

**Table 2: Protocol Violations Categories**

**01 Informed Consent procedures**

- a) No Consent/Assent obtained
- b) No proxy (participant representative), if appropriate, obtained
- c) Invalid/incomplete informed consent
- d) Unauthorized assessments and/or procedures conducted prior to obtaining informed consent
- e) Other

**02 Inclusion/Exclusion criteria**

**03 Concomitant Medication/Therapy** (such as participant used a medication or therapy expressly not allowed by the protocol during the phases(s) in the protocol when the medication or therapy is not allowed)

**04 Laboratory Assessments/Procedures**

- a) Required testing not obtained
- b) Testing completed outside window
- c) Testing not completed as per protocol
- d) Unauthorized test/procedure obtained
- e) Other

**05 Study Procedures/Assessments**

- a) Protocol required procedures not obtained
- b) Procedures/Assessments not completed as per protocol (i.e. personnel conducting procedure does not meet criteria as specified in the protocol, non-certified/non-trained personnel administering assessments, or assessments not completed as specified in the protocol)
- c) Procedures/Assessments obtained outside the visit (window) timeframes.
- d) Other

**06 Serious Adverse Events**

- a) SAE not reported
- b) SAE reported out of time window (Expedited Adverse Events reported out of specified timeframe)
- c) Other

**07 Randomization Procedures**

- a) Randomization procedures not followed, i.e. outside the window, out of sequence
- b) Ineligible participant randomized
- c) Improper unblinding procedures (as specified in the protocol)
- d) Other

**08 Study Drug Dosing**

- a) Ineligible participant dispensed (given) medication
- b) Incorrect medication dispensed (given to participant)
- c) Medication dosage or amount of medication dispensed (given to participant)
- d) Other

**09 Behavioral Intervention**

- a) Intervention not provided per protocol schedule or visit window timeframes
- b) Incorrect intervention assignment, i.e. ineligible participant assigned to behavioral intervention
- c) participant attended incorrect behavioral intervention

**10 Visit Schedule/Interval**

- a) Visit conducted outside of window

**99 Other Significant Violations**

- a) Destroying study materials
- b) Participating site starting the study prior to obtaining necessary approvals
- c) Using advertising materials or brochures without prior IRB approval
- d) Other