SAE Reporting

SAE's from QMC study

Deaths must be reported within 24 hours

All serious adverse event occurring on QMC RIRC approved research study subjects must be reported by the investigator to the RIRC within 5 days. To report an adverse event, either:

A. Use Medwatch form (FDA Form 3500A Mandatory Reporting) (make sure you use the current version by going to http://www.fda.gov/Safety/MedWatch/HowtoReport/DownloadForms/default.htm)

OR

B. If not using Medwatch form, then provide the following:
   1. RA number and title of study
   2. Principal Investigator
   3. Name of study drug/device (if applicable)
   4. IND, IDE, HUD number (if applicable)
   5. Provide information about drug or device (manufacturer, model, name, strength, dose, etc.)
   6. Number or coding for subject along with
      a. Age/birthdate
      b. Gender
      c. diagnosis
   7. Date of Event
   8. Descriptive narrative of event including listing of concurrent drugs, diagnostic test results if relevant
   9. Any other history or preexisting medical condition
   10. Descriptive narrative of any action taken as a result of event
   11. Outcomes Attributed to Adverse Event:
      a. Death (list date)
      b. Life-threatening
      c. Hospitalization (initial or prolonged)
      d. Required intervention to prevent permanent impairment/damage (devices)
      e. Disability or permanent damage
      f. Congenital anomaly/birth defect
      g. Other Serious (Important medical events)
   12. A statement as to whether the investigator feels the event was:
      a. Definitely related to subject participation
      b. Probably related
      c. Possibility related
      d. Unlikely/remote
      e. Definitely not related
   13. A statement as to whether the consent form requires revision.

14. A statement as to whether the protocol requires revision
15. An explanation of whether risk/benefit relationship has changed. (still acceptable in light of information regarding adverse event?)

SAEs from sponsor

Sponsor-generated safety reports must be submitted to the RIRC within 30 days of their receipt by the investigator.