Name:

Enrolment No:

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UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2021

Course: Bio statistical Methods In Clinical Research **Semester:** I
Program: M.Sc.-.Clinical Research **Time: 03 hrs.**
Course Code: HSCC7006 **Max. Marks: 100**

Instructions: Read question carefully.

SECTION A

S. No.	MCQ's /Fill in the blanks/ T&F (1.5 marks each)	**30 Marks**	**CO**
1	Preclinical studies are conducted on animals and artificial cells in labs a)True b)False	**1.5**	**CO1**
2	The mean age of 25 patient in the hospital is 36. The mean age of first 13 patient is 32 and that of last 13 patient is 39. What is the age of 13th patient? a. 20 b. 23 c. 32 d. 40	**1.5**	**CO1**
3	For what value of x, the mode of the following data is 25? 25, 26, 27, 23, 27, 26, 24, x, 27, 26, 25, 25, 20. a)27 b)25 c)26 d)24	**1.5**	**CO1**
4	The **Mann-Whitney U test** is preferred to a test when a)Data is paired b)sample size is small c)the assumption of normality is not met d)sample is dependent	**1.5**	**CO1**
5	Consider a set of 18 samples from a standard normal distribution. We square each sample and sum all the squares. The number of degrees of freedom for a **Chi Square** distribution will be? a) 17 b) 18 c) 19 d) 20	**1.5**	**CO1**
6	**t-test** is a significance test that assesses a. The means of two independent groups b. The medians of two dependent groups c. The modes of two independent variables d. The standard deviation of three independent variables	**1.5**	**CO1**
7	The mean age of combined group of men and women is 25 years. If the mean age of group of men is 26 and that of group of women is 21, then percentage of men and women in the group respectively is: a. 60, 40 b. 80, 20 c. 30, 70 d. 50, 50	**1.5**	**CO1**
8	The correlation coefficient is used to determine: a. A specific value of the y-variable given a specific value of the x-variable b. A specific value of the x-variable given a specific value of the y-variable c. The strength of the relationship between the x and y variables d. None of these	**1.5**	**CO1**

9	In which of the following cases could you use a paired-samples t-test? a. When comparing the same participants performance before and after training b. When comparing two separate groups c. When assessing three groups or more d. When assessing relationships between two groups e. When assessing goodness of fit	**1.5**	**CO1**
10	For an experiment comparing more than two treatment conditions you should use **analysis of variance (ANOVA)** rather than separate t tests because: a. Conducting several t tests would inflate the risk of a Type I error. b. Separate t tests would require substantially more computations. c. A test based on variances is more sensitive than a test based on means. d. There is no differences between the two tests, you can use either one.	**1.5**	**CO2**
11	**Chi-square test** is used to analyze**:** a. Scores b. Ranks c. Frequencies d. Any of these e. None of these	**1.5**	**CO2**
12	**Normal Distribution** is symmetric about its _____ a)Variance b)Mean c)Standard deviation d)Covariance e)Mean as well as Standard Deviation	**1.5**	**CO2**
13	**Type I error** is defined as a. rejecting a null hypothesis when it is in fact true b. failing to reject a false null hypothesis c. rejecting a false null hypothesis d. failing to reject a true null hypothesis	**1.5**	**CO3**
14	Which of the following is an assumption of **one-way ANOVA** comparing samples from three or more experimental treatments? a. All the response variables within the k populations follow a normal distributions. b. The samples associated with each population are randomly selected and are independent from all other samples. c. The response variable within each of the k populations have equal variances. d. All of the above.	**1.5**	**CO3**
15	A **Type I error** occurs when you conclude that a treatment effect exists, but the treatment has no effect. a. True b. False	**1.5**	**CO4**
16	The shape of the normal curve depends on its _____ a. Mean deviation b. Standard deviation c. Quartile deviation d. Correlation	**1.5**	**CO4**
17	The mean of 9 observations is 16. One more observation is included and the new mean becomes 17. The 10th observation is a. 18 b. 26 c. 30 d. 7	**1.5**	**CO3**
18	Ogive is also called…….graph a)Frequency b)Cumulative Frequency c)Cumulative Percentage Frequency d)Frequency Polygon	**1.5**	**CO3**

