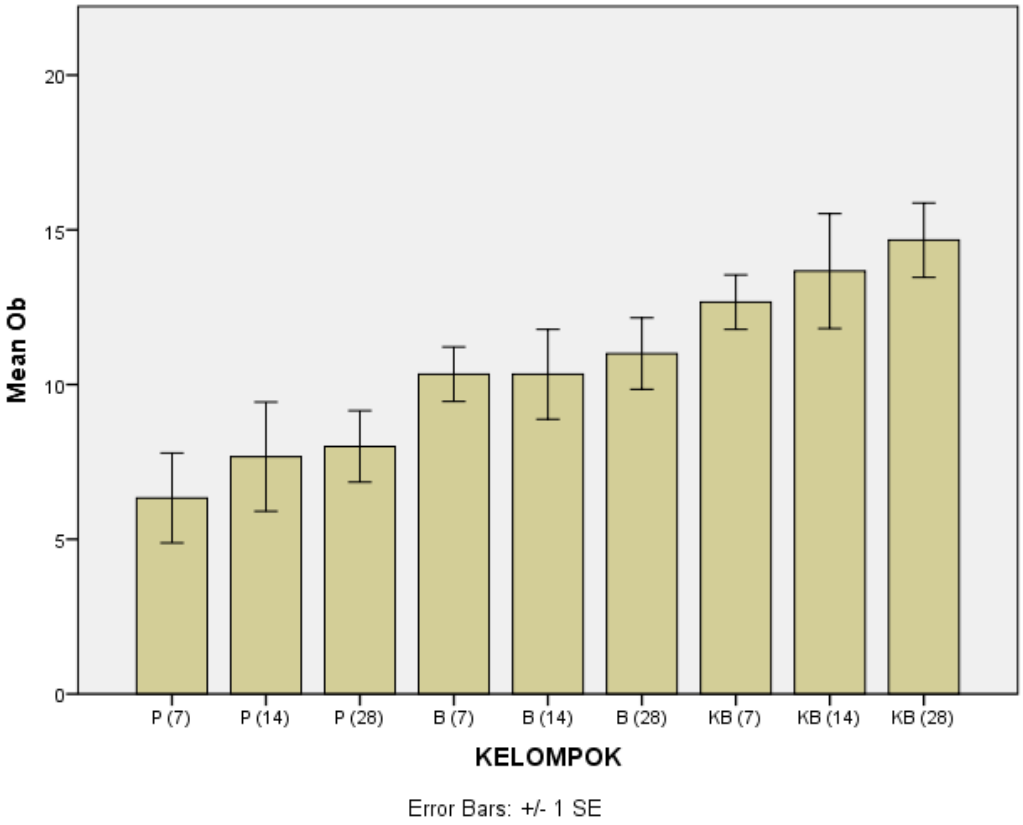
Notes

Output Created		01-OCT-2021 12:40:17
Comments		
Input	Data	C:\Users\Panasonic\Documents\SHERLYHE.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	27

Syntax		GGRAPH
		  /GRAPHDATASET
		NAME="graphdataset"
		VARIABLES=KELOMPOK MEANSE(Ob, 1)[name="MEAN_Ob"
		LOW="MEAN_Ob_LOW"
		HIGH="MEAN_Ob_HIGH"]
		MISSING=LISTWISE
		REPORTMISSING=NO
		  /GRAPHSPEC SOURCE=INLINE.
		BEGIN GPL
		  SOURCE: s=userSource(id("graphdataset"))
		  DATA: KELOMPOK=col(source(s), name("KELOMPOK"), unit.category())
		  DATA: MEAN_Ob=col(source(s), name("MEAN_Ob"))
		  DATA: LOW=col(source(s), name("MEAN_Ob_LOW"))
		  DATA: HIGH=col(source(s), name("MEAN_Ob_HIGH"))
		  GUIDE: axis(dim(1), label("KELOMPOK"))
		  GUIDE: axis(dim(2), label("Mean Ob"))
		  GUIDE: text.footnote(label("Error Bars: +/- 1 SE"))
		  SCALE: cat(dim(1), include("2", "3", "4", "6", "7", "8", "14", "15", "16"))
		  SCALE: linear(dim(2), include(0))
		  ELEMENT: interval(position(KELOMPOK*MEAN_Ob), shape.interior(shape.square))
		  ELEMENT: interval(position(region.spread.range(KELOMPOK*(LOW+HIGH))), shape.interior(shape.ibeam))
		END GPL.

