



Subject: **Clinical Research**

Answer of the following

1 x 20 = 20

1. The primary vehicle for human subject's protection of dignity, well-being and safety is

- IB
- ICF
- PIF
- CRF

2. One of the following serves for the safety reporting

- PSER
- PSUR
- SRUF
- ERFB

3. 'BAD BLOOD' is related to one of the following

- Nazi war crime
- Japan's war fare
- Tuskegee's study
- TGN

4. One of the following has greatest impact on the quality of the data

- CRF
- ICF
- PIS
- FORM 1572

5. Drug accountability should be done

- Throughout the study
- At study close out only
- Depending on the study
- Never done

6. All advertisement related to the clinical study must be approved by Ethics Committee

- True
- False

7. The final study report prepared by the

Investigator
Sponsor
CRA
CRC

8. An at involving and intentional deviation from the truth or accuracy is

Errors
Misconduct
Fraud
All

9. One of the following must be supplied to the investigator before the clinical agreement

Protocol synopsis
IB
IP
None

10. Reasons for reporting AEs are

The medical monitor under stands the medicinal product better.
To satisfy regulatory requirements
Investigators responsibility.
All of the above

11. Initial SAE report faxed to the sponsor comprises of the following

SAE CRF page
Notification letter to the sponsor.
Notification letter to the chairperson along with the acknowledged receipt form the IRB
Notification letter to the FDA

12. During the Investigator Meeting the following are the sponsors' optional attendees?

Biostatistician
Preclinical representative
Medical monitor
Drug development representative

13. Statement that the study involving research is

Primary elements of the ICF
Additional elements of the ICF
Some time present in the ICF
Not related to the ICF

14. One of the following document maintain at the file of the sponsor only

Muster ICF
Muster Randomization list
Normal value
Subject's Enrolment Log

15. Investigator is not responsible for the following

Designing and updating protocol
Attending Ethics Committee
Submitting documents to DCGI
Compensation for trial subjects

16. Which one of the following document is term as the Blue Print for a study?

IB
Protocol
CRF
ICF

17. CRC performance is evaluated by the Investigator when

Patient recruitment is high
Documentation adequate and appropriate
Drop out rate < 20
Monitor satisfied with the project

18. Financial disclosure document has to be filed and documented by the following personnel?

Investigator
CRC
Investigative Site Manager
Monitor

19. Screen fail CRF binders comprises of the following

Medical history
Investigator signature page
Inclusion / Exclusion
None of the above

20. One of the following document maintain at the file of the Investigator only

Muster ICF
Muster Randomization list
Normal value
Subject's Enrolment Log