19	Approximately what percentage of scores falls within +1 standard deviation and +2 standard deviation in the standard normal distribution curve? a. 53% b. 76% c. 99.5% d. 84% e. None of the above	**1.5**	**CO2**
20	Suppose that a one-tail t test is being applied to find out if the population mean is less than100. The level of significance is .05 and 25 observations were sampled. The rejection region is: a. $t > 1.708$ b. $t < -1.711$ c. $t > 1.318$ d. $t < -1.316$	**1.5**	**CO4**

SECTION B (5 marks each question)

Q	Short Answer Type Question (5 marks each) Attempt any 4 questions. Word limit (100-120)	20 Marks	CO
1	What is the importance of sampling process in Clinical Research? Discus Double sampling plan in detail?	5 (2+3)	CO1
2	The following table shows the marks obtained by 120 students in a cycle test-I. Draw the more than Ogive and less than Ogive curve for the following data and hence calculate the Median using the curve:	5	CO5
3	The outside diameter of the mechanical part used in clinical testing is known to be normally distributed with mean 40mm and standard deviation 2.5mm. Find the % of products whose diameter is more than 44.5mm.	5	CO4
4	What are the TYPE I and TYPE II error associated with sampling in clinical testing? Give example to explain your answer?(3+2)	5	CO2
5	Write the short notes on any two of the following 1) Fischer exact test 2) Mann-Whitney 3) The Spearman Test	5 (2.5+2.5)	CO3

Marks	0-10	10-20	20-30	30-40	40-50	50-60	60-70	70-80	80-90	90-100
No. of students	2	6	8	20	30	22	18	8	4	2

SECTION C 30 marks

Q	Two case studies 15 marks each subsections	30 Marks	CO
1	a)Following table gives the output of sixty rolls (n=60) of die with sample average is 3.75. If we consider null hypothesis as "THE DIE IS FAIR". Apply χ2 test at 5% of significance level to check the null hypothesis.	15	CO1
	b) A research study was conducted to examine the differences between older and younger adults on perceived life satisfaction level. A pilot study was conducted to examine this hypothesis. Ten older adults (over the age of 70) and ten younger adults (between 20 and 30) were give a life satisfaction level test (known to have high reliability and validity). Scores on the measure range from 0 to 60 with high scores indicative of high life satisfaction; low scores indicative of low life satisfaction. The data are presented below. Compute the appropriate t-test at 5% significance level.	(7+8)	

Table 1. Sixty rolls of a die, which may be loaded.

4	3	3	1	2	3	4	6	5	6
2	4	1	3	3	5	3	4	3	4
3	3	4	5	4	5	6	4	5	1
6	4	4	2	3	3	2	4	4	5
6	3	6	2	4	6	4	6	3	2
5	4	6	3	3	3	5	3	1	4

Older Adults	Younger Adults
45	34
38	22
52	15

	48	27		
	25	37		
	39	41		
	51	24		
	46	19		
	55	26		
	46	36		
2	Study carried out a population-based medical record review in southern Taiwan, where the only chest specialty hospital geared towards specialized thoracic disease care, mainly for TB, is located. Hospitals and primary practitioners that provided TB care in the same region can be used as comparative care providers. Study areas include seven region whose population is given in the table given below. As mandated by law in Taiwan, all suspected and confirmed TB cases must be reported in a timely manner to the national computerized registry maintained by the Taiwan Center for Disease Control (CDC). Reporting of cases has been encouraged and reinforced through the implementation of a no-notification, no-reimbursement policy and a notification-for-fee policy. The comparative data on all suspected and confirmed TB patients residing in the studied areas with respect to corresponding population was recorded in the registry for the period 1 January to 2021 to 31st November 2021. Based on the following data set give the answer of the following question .		**15 (6+6+3)**	**CO2**

REGION NUMBER	APPROXIMATE POPULATION (X10000)	EXPECTED AND CONFIRM TB CASES
1	23	129
2	12	321
3	11	100
4	23	198
5	44	328
6	53	118
7	22	92

Q-1 Based on the above data calculate the Karl Pearson Coefficient of correlation between given two variable and also draw the conclusion from the result obtain?
Q-2 Derive the two regression equation and also calculate the regression coefficient Byx and Bxy
Q-3 Find the mean TB patient in individual region and also calculate the value of standard deviation for the available given data.

