****IV ARTESUNATE IS AN INVESTIGATIONAL PRODUCT. THEREFORE, INFORMED CONSENT MUST BE OBTAINED (APPENDIX V)****

Reminder Checklist -- WRAIR (DOD)

NOTE: There are TWO different formulations of Artesunate that CDC releases (DOD and Guilin), make sure to use the protocol for the correct formulation.

The following checklist outlines the required steps that must be completed in using IV artesunate (IV AS) under this IND for your patient. Please use this checklist to help your hospital ensure compliance with federal requirements for use of IV AS.

Pharmacist Responsibility		**Check (X) when complete**
1*.	Read IV AS protocol Section 8.1 ("Reconstitution and administration