I have not cheated in any way, shape, or form — Sign here:\_\_\_\_\_

## The following 4 questions are based on the following information

A pharmaceutical manufacturer wishes to compare the bioavailabilities among three brands of gelatin coatings for capsules of its drug. They take a random sample of 18 healthy subjects, giving each subject each drug (in random order), and measuring AUC, the area under the concentration-time curve. They obtain the following Analysis of Variance table.

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Source	Degrees of Freedom	Sum of Squares	Mean Squ
Treatments	2	100.0	50.0
Blocks	17	3400	200.0
Error	34	850.0	25.0

53

They wish to test whether mean bioavailabilities differ among the three brands of gelatin coatings. The null and alternative hypotheses are (where  $\mu_i$  is the true mean for the  $i^{th}$  brand):

4350.0

 $H_0: \mu_1 = \mu_2 = \mu_3$   $H_A:$  Not all  $\mu_i$  are equal

1) Give the test statistic:

Total

2) Clearly state and sketch the rejection region, based on  $\alpha = 0.05$ 

3) Based on your previous answers, can we conclude that the mean AUC levels differ among the three brands? **Yes/No** 

4) Based on your previous answers, what is the *P*-value with respect to 0.05? Higher/Lower

 $\hat{y}$ 

5) A nonlinear regression model is fit, relating the rapeutic response (y) to dose of the drug (x). The following estimated equation is obtained:

$$= \frac{100x}{5+x}$$

Give the fitted responses for patients with doses of 10, 20, and 30.

 $\hat{y}_{10} =$ \_\_\_\_\_

 $\hat{y}_{20} =$ \_\_\_\_\_\_

 $\hat{y}_{30} =$ \_\_\_\_\_\_

<sup>6)</sup> Based on the previous question, in which range is the therapeutic effect largest? 10-20/20-30

## The following 3 questions are based on the following information

A pharmacist is interested in the relationship between the age of her customer (X) and the time to fill the customer's order (Y) in minutes. She obtains the following estimated regression equation, based on a sample of n = 500 transactions:

$$\hat{y} = -2.0 + 0.20x$$
  $\hat{\sigma}_{\hat{\beta}_1} = 0.02$ 

7) Give a 95% confidence interval for  $\beta_1$ .

8) Based on your previous question, can we conclude that there is an association between customer age and time to fulfill order at the  $\alpha = 0.05$  significance level? Yes/No.

- 9) The interpretation of  $\beta_1$  in this problem is:
- a) The mean time to fill all orders among patients of all ages.
- b) The change in mean age per unit increase in time to fill order.
- c) The change in mean time to fill order per unit increase in age.
- d) The mean time to fill orders among patients of the mean age.

10) A group of researchers are interested in the effect of dose  $(X_1)$  on therapeutic response (Y) in two patient populations (patients with  $(X_2 = 1)$  and without condition A  $(X_2 = 0)$ ). Within the therapeutic window, they find that response is linearly increasing with dose for both groups. They find significantly higher mean responses for patients without condition A than patients with condition A. Which of the following plots is consistent with their study results?

11) A researcher is interested in determining whether the incidence of a patient suffering from an adverse reaction from a single dose of a cholesterol reducing medication is associated with the patient's body mass index. The appropriate regression model is:

- a) Linear Regression
- b) Logistic Regression
- c) Nonlinear Regression
- d) Proportional Hazards Regression

12) Researchers have found that Drug A provides significantly better survival times than Drug B, based on a survival analysis in patients with a certain disease. Which of the following figures representing Kaplan– Meier estimates of survival functions is consistent with their results?

## The following 3 questions are based on the following information

A drugmaker wishes to determine whether its new compound reduces risk of fractures in the elderly. They run a controlled trial, randomly assigning 1000 subjects to treatment (their drug or placebo). However, they acknowledge that gender, age, and body mass index (BMI) are also related to risk of fractures. They fit a proportional hazards regression model relating the following independent (predictor) variables to time to fracture:

 $RR(t; x_1, x_2, x_3, x_4) = e^{\beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4}$ 

 $x_1$  — Treatment (1=Placebo, 0=Active Drug)

 $x_2$  — Gender (1=Female, 0=Male)

 $x_3$  — Age (1=60+, 0=59-)

 $x_4 - BMI (1=24-, 0=25+)$ 

13) Which of the following individuals is representative of the baseline group?

14) Based on the following table, give a 95% confidence interval for the relative risk of fracture for subjects receiving placebo relative to those receiving the active drug, controlling for gender, age, and BMI.

$Variable(x_i)$	Estimate $(\hat{\beta}_i)$	Std Error $\hat{\sigma}_{\hat{\beta}}$	Rel Risk $(e^{\hat{\beta}_i})$	$95\%~{ m CI}$
Trt $(x_1)$	2.00	0.50	7.39	(2.72, 20.09)
Gender $(x_2)$	1.00	0.80	2.72	(0.55, 13.46)
Age $(x_3)$	0.05	0.02	1.05	(1.01, 1.09)
BMI $(x_4)$	-0.20	0.08	0.82	(0.70, 0.96)

15) Based on your previous answer, which statement is appropriate at the  $\alpha = 0.05$  significance level?

a) Conclude that subjects have a higher risk of fracture on placebo.

b) Conclude that subjects have a higher risk of fracture on the active drug.

c) Cannot conclude that risks of fracture differ between the active drug and placebo groups.

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