Resources	Processor Time	00:00:00,48
	Elapsed Time	00:00:01,01

```
[DataSet1] C:\Users\Panasonic\Documents\SHERLY HE.sav
```




```
ONEWAY Ob BY KELOMPOK
  /STATISTICS DESCRIPTIVES HOMOGENEITY
  /MISSING ANALYSIS
  /POSTHOC=TUKEY ALPHA(0.05).
```

Oneway

Notes

Output Created		01-OCT-2021 12:40:26
Comments		
Input	Data	C:\Users\Panasonic\Documents\SHERLY HE.sav
	Active Dataset	DataSet1
	Filter	<none>
	Weight	<none>
	Split File	<none>
	N of Rows in Working Data File	27

Missing Value Handling	Definition of Missing	User-defined missing values are treated as missing.
	Cases Used	Statistics for each analysis are based on cases with no missing data for any variable in the analysis.
Syntax		ONEWAY Ob BY KELOMPOK /STATISTICS DESCRIPTIVES HOMOGENEITY /MISSING ANALYSIS /POSTHOC=TUKEY ALPHA(0.05).
Resources	Processor Time	00:00:00,09
	Elapsed Time	00:00:00,16

```
[DataSet1] C:\Users\Panasonic\Documents\SHERLY HE.sav
```

Descriptives

Ob

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
P (7)	3	6,33	2,517	1,453	,08	12,58	4	9
P (14)	3	7,67	3,055	1,764	,08	15,26	5	11
P (28)	3	8,00	2,000	1,155	3,03	12,97	6	10
B (7)	3	10,33	1,528	,882	6,54	14,13	9	12
B (14)	3	10,33	2,517	1,453	4,08	16,58	8	13
B (28)	3	11,00	2,000	1,155	6,03	15,97	9	13
KB (7)	3	12,67	1,528	,882	8,87	16,46	11	14
KB (14)	3	13,67	3,215	1,856	5,68	21,65	10	16
KB (28)	3	14,67	2,082	1,202	9,50	19,84	13	17
Total	27	10,52	3,344	,644	9,20	11,84	4	17

Test of Homogeneity of Variances

Ob

Levene Statistic	df1	df2	Sig.
,555	8	18	,800

ANOVA

Ob

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	192,074	8	24,009	4,380	,004
Within Groups	98,667	18	5,481		
Total	290,741	26			

Post Hoc Tests

Multiple Comparisons

Dependent Variable: Ob

Tukey HSD

(I) KELOMPOK	(J) KELOMPOK	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
P (7)	P (14)	-1,333	1,912	,998	-8,03	5,36
	P (28)	-1,667	1,912	,992	-8,36	5,03
	B (7)	-4,000	1,912	,507	-10,70	2,70
	B (14)	-4,000	1,912	,507	-10,70	2,70
	B (28)	-4,667	1,912	,320	-11,36	2,03
	KB (7)	-6,333*	1,912	,027	-13,03	,36
	KB (14)	-7,333*	1,912	,026	-14,03	-,64
	KB (28)	-8,333*	1,912	,009	-15,03	-1,64
P (14)	P (7)	1,333	1,912	,998	-5,36	8,03
	P (28)	-,333	1,912	1,000	-7,03	6,36
	B (7)	-2,667	1,912	,886	-9,36	4,03
	B (14)	-2,667	1,912	,886	-9,36	4,03
	B (28)	-3,333	1,912	,715	-10,03	3,36
	KB (7)	-5,000	1,912	,246	-11,70	1,70
	KB (14)	-6,000*	1,912	,010	-12,70	,70
	KB (28)	-7,000*	1,912	,037	-13,70	-,30
P (28)	P (7)	1,667	1,912	,992	-5,03	8,36
	P (14)	,333	1,912	1,000	-6,36	7,03
	B (7)	-2,333	1,912	,941	-9,03	4,36
	B (14)	-2,333	1,912	,941	-9,03	4,36
	B (28)	-3,000	1,912	,809	-9,70	3,70

	KB (7)	-4,667	1,912	,320	-11,36	2,03
	KB (14)	-5,667	1,912	,137	-12,36	1,03
	KB (28)	-6,667*	1,912	,050	-13,36	,03
B (7)	P (7)	4,000	1,912	,507	-2,70	10,70
	P (14)	2,667	1,912	,886	-4,03	9,36
	P (28)	2,333	1,912	,941	-4,36	9,03
	B (14)	,000	1,912	1,000	-6,70	6,70
	B (28)	-,667	1,912	1,000	-7,36	6,03
	KB (7)	-2,333	1,912	,941	-9,03	4,36
	KB (14)	-3,333	1,912	,715	-10,03	3,36
	KB (28)	-4,333	1,912	,408	-11,03	2,36
B (14)	P (7)	4,000	1,912	,507	-2,70	10,70
	P (14)	2,667	1,912	,886	-4,03	9,36
	P (28)	2,333	1,912	,941	-4,36	9,03
	B (7)	,000	1,912	1,000	-6,70	6,70
	B (28)	-,667	1,912	1,000	-7,36	6,03
	KB (7)	-2,333	1,912	,941	-9,03	4,36
	KB (14)	-3,333	1,912	,715	-10,03	3,36
	KB (28)	-4,333	1,912	,408	-11,03	2,36
B (28)	P (7)	4,667	1,912	,320	-2,03	11,36
	P (14)	3,333	1,912	,715	-3,36	10,03
	P (28)	3,000	1,912	,809	-3,70	9,70
	B (7)	,667	1,912	1,000	-6,03	7,36
	B (14)	,667	1,912	1,000	-6,03	7,36
	KB (7)	-1,667	1,912	,992	-8,36	5,03
	KB (14)	-2,667	1,912	,886	-9,36	4,03
	KB (28)	-3,667	1,912	,611	-10,36	3,03
KB (7)	P (7)	6,333*	1,912	,027	-,36	13,03
	P (14)	5,000	1,912	,246	-1,70	11,70
	P (28)	4,667	1,912	,320	-2,03	11,36
	B (7)	2,333	1,912	,941	-4,36	9,03
	B (14)	2,333	1,912	,941	-4,36	9,03
	B (28)	1,667	1,912	,992	-5,03	8,36
	KB (14)	-1,000	1,912	1,000	-7,70	5,70
	KB (28)	-2,000	1,912	,975	-8,70	4,70
KB (14)	P (7)	7,333*	1,912	,026	,64	14,03

