8. CHANGE IN PARTICIPANT STATUS

8.1 Off Study Agent

A study participant may discontinue use of a study agent but continue to be followed in a study. In this case, the participant's status becomes "Off Study Agent," and the participant continues to be followed as specified by the protocol. Participants who complete the protocol interventions and any protocol-specified followup period or evaluations are also considered "Off Study Agent." Reasons why participants may stop a study agent include:

- Completed protocol-prescribed intervention;
- AE/SAE;
  - Inadequate agent supply (e.g., participant had no agent or site had no agent)
  - Non-compliant participant (includes refused study agent and/or assessments)
- Concomitant medication;
- Medical contraindication (e.g., pregnancy); and
- Other.

When a participant is permanently discontinued from the study agent, the final study visit, clinical, and laboratory evaluations must be obtained as specified in the protocol. All study agents or supplies need to be returned to the site staff.

8.1.1 Required Followup for Off Study Agent Status

The study forms required at the time of permanent discontinuation of a study agent are specified in the "Off Study Agent" section in the protocol. The procedures and/or clinical evaluations completed for "Off Study Agent" is specified in the protocol and should be consistent with the endpoints described in the objectives and statistical analysis sections of the protocol.

8.1.2 Off Study

Participants who are considered to be "off study" are those who are permanently discontinued from study agent and do not wish to participate in the study any longer. They do not require followup. The following are some reasons a participant can go off study:

- Completed (completed protocol intervention and any protocol-specified followup period or evaluations);
- AE/SAE;
- Death (complete Death Report form);
- Lost to followup;
- Non-compliant participant (includes refused study agent, assessments);
- Concomitant medication;
- Medical contraindication (e.g., pregnancy);
- Withdrew consent;
- Death; and
- Other.

NOTE: Any participant who is withdrawn for adverse events or pregnancy must be followed until resolution or until the Principal Investigator considers it unnecessary to continue followup. Documentation of this followup must be maintained in the participant's study chart and on the "Continuing AE" section of the Off Study Form.

8.2 Death

All deaths of participants at DCP-funded clinical sites need to be reported as a Serious Adverse Event (SAE) regardless of the relationship to the study agent. The SAE report is forwarded to the DCP Medical Monitor for review. For information about timeframes for submission of SAE forms and further instructions, please refer to the SAE procedures in Chapter 6 of this manual.

Deaths need to be reported using the protocol-specific death form. One Death Report form needs to be completed for each protocol in which the participant was enrolled. The purpose of this form is to gather information regarding the participant's death and when it occurred during the study. If the exact Date and Time are unknown, estimates are allowed. The following information should be submitted on the SAE form at the time the event is reported:

- Name and phone number of the reporter;
- Participant's PID number;
- Date of death;
- Primary cause of death;
- Name of study agent(s);
- Date study agent(s) last given;
- If death is related to study agent; and
- Brief history leading to death. (Submit autopsy report if available.)