1. Select the best answer.
   
   a.) Randomized controlled trials are considered the “gold standard” of epidemiology study designs because randomization guarantees comparability of study arms.
   
   b.) A weakness of randomized controlled trials is that they are prone to misclassification of exposure status.
   
   c.) It is difficult to perform intention-to-treat analyses with randomized controlled trials.
   
   d.) Randomized controlled trials are observation studies because study arms are observed for outcomes.
   
   e.) Randomized controlled trials are not an effective study design for assessing rare outcomes.

2. Investigators know the assignments of subjects in a randomized controlled trial. What might be done to help avoid random (non-differential) misclassification of outcomes in the trial? Select the best answer.
   
   a.) Blind the subjects to the purpose of the trial.
   
   b.) Have a precise and well-defined definition of the outcome.
   
   c.) Increase the study’s power.
   
   d.) Assure that the study arms are comparable by performing an adjustment if necessary.
   
   e.) Ask a blinded outcome assessment committee to assess outcomes.
3. Select the correct statement concerning retrospective and prospective studies.
   a. Retrospective studies are less subject to misclassification of outcome status compared to prospective studies.
   b. Retrospective studies are less subject to misclassification of exposure status compared to prospective studies.
   c. Retrospective studies are usually less costly to conduct compared to prospective studies.
   d. Relative risks can’t be calculated in retrospective studies.
   e. Multiple outcomes can’t be assessed in retrospective studies.

4. As defined in this course, which of the following is not a major environmental determinant of health:
   a. health care
   b. inherited genes
   c. socioeconomic status
   d. health behaviors
   e. stress

5. Select the correct statement:
   a. The p-value is always calculated under the assumption that the null hypothesis is true.
   b. The p-value is a good estimate of how likely the null hypothesis is incorrect.
   c. The lower the p-value, the more likely the study results will benefit patients.
   d. The p-value is a good estimate of how likely the null hypothesis is correct.
   e. The p-value is calculated under the assumption that the alternative hypothesis is true.
6. Researchers are concerned that smoking could be a significant confounder in a randomized controlled trial they are planning to conduct. Select the best statement concerning the researchers’ desire to avoid confounding by smoking:

   a. The researchers should match study arms for cigarette smoking to eliminate smoking as a potential confounder.
   b. The researchers should develop a protocol to help assure that the loss to follow-up is less than 10%.
   c. The researchers should change their study design such that only smokers are allowed to participate in the trial.
   d. The researchers should compare their crude rate to the smoking-adjusted rate when the study is completed.
   e. The researchers should compare their crude rate to the smoking-adjusted rate when the study is completed to assess for interaction.

7. Select the correct statement:

   a. The shapes of normal distributions can vary, reflective of different variances.
   b. 5% of the variables in a normal distribution are above the positive second standard deviation.
   c. Data in a skewed distribution can be transformed to normally distributed data by multivariate adjustment.
   d. If the standard deviation in a normal distribution is 16, the variance is four.
   e. As a general statement, data in a normal distribution are more useful clinically than data in a skewed distribution.

8. Researchers want to assess if there is an association between cocaine use and congestive heart failure. Select the correct statement:

   a. The researchers should perform a randomized controlled trial.
   b. The researchers should be concerned about recall bias if they choose to perform a retrospective cohort study.
   c. By strictly defining congestive heart failure, the researchers should avoid confounding.
   d. The researchers should avoid selection bias by assuring comparability of study arms.
   e. The researchers should be concerned about reporting bias if they conduct a case control study.
9. A study published in a medical journal reported that there was no association between eating fish and the risk of a heart attack. Two months later, the same medical journal published another study that reported there was an association between eating fish and the risk of a heart attack. In both studies the subjects’ responses were either yes or no, that is they either eat fish or they do not eat fish. Which of the following statements is a possible explanation for the differing conclusions.

   a. The exclusionary criteria were different for the two studies.
   b. A Type I error occurred in the first published study.
   c. There was interaction by fish eating in the second published study.
   d. The second published study had insufficient power.
   e. A Type II error occurred in the second published study.

10. Researchers want to assess if there is an association between cigarette smoking and strokes. Of the following, which is the best study design to assess for this association?

   a. Case series
   b. Cross-Sectional study
   c. Prospective cohort study
   d. Randomized controlled trial
   e. Intervention study

GO TO THE NEXT PAGE TO CONTINUE WITH THE EXAM
11. Define power.

12. Researchers conducted a trial comparing Med A vs. Med B in the prevention of heart attacks. Table 1 follows:

<table>
<thead>
<tr>
<th></th>
<th>Med A n=50</th>
<th>Med B n=60</th>
</tr>
</thead>
<tbody>
<tr>
<td>% cigarette smokers</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>% hypertensive (high blood pressure)</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>% active exercisers</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>% with high cholesterol</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

The investigators report a crude relative risk of 1.0. Given the data listed in Table 1, what should the investigators also report? Be specific.

13. How should the investigators in problem # 12 above determine if there is interaction (effect modification) by cigarette smoking? Be specific.
14. List four guidelines for determining if an association is causal.

15. List two potential weaknesses of a prospective cohort study.

16. What are the main characteristics (descriptors) in describing the natural history of disease?

17. What is the biggest concern when only reporting a crude rate?

18. What is the difference between an intention-to-treat analysis and an efficacy analysis?

19. Surgeons perform a new surgical procedure on 10 patients and report their outcomes. What kind of study is this?

20. Define internal validity and external validity.

END OF EXAM