Protocol Deviation Form

How to Report:

Section I:

CHRMS or CHRBS Number:
Principal Investigator: The name of the local Principal Investigator.
Protocol/Project Title: The title should be the complete and full title of the research protocol.

Section II:

Date deviation was first discovered by PI or study team: Indicate the date.
Describe the protocol deviation below. Include as many details as possible.
How did the deviation affect the health and welfare of the subject? Describe here.
Did this deviation result in a serious adverse event? If “yes” complete a Report of Serious or Unexpected Adverse Event form and attach to this submission.
Is the subject continuing participation in the protocol? Check yes or no.
What can this deviation be attributed to? Check appropriate box or explain.

Section III:

Provide a summary of what steps were taken to resolve this particular occurrence. Provide as many details as possible.
Describe what has been or is being done to prevent similar occurrences in the future. This could range from a simple change in procedure to implementation of a set of standard operating procedures. The Committee may require that additional actions be taken.
Will an amendment to the protocol be submitted? If no, provide rationale.
Additional Comments:
Section IV:

Has a FAHC SAFE report been filed with FAHC? Check yes or no. See FAHC policy on reporting events occurring at FAHC.

Has a Medwatch Form been filed with the FDA? Check yes or no. If yes, attach a copy of the form.

Is this a General Clinical Research Center or Vermont Cancer Center Study? Indicate if the protocol has also been reviewed by either the General Clinical Research Center (GCRC) or Vermont Cancer Center (VCC). If “Yes”, send copies of the report to the appropriate center (s).

Section V:

Principal Investigator Signature: The principal investigator must review, sign and date the form.