Data Quality Management Quiz Key

1. What type of monitoring can a study team perform to identify possible issues with data quality or integrity?

   ____ a. For-cause auditing System: Incorrect. Internal monitoring by the study team is the correct answer.

   ____ b. Internal monitoring System: Yes, that is correct!

   ____ c. Random monitoring System: (Use response to item a.)

2. Some elements of Data Quality Management (DQM) include establishing a Data Monitoring Plan (DMP) in the protocol and maintaining the regulatory file.

   ____ True System: Yes, that is correct!

   ____ False System: Incorrect, establishing a Data Monitoring Plan (DMP) is an important component of Data Quality Management.

3. Some elements of a DMP include:

   ____ a. A corrective and preventative action (CAPA) plan System: Incorrect: Defining the source documentation and the case report forms (CRFs) and planning for QC/QI of raw and transformed data are elements of a DMP.

   ____ b. Definition of source documentation and Case Report Forms (CRFs) System: Partially correct, this element and the Plan for QC/QI of raw and transformed data are both elements of a DMP.

   ____ c. Plan for QC/QI of raw and transformed data System: Partially correct, this element and the definition of source documentation and CRFs are both elements of a DMP.

   ____ d. a and b System: (Use response to item a.)

   ____ e. b and c System: That is correct!

4. Research staff is responsible for establishing and maintaining the regulatory files.

   ____ True System: That is correct!

____ False System: That is incorrect. Investigators and/or research staff *are* responsible for establishing and maintaining the regulatory files.

5. Should copies of the signed informed consents to be retained in the research files or regulatory binder?

   __Yes System: That is correct!

   __No System: That is incorrect. Copies of the signed informed consents are maintained as part of the research files or regulatory binder. At the NIH Clinical Center (CC), the original signed consents obtained at the CC are provided to Medical Records Department.

6. Regulatory files are not only for use by the research team, they may be inspected by monitoring entities.

   ____ True System: That is correct!

   ____ False System: That is incorrect. The regulatory files must be made available for inspection by monitoring entities, (e.g. IC or Sponsor monitors, or FDA inspectors/auditors.

7. Quality Control (QC) of study data should occur:

   ____ a. on a random basis by an auditor System: That is incorrect. QC is the responsibility of the study team and should take place on a regular basis.

   ____ b. on a regular basis by the study team System: That is correct!

   ____ c. on a pre-determined basis by the IC QA monitor System: That is incorrect. QC is the responsibility of the study team and should take place on a regular basis.

8. The PI should promptly notify the IRB if protocol deviations are uncovered by the monitoring of the study and what the corrective action plan is.

   ____ True System: That is correct!

   ____ False System: That is incorrect. PI's are required to report protocol deviations to the IRB, regardless of how they are identified, per HRPP SOP 16 -

Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations.

9. Good Clinical Practice Guidelines covers:

____ a. quality and integrity of study data and results System: That is partially correct. GCP also covers: contents of the regulatory file, and rights, safety and welfare of research subjects as well as other topics.

____ b. contents of the regulatory files System: That is partially correct. GCP also covers: quality and integrity of study data/results and, rights and safety and welfare of research subjects, as well as other topics.

____ c. Rights, safety and welfare of research participants System: That is partially correct. GCP also covers: quality and integrity of study data/results and contents of the regulatory file, as well as other topics.

____ d. all of the above System: That is correct!

____ e. a and c System: System: That is incorrect. GCP covers all of the following: quality and integrity of study data/results, contents of the regulatory file, and rights, safety and welfare of research subjects, as well as other topics.

10. The entire research team has a role to play in Data Quality Management.

____ True System: That is correct!

____ False System: That is incorrect, the *entire* research team as a role to play.