



Off Protocol

GENERAL INSTRUCTIONS

This form captures any occurrences which are considered to be protocol deviations (do not adhere to standards established in the protocol). Protocol deviations can occur at different times during the course of the study. An Off Protocol form should be completed for any deviation from protocol, when the deviation occurs or as soon as the protocol deviation is recognized.

SPECIFIC INSTRUCTIONS

Patient ID: Record the Patient ID

Date form completed: Record the date (month/day/year) that the form is completed.

Protocol Deviations: Check the box to indicate the deviation being reported. Deviations should be recorded as you become aware of them. Only one protocol deviation can be reported on a form.

Ineligible patient Check if a patient who did not meet one or more of the enrollment criteria was enrolled. Additional deviations might include enrolling a patient who stated prior to enrollment that they were not willing to adhere to a component of the protocol, such as collection of the research samples.

Follow-Up evaluation not completed in-person Check if some or all components of a follow-up evaluation were completed, but the component(s) were not completed via in-person visit. Specify the reason that the follow-up evaluation was not able to be conducted via an in-person visit.

If all components of a follow-up visit are not completed and the visit was missed, do not complete the OP form, but use the Missed/Incomplete Visit Utility in the Data Management System to report that the visit was not completed.

Time-point: Check the time-point of the follow-up visit

Method of follow-up: Check the method(s) used to acquire the follow-up information