CRC Policy on Missing Safety Data in Interventional Clinical Trials

The Clinical Research Center has implemented a new policy for reporting back to research teams when protocol-specified safety data are missing (or seem to be missing). The purpose of this policy is to help the investigator be accountable to research subjects, the IRB, and BCH.

The CRC provides several services and resources in order to assist investigators with interventional trials. Some or all of these may apply:
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- Research coordinator effort, for example filling out case report forms or collecting patient-reported outcomes
- Database management; paper or on-line case report form entry
- Statistician effort, as trial statistician, DSMB statistician, or consultant
- Survey design and administration
- Project management

In the course of these regular duties, CRC staff members may become aware of missing protocol-required procedures or data; for example, in monthly or quarterly data report summaries, one or more forms or tests from one or more active study patients may be absent. There are many possible reasons for missing data. Examples include missing a timed visit within the prescribed window because of travel or weather interruptions; a CBC that was clotted and therefore not run; tests done at outside labs or study centers that were completed but not entered in the database.

Strictly speaking, the integrity of the data is always the responsibility of the investigator. Oversight may come from a Data/Safety Monitoring Board, or may not. The IRB always has supervisory authority over trial conduct, whether or not there is a DSMB. The CRC staff cannot and will not become the “trial police” or official monitors. But, we can help investigators best by prompt and clear notification about missing data.

CRC staff will make study team members aware if they encounter missing safety data in the course of their duties. Our CRC team members will let CRC managers know if there is any concern about persistent patterns of missing data. The managers or co-chiefs will contact the investigators directly in such cases to ascertain the reasons for missing safety information, and to learn whether or not a corrective plan is necessary, whether such a plan is in place, and whether the IRB has been involved. We expect that in most cases, early and open communication about missing safety data will be sufficient for all to be reassured about the safe conduct of the study.