	SECTION- D 20 marks		
Q	Long Answer type Questions (10 marks each) Word limit 200-250	**20 Marks**	**CO**
1	Explain Intention-to-treat (ITT) Principle in Randomized Controlled Trials in clinical research. How it is different from Per-protocol (PP) and Treatment-received (TR) analyses of results in clinical research. Give example to explain your answer?	**10 (4+3+3)**	**CO4**

2	Three type of medicine A, B, C are used on 12 persons in order to test their impact on persons. Medicine are applied to each person randomly, Details of the effect are given below in table (1-10 Scale is used), Test the hypothesis that the effect of all three medicine is same (ANOVA) (Significance Level 0.5)	**10**	**CO5**

	A	B	C
1	3	10	5
2	4	7	4
3	6	8	5
4	4	6	5

Chi-Square (χ^2) Distribution

Degrees of Freedom	Area to the Right of Critical Value									
	0.995	0.99	0.975	0.95	0.90	0.10	0.05	0.025	0.01	0.005
1	—	—	0.001	0.004	0.016	2.706	3.841	5.024	6.635	7.879
2	0.010	0.020	0.051	0.103	0.211	4.605	5.991	7.378	9.210	10.597
3	0.072	0.115	0.216	0.352	0.584	6.251	7.815	9.348	11.345	12.838
4	0.207	0.297	0.484	0.711	1.064	7.779	9.488	11.143	13.277	14.860
5	0.412	0.554	0.831	1.145	1.610	9.236	11.071	12.833	15.086	16.750
6	0.676	0.872	1.237	1.635	2.204	10.645	12.592	14.449	16.812	18.548
7	0.989	1.239	1.690	2.167	2.833	12.017	14.067	16.013	18.475	20.278
8	1.344	1.646	2.180	2.733	3.490	13.362	15.507	17.535	20.090	21.955
9	1.735	2.088	2.700	3.325	4.168	14.684	16.919	19.023	21.666	23.589
10	2.156	2.558	3.247	3.940	4.865	15.987	18.307	20.483	23.209	25.188
11	2.603	3.053	3.816	4.575	5.578	17.275	19.675	21.920	24.725	26.757
12	3.074	3.571	4.404	5.226	6.304	18.549	21.026	23.337	26.217	28.299
13	3.565	4.107	5.009	5.892	7.042	19.812	22.362	24.736	27.688	29.819
14	4.075	4.660	5.629	6.571	7.790	21.064	23.685	26.119	29.141	31.319
15	4.601	5.229	6.262	7.261	8.547	22.307	24.996	27.488	30.578	32.801
16	5.142	5.812	6.908	7.962	9.312	23.542	26.296	28.845	32.000	34.267
17	5.697	6.408	7.564	8.672	10.085	24.769	27.587	30.191	33.409	35.718
18	6.265	7.015	8.231	9.390	10.865	25.989	28.869	31.526	34.805	37.156
19	6.844	7.633	8.907	10.117	11.651	27.204	30.144	32.852	36.191	38.582
20	7.434	8.260	9.591	10.851	12.443	28.412	31.410	34.170	37.566	39.997
21	8.034	8.897	10.283	11.591	13.240	29.615	32.671	35.479	38.932	41.401
22	8.643	9.542	10.982	12.338	14.042	30.813	33.924	36.781	40.289	42.796
23	9.260	10.196	11.689	13.091	14.848	32.007	35.172	38.076	41.638	44.181
24	9.886	10.856	12.401	13.848	15.659	33.196	36.415	39.364	42.980	45.559
25	10.520	11.524	13.120	14.611	16.473	34.382	37.652	40.646	44.314	46.928
26	11.160	12.198	13.844	15.379	17.292	35.563	38.885	41.923	45.642	48.290
27	11.808	12.879	14.573	16.151	18.114	36.741	40.113	43.194	46.963	49.645
28	12.461	13.565	15.308	16.928	18.939	37.916	41.337	44.461	48.278	50.993
29	13.121	14.257	16.047	17.708	19.768	39.087	42.557	45.722	49.588	52.336
30	13.787	14.954	16.791	18.493	20.599	40.256	43.773	46.979	50.892	53.672
40	20.707	22.164	24.433	26.509	29.051	51.805	55.758	59.342	63.691	66.766
50	27.991	29.707	32.357	34.764	37.689	63.167	67.505	71.420	76.154	79.490
60	35.534	37.485	40.482	43.188	46.459	74.397	79.082	83.298	88.379	91.952
70	43.275	45.442	48.758	51.739	55.329	85.527	90.531	95.023	100.425	104.215
80	51.172	53.540	57.153	60.391	64.278	96.578	101.879	106.629	112.329	116.321
90	59.196	61.754	65.647	69.126	73.291	107.565	113.145	118.136	124.116	128.299
100	67.328	70.065	74.222	77.929	82.358	118.498	124.342	129.561	135.807	140.169