	P (14)	6,000*	1,912	,010	-,70	12,70
	P (28)	5,667	1,912	,137	-1,03	12,36
	B (7)	3,333	1,912	,715	-3,36	10,03
	B (14)	3,333	1,912	,715	-3,36	10,03
	B (28)	2,667	1,912	,886	-4,03	9,36
	KB (7)	1,000	1,912	1,000	-5,70	7,70
	KB (28)	-1,000	1,912	1,000	-7,70	5,70
KB (28)	P (7)	8,333*	1,912	,009	1,64	15,03
	P (14)	7,000*	1,912	,037	,30	13,70
	P (28)	6,667*	1,912	,050	-,03	13,36
	B (7)	4,333	1,912	,408	-2,36	11,03
	B (14)	4,333	1,912	,408	-2,36	11,03
	B (28)	3,667	1,912	,611	-3,03	10,36
	KB (7)	2,000	1,912	,975	-4,70	8,70
	KB (14)	1,000	1,912	1,000	-5,70	7,70

*. The mean difference is significant at the 0.05 level.

Homogeneous Subsets

Ob

Tukey HSD[a]

KELOMPOK	N	Subset for alpha = 0.05		
		1	2	3
P (7)	3	6,33		
P (14)	3	7,67	7,67	
P (28)	3	8,00	8,00	8,00
B (7)	3	10,33	10,33	10,33
B (14)	3	10,33	10,33	10,33
B (28)	3	11,00	11,00	11,00
KB (7)	3	12,67	12,67	12,67
KB (14)	3		13,67	13,67
KB (28)	3			14,67
Sig.		,072	,100	,052

Means for groups in homogeneous subsets are displayed.

a. Uses Harmonic Mean Sample Size = 3,000.

KEMENTERIAN RISET, TEKNOLOGI DAN PENDIDIKAN TINGGI
UNIVERSITAS HASANUDDIN
FAKULTAS KEDOKTERAN GIGI
RUMAH SAKIT GIGI DAN MULUT
KOMITE ETIK PENELITIAN KESEHATAN
Sekretariat : Lantai 2, Gedung Lama RSGM Unhas
JL.Kandea No. 5 Makassar
Contact Person: drg. Muhammad Ikbal, Sp.Pros/Nur Aedah AR TELP. 081342971011/08114919191

RSGMP

REKOMENDASI PERSETUJUAN ETIK

Nomor: 0052/PL.09/KEPK FKG-RSGM UNHAS/2021

Tanggal: 27 Mei 2021

Dengan ini menyatakan bahwa protokol dan dokumen yang berhubungan dengan protokol berikut ini telah mendapatkan persetujuan etik:

No. Protokol	UH 17120454	No Protokol Sponsor	
Peneliti Utama	Drg. Sherly Endang	Sponsor	Pribadi
Judul Peneliti	Efektivitas Kombinasi Kitosan Sisik Ikan Bandeng (Chanos Chanos) dan Bovine Hidrosiapatit terhadap Jumlah Osteoblas pada Pencabutan Gigi Marmut (Cavia Cobaya)		
No. Versi Protokol	1	Tanggal Versi	24 Mei 2021
No. Versi Protokol		Tanggal Versi	
Tempat Penelitian	1. Laboratorium Biologi FMIPA UNM 2. Klinik Hewan Lacoste 3. Laboratorium Patologi Anatomi RSPTN Unhas 4. Laboratorium Biokimia-Biomolekuler FK Universitas Brawijaya		
Dokumen Lain			
Jenis Review	[ ] Exempted [x] Expedited [ ] Fullboard	Masa Berlaku 27 Mei 2021-27 Mei 2022	Frekuensi Review Lanjutan
Ketua Komisi Etik Penelitian	Nama: Dr. drg. Marhamah, M.Kes	Tanda Tangan	Tanggal
Sekretaris Komisi Etik Penelitian	Nama: drg. Muhammad Ikbal, Sp.Pros	Tanda Tangan	Tanggal

Kewajiban peneliti utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum diimplementasikan
- 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 protokol yang disetujui (*protocol deviation/violation*)
- Mematuhi semua aturan yang berlaku.