

Appendix I. Protocol Deviation Checklist

Please complete an OT13 Protocol Deviation Form for any of the following reasons:

- Visit missed: *Example –study visit missed as indicated per protocol*
- Visit completed outside of allowable visit window: *Example –study visit missed as indicated per protocol within window, but did occur at a later date*
- Samples collected outside of allowable visit window: *Example –samples not collected as indicated per protocol within window, but were collected at a later date*
- Sample collection missed: *Example – samples not collected as required per protocol due to failed IV placement during visits*
- Samples collected in error: *Example – RNA sample collected for subject that was by accident; Any sample collected not required per protocol*
- Mechanistic samples (PBMC/Plasma and RNA) collected outside of window or not collected (participating sites only)
- Pharmacy error/drug related error: *Example – More than seven bottles were dispensed at a visit.*
- Ineligible subject randomized (and eligibility committee **did not** approve): *Example – Subject did not meet \geq one inclusion criterion*
- Study procedure not completed: *Example: No physical exam or only completed a limited physical exam when the schedule of assessments required a full physical exam.*
- More than 4 weeks lapses from the participant’s randomization date to treatment start date.

****IMPORTANT NOTE:** Local IRB(s) can define what deviations/violations they want reported. No matter how the TNCC defines reporting of protocol deviations/violations, the study site/PI are not exempt from following their own institutional/IRB SOP(s) regarding what constitutes appropriate reporting of deviations/violations.