Paired T Test Table

Two Tailed Significance						
Degrees of freedom (n-1)	$\alpha = 0.20$	0.10	0.05	0.02	0.01	0.002
1	3.078	6.314	12.706	31.821	63.657	318.300
2	1.886	2.920	4.303	6.965	9.925	22.327
3	1.638	2.353	3.182	4.541	5.841	10.214
4	1.533	2.132	2.776	3.747	4.604	7.173
5	1.476	2.015	2.571	3.305	4.032	5.893
6	1.440	1.943	2.447	3.143	3.707	5.208
7	1.415	1.895	2.365	2.998	3.499	4.785
8	1.397	1.860	2.306	2.896	3.355	4.501
9	1.383	1.833	2.262	2.821	3.250	4.297
10	1.372	1.812	2.228	2.764	3.169	4.144
11	1.363	1.796	2.201	2.718	3.106	4.025
12	1.356	1.782	2.179	2.681	3.055	3.930
13	1.350	1.771	2.160	2.650	3.012	3.852
14	1.345	1.761	2.145	2.624	2.977	3.787
15	1.341	1.753	2.131	2.602	2.947	3.733

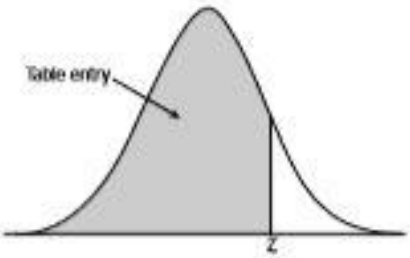
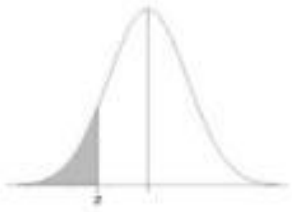


Table entry for z is the area under the standard normal curve to the left of z.

