Data Safety Monitoring Plan
Draft Language

Adverse events and protocol deviations will be reported by one of 2 mechanisms:

1) The University of Vermont Committees on Human Research (serving both UVM and FAHC) adverse event reporting document. These reports will be forwarded to the office of the Committee on Human Research in the Medical Science (CHRMS - 213 Waterman Building, UVM) within 5 days of the event. This will be the responsibility of the principal investigator. The CHRMS will make a determination as to whether additional reporting requirements are indicated.

2) The Safety Alert for Events Reporting Form (SAFE) {an FAHC mechanism} may be initiated by CRC nursing staff or study personnel.