Off Protocol (Adult)

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 in the top right hand corner.
Deviation related to:	Check the box to indicate that the protocol deviation is related to Enrollment, Randomization, Protocol Visits, or Biospecimen collection.
Enrollment:	Check all that apply to indicate the type(s) of protocol deviation related to patient eligibility or enrollment. If the initial supply of study medication was not dispensed at the baseline (day 0) visit indicate the reason that the study medication was not dispensed at the baseline visit. If the patient did not take the first dose of study medication on time per protocol, indicate the date that the patient took the first dose of study medication. If the initial dose of study medication was not per protocol, indicate the starting dose for each study medication.
Randomization:	Check all that apply to indicate the type(s) of protocol deviation related to patient randomization. If the patient was randomized according to the wrong stratum, indicate the correct center or age category that should have been used for randomization.
Protocol Visits:	Check if some or all components of a protocol visit were completed, but the component(s) were not completed via an in person visit, when an in people visit was required per protocol. Forms not completed in person: Check each form that was completed, but not completed in person. Reason component(s) not completed in person: specify the reason the component(s) were not able to be completed via an in person visit. Timepoint: Record the timepoint of the follow-up visit. Method of data collection: Check the method(s) used to obtain the protocol visit data.
Biospecimens:	Check the box if a result from a test performed locally was used in place of a result for a test that should have been performed at the central lab, regardless of the reason that the result from the local lab was used in place of the result from the central lab. Do not consider the HBV DNA results that are performed as screening labs to determine patient eligibility. Results from HBV DNA tests performed locally may be used to determine patient eligibility. However, a serum sample must be sent to the central lab from the screening visit. The results from the central lab will always be used to determine study endpoints.

Treatment disc (Week 192) or Reinitiation of study drug:

Disc study drug:	Check the box if the discontinuation of study drug at Week 192 procedures were not followed per protocol. Then check the box that corresponds to the specific protocol deviation 1) Eligible to discontinue study drug, but drug was not discontinued. 2) Not eligible, but study drug discontinued. Check Other if neither scenario applies and provide reason in specify field.
Reinitiation HBV tx:	Check the box if the reinitiation of HBV therapy procedures were not followed per protocol. Then check the box that corresponds to the specific protocol deviation 1) Eligible to restart treatment, but treatment not restarted. 2) Not eligible to restart treatment, but restarted treatment. Check Other if neither scenario applies and provide reason in specify field.