z	.00	.01	.02	.03	.04	.05	.06	.07	.08	.09
0.0	.5000	.5040	.5080	.5120	.5160	.5199	.5239	.5279	.5319	.5359
0.1	.5398	.5438	.5478	.5517	.5557	.5596	.5636	.5675	.5714	.5753
0.2	.5793	.5832	.5871	.5910	.5948	.5987	.6026	.6064	.6103	.6141
0.3	.6179	.6217	.6255	.6293	.6331	.6368	.6406	.6443	.6480	.6517
0.4	.6554	.6591	.6628	.6664	.6700	.6736	.6772	.6808	.6844	.6879
0.5	.6915	.6950	.6985	.7019	.7054	.7088	.7123	.7157	.7190	.7224
0.6	.7257	.7291	.7324	.7357	.7389	.7422	.7454	.7486	.7517	.7549
0.7	.7580	.7611	.7642	.7673	.7704	.7734	.7764	.7794	.7823	.7852
0.8	.7881	.7910	.7939	.7967	.7995	.8023	.8051	.8078	.8106	.8133
0.9	.8159	.8186	.8212	.8238	.8264	.8289	.8315	.8340	.8365	.8389
1.0	.8413	.8438	.8461	.8485	.8508	.8531	.8554	.8577	.8599	.8621
1.1	.8643	.8665	.8686	.8708	.8729	.8749	.8770	.8790	.8810	.8830
1.2	.8849	.8869	.8888	.8907	.8925	.8944	.8962	.8980	.8997	.9015
1.3	.9032	.9049	.9066	.9082	.9099	.9115	.9131	.9147	.9162	.9177
1.4	.9192	.9207	.9222	.9236	.9251	.9265	.9279	.9292	.9306	.9319
1.5	.9332	.9345	.9357	.9370	.9382	.9394	.9406	.9418	.9429	.9441
1.6	.9452	.9463	.9474	.9484	.9495	.9505	.9515	.9525	.9535	.9545
1.7	.9554	.9564	.9573	.9582	.9591	.9599	.9608	.9616	.9625	.9633
1.8	.9641	.9649	.9656	.9664	.9671	.9678	.9686	.9693	.9699	.9706
1.9	.9713	.9719	.9726	.9732	.9738	.9744	.9750	.9756	.9761	.9767
2.0	.9772	.9778	.9783	.9788	.9793	.9798	.9803	.9808	.9812	.9817
2.1	.9821	.9826	.9830	.9834	.9838	.9842	.9846	.9850	.9854	.9857
2.2	.9861	.9864	.9868	.9871	.9875	.9878	.9881	.9884	.9887	.9890
2.3	.9893	.9896	.9898	.9901	.9904	.9906	.9909	.9911	.9913	.9916
2.4	.9918	.9920	.9922	.9925	.9927	.9929	.9931	.9932	.9934	.9936
2.5	.9938	.9940	.9941	.9943	.9945	.9946	.9948	.9949	.9951	.9952
2.6	.9953	.9955	.9956	.9957	.9959	.9960	.9961	.9962	.9963	.9964
2.7	.9965	.9966	.9967	.9968	.9969	.9970	.9971	.9972	.9973	.9974
2.8	.9974	.9975	.9976	.9977	.9977	.9978	.9979	.9979	.9980	.9981
2.9	.9981	.9982	.9982	.9983	.9984	.9984	.9985	.9985	.9986	.9986
3.0	.9987	.9987	.9987	.9988	.9988	.9989	.9989	.9989	.9990	.9990
3.1	.9990	.9991	.9991	.9991	.9992	.9992	.9992	.9992	.9993	.9993
3.2	.9993	.9993	.9994	.9994	.9994	.9994	.9994	.9995	.9995	.9995
3.3	.9995	.9995	.9995	.9996	.9996	.9996	.9996	.9996	.9996	.9997
3.4	.9997	.9997	.9997	.9997	.9997	.9997	.9997	.9997	.9997	.9998

Standard Normal Cumulative Probability Table



Cumulative probabilities for NEGATIVE z-values are shown in the following table:

z	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
-3.4	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0003	0.0002
-3.3	0.0005	0.0005	0.0005	0.0004	0.0004	0.0004	0.0004	0.0004	0.0004	0.0003
-3.2	0.0007	0.0007	0.0006	0.0006	0.0006	0.0006	0.0006	0.0005	0.0005	0.0005
-3.1	0.0010	0.0009	0.0009	0.0009	0.0008	0.0008	0.0008	0.0008	0.0007	0.0007
-3.0	0.0013	0.0013	0.0013	0.0012	0.0012	0.0011	0.0011	0.0011	0.0010	0.0010
-2.9	0.0019	0.0018	0.0018	0.0017	0.0016	0.0016	0.0015	0.0015	0.0014	0.0014
-2.8	0.0026	0.0025	0.0024	0.0023	0.0023	0.0022	0.0021	0.0021	0.0020	0.0019
-2.7	0.0035	0.0034	0.0033	0.0032	0.0031	0.0030	0.0029	0.0028	0.0027	0.0026
-2.6	0.0047	0.0045	0.0044	0.0043	0.0041	0.0040	0.0039	0.0038	0.0037	0.0036
-2.5	0.0062	0.0060	0.0059	0.0057	0.0055	0.0054	0.0052	0.0051	0.0049	0.0048
-2.4	0.0082	0.0080	0.0078	0.0075	0.0073	0.0071	0.0069	0.0068	0.0066	0.0064
-2.3	0.0107	0.0104	0.0102	0.0099	0.0096	0.0094	0.0091	0.0089	0.0087	0.0084
-2.2	0.0139	0.0136	0.0132	0.0129	0.0125	0.0122	0.0119	0.0116	0.0113	0.0110
-2.1	0.0179	0.0174	0.0170	0.0166	0.0162	0.0158	0.0154	0.0150	0.0146	0.0143
-2.0	0.0228	0.0222	0.0217	0.0212	0.0207	0.0202	0.0197	0.0192	0.0188	0.0183
-1.9	0.0287	0.0281	0.0274	0.0268	0.0262	0.0256	0.0250	0.0244	0.0239	0.0233
-1.8	0.0359	0.0351	0.0344	0.0336	0.0329	0.0322	0.0314	0.0307	0.0301	0.0294
-1.7	0.0446	0.0436	0.0427	0.0418	0.0409	0.0401	0.0392	0.0384	0.0375	0.0367
-1.6	0.0548	0.0537	0.0526	0.0516	0.0505	0.0495	0.0485	0.0475	0.0465	0.0455
-1.5	0.0668	0.0655	0.0643	0.0630	0.0618	0.0606	0.0594	0.0582	0.0571	0.0559
-1.4	0.0808	0.0793	0.0778	0.0764	0.0749	0.0735	0.0721	0.0708	0.0694	0.0681
-1.3	0.0968	0.0951	0.0934	0.0918	0.0901	0.0885	0.0869	0.0853	0.0838	0.0823
-1.2	0.1151	0.1131	0.1112	0.1093	0.1075	0.1056	0.1038	0.1020	0.1003	0.0985
-1.1	0.1357	0.1335	0.1314	0.1292	0.1271	0.1251	0.1230	0.1210	0.1190	0.1170
-1.0	0.1587	0.1562	0.1539	0.1515	0.1492	0.1469	0.1446	0.1423	0.1401	0.1379
-0.9	0.1841	0.1814	0.1788	0.1762	0.1736	0.1711	0.1685	0.1660	0.1635	0.1611
-0.8	0.2119	0.2090	0.2061	0.2033	0.2005	0.1977	0.1949	0.1922	0.1894	0.1867
-0.7	0.2420	0.2389	0.2358	0.2327	0.2296	0.2266	0.2236	0.2206	0.2177	0.2148
-0.6	0.2743	0.2709	0.2676	0.2643	0.2611	0.2578	0.2546	0.2514	0.2483	0.2451
-0.5	0.3085	0.3050	0.3015	0.2981	0.2946	0.2912	0.2877	0.2843	0.2810	0.2776
-0.4	0.3446	0.3409	0.3372	0.3336	0.3300	0.3264	0.3228	0.3192	0.3156	0.3121
-0.3	0.3821	0.3783	0.3745	0.3707	0.3669	0.3632	0.3594	0.3557	0.3520	0.3483
-0.2	0.4207	0.4168	0.4129	0.4090	0.4052	0.4013	0.3974	0.3936	0.3897	0.3859
-0.1	0.4602	0.4562	0.4522	0.4483	0.4443	0.4404	0.4364	0.4325	0.4286	0.4247
0.0	0.5000	0.4960	0.4920	0.4880	0.4840	0.4801	0.4761	0.4721	0.4681	0.4641