

PROCEDURE NO. 108 SAFETY/NONCOMPLIANCE REPORTING REQUIREMENTS

Date Effective: February 1, 2001

Supersedes: January 1, 2000

PURPOSE

To establish guidelines on reporting relevant safety problems in ongoing studies.

PROCEDURE

1. IND Safety Reports will be submitted to the Board on an ongoing basis. Each investigator can do this or in the case of multicenter trials, the IND safety reports may be submitted by the sponsor to the board on behalf of all investigators using the central IRB. Upon receipt from the investigator or sponsor/CRO/SMO the IRB staff will review these IND Safety Reports. The Board will be notified of all IND Safety Reports at a convened meeting. These reports shall be furnished to the Board as part of the continuing review process until the study is either canceled or completed. The Board will acknowledge receipt of each IND Safety Report to the investigator either by follow-up letter or other method.
2. The IRB should be informed in a timely manner of Serious Adverse Events (SAEs) occurring at the site. Investigators should send all SAE information to the IRB as soon as possible. The IRB staff will review the SAEs and report any unexpected trends to the board.
3. The Board shall be informed of any problems in a study that may place subjects or others at an increased risk, and of any changes to a study, which may be material to the Board's duties. Investigators or Sponsors/CROs/SMOs served by the Board are required to report to the Board any serious or continuing noncompliance recognized during the conduct of the study.
4. The Chairperson or designee shall have the right to temporarily suspend any research activities when there is concern regarding increased risk to the subject. In the event this occurs, the proposal will be re-evaluated and a decision reached by the Full Board and documented at its next regularly scheduled meeting. The Board may suspend or stop research not conducted according to its requirements or associated with unexpected, serious harm to its subjects.
5. If an investigator fails to comply with continuing review or other requirements of the IRB, he or she will be contacted by an IRB staff member and instructed not to enroll any new subjects until corrective action is deemed acceptable by the board and/or IRB staff. The sponsor may also be contacted. If non-compliance is not corrected the investigator site will be closed and the investigator will be reported to the appropriate federal oversight branch. In the event that research is suspended or stopped at an investigative site, the Principal Investigator will outline for the Board the course of action he/she will take to ensure the safety and well being of each enrolled research subject until a new Principal Investigator is approved by the Board.
6. The Board is responsible for reporting investigator noncompliance as required by applicable Federal regulations
7. A board member or designee may conduct investigator site audits on a random or for cause basis. Copernicus Group IRB reserves the right to inspect any site at any time with appropriate notice.



President

2/1/01

Date