Tufts University School of Dental Medicine

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dental Research Administration

Good Clinical Practices Quiz

***Note: A Passing Grade of 75% is required***

1. What is the purpose of the GCP standard?
   1. To protect study participants
   2. To protect the study sponsor
   3. To protect the study investigator
   4. To protect the consumer

1. A clinical trial should only be initiated if the anticipated benefits justify the risk.
   1. True
   2. False
2. Once an informed consent form has been signed, participants are not allowed to withdraw from a study.
   1. True
   2. False
3. If information is missing on a signed consent form (e.g. initials, date, witness signature), it is not okay to add them after the fact.
   1. True
   2. False

1. Which of the following is not an exception to the confidentiality requirement:
   1. Medical emergencies
   2. Danger to self or others
   3. Criminal activity
   4. Non-compliance with study procedures
2. Patient contact information is considered to be Protected Health Information (PHI).
   1. True
   2. False
3. A study patient presents for a follow up visit and complains of severe headaches that started around the same time as the investigational product was distributed. What is the appropriate course of action?
   1. Note in patient record
   2. Take no action
   3. Note in patient record, notify Tufts Research Administration promptly, treat patient according to site specific SOP, and follow up at each subsequent visit until resolved
   4. Direct patient to treat with over the counter medication
4. Which of the following is not considered a source document?
   1. Appointment date reminders
   2. Participant diary
   3. Signed/dated consent form
   4. Progress notes
5. Which of the following are study personnel not responsible for?
   1. Complying with study protocol
   2. Approving investigational device use
   3. Reporting study data accurately & completely
   4. Protecting the rights and safety of participants
6. The interests of science & society prevail over the safety and well-being of study trial subjects.
   1. True
   2. False
7. Study patient files can be kept wherever there is room in the clinic.
   1. True
   2. False
8. All medical care given to or decisions made on behalf of study participants can be made by any member of the study team.
   1. True
   2. False
9. Which of these is an adverse event that would be classified as serious?
10. Loss of a tooth root into the maxillary sinus
11. Osteonecrosis of the jaw
12. Allergic bronchospasm resulting in hospitalization
13. Soft tissue or nerve injury (numbness)
14. Any changes to the study protocol, ICF, or supporting documents must be approved by the IRB before use:
15. True
16. False
17. An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that must have a causal relationship with this treatment.
18. True
19. False
20. Data reported on the \_\_\_\_\_\_, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.
21. Protocol
22. Case Report Form (CRF)
23. Statistical Analysis Plan
24. Informed consent form
25. If a research subject decides to withdraw from the study, the study team should:
26. Try to convince them to stay in the study
27. Destroy the consent form and all study data for that participant
28. Make a reasonable effort to determine their reason for premature withdrawal
29. All of the above