1. **\*Off study date** (m m / d d / y y y y):
2. **\*Off study reason** (Choose most appropriate answer) :

Completed study

Refused further participation (or withdrew consent)

Lost to follow-up (or cannot be located)

Died

**Did participant/subject discontinue intervention before planned end of study?**

Yes (If Yes, answer items a and b below)

No (Stop)

* 1. **Date of last known intervention** (m m / d d / y y y y):
  2. **Reason for premature intervention discontinuation** (Choose most appropriate answer):

Participant’s/ Subject’s decision (e.g., unwilling/unable to commit time and/or resources, moved from area, etc.)

Other clinical decision (e.g., investigator decision, primary care provider decision, etc.) **OR** other reason specified by the protocol (i.e., institutionalization, pregnancy, etc.)

Adverse Event

Death

Lost to follow-up

Other, specify:

*\**Element is classified as Core

## General Instructions

The Study Discontinuation/Completion Form captures each participant’s/subject’s status at the end of the study. It provides an anchor for quality control and analysis. The status, in aggregate, also defines the study population -- those completed, lost, etc.

The form should be completed at the last study visit. If a participant/subject chooses to discontinue intervention, he/she should be encouraged to continue follow-up visits. Thus the form captures intervention status as well as study completion status. The intervention status questions are probably only appropriate for clinical trials. The suggested form provides a simple capture of status. It may need to be more complex to reflect a study with numerous procedures before enrollment, or a more difficult population to track, etc.

Important note: Two of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). The remainder of the data elements are supplemental and should be collected only if the research team considers them appropriate for their study.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* **Off Study Date** – Record the date (and time) of the participant’s/ subject's last study related-contact. This may be the study completion visit or follow-up visit/phone call. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* **Off Study Reason** – Choose one. Specify the status of the participant/subject at his/her last study related contact. If the final study contact status is "Died" then a Death Report Form should be completed for this participant/subject.
* **Discontinue Intervention Prematurely?** – Choose one. Record whether or not the participant/subject discontinued the study intervention before the planned end of the study. This CDE is meaningful for clinical trials only. If this study is not a clinical trial, this question should be deleted from the CRF.
* **Date of Last Known Intervention** – Record the date (and time) of the participant’s/ subject's last known study intervention. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database. This CDE is meaningful for clinical trials only. If this study is not a clinical trial it should be removed from the CRF.
* **Reason for Premature Intervention Discontinuation** – Choose one. Specify the participant’s/ subject's primary reason for intervention discontinuation. If the primary reason for interventions discontinuation is "Adverse Event" then an Adverse Event CRF must be completed for this participant/ subject. This CDE is meaningful for clinical trials only. If this study is not a clinical trial it should be removed from the CRF.