1. What are two key differences between study monitoring and data and safety monitoring?

2. What is the name of the UCLA office responsible for human research subject protections?
   a) Institutional Review Board (IRB)
   b) Office of the Human Research Protection Program (OHRPP)
   c) Office for Human Research Protections (OHRP)
   d) Clinical and Translational Science Institute (CTSI)

3. Are the methods for conducting quality assurance included in a data and safety monitoring plan? 
   (circle one) YES  NO

4. What are some of the study considerations for formulating a data and safety monitoring plan?
   a) Risk to participants
   b) Complexity of the study
   c) Experience of the investigator
   d) Investigator IND
   e) All of the above

5. An investigator is conducting a gene transfer study in cognitively impaired elder adults. He would like to serve as his own data and safety monitor. Is this acceptable? Explain your answer, providing proof to support your answer and any alternatives.

6. Please check the sections that would typically be on an AE log
   □ Start Date
   □ End Date
   □ Dose of study drug
   □ Event Description
   □ Concomitant medications
   □ Grade
   □ EKG strip
   □ Relationship to Study
   □ Co-morbid conditions

7. List 3 sources where one could determine if an adverse event is an expected event.

8. OHRPP requires reporting on unanticipated problems that are: (circle the right answer on each line)
   Expected  Unexpected
   Related/possibly related  Unrelated
   Places subjects at lesser risk than before  Places subjects at greater risk than before

9. Which type of AE usually requires expedited reporting per protocol?
   a) Mild and moderate
   b) Severe
   c) Serious
   d) Related to study
   e) None of the above
10. Who is ultimately responsible for AE reporting and documentation at the site?
   a) Principal Investigator and Co-investigators
   b) Study coordinator
   c) Regulatory coordinator
   d) Sponsor
   e) IRB

11. What are SOPs and how, when, and why are they used in clinical research?

12. What are the possible outcomes to the study based upon DSMB deliberations and recommendations?
   a) Suspension
   b) Termination
   c) Modification
   d) No action
   e) All of the above

13. Explain each of the following four main reasons for stopping a study by a DSMB.
   Superiority or efficacy
   Safety
   Quality
   Futility

14. A study coordinator documents that she has measured the weight of subjects as they come in to receive their infusions. The infusion dose is based upon weight. However, the scale is down the hall and on occasion, she does not have the time to escort a subject down there before placing the pharmacy order. Instead, she writes in random plausible weights on the source document. She does not tell anyone because it is likely to be only a few kilos off and she knows that no one bothers to do internal quality assurance. Is this an error, misconduct, and/or fraud? How does one prevent such behaviors?

15. What is a DSMB charter?
   a) A sub-study protocol of the main study
   b) A listing of the DSMB members who wrote the protocol
   c) Procedures for how the DSMB will discuss, communicate, document and report their findings.
   d) Charters are not used in clinical research
   e) None of the above

16. What are the main components of adverse event follow-up and their sequence?
   a) Recognize, record, evaluate and report
   b) Recognize, report, evaluate, and refer
   c) Describe, discuss, report to PI, and tell subject
   d) Diagnose, refer, report to IRB, and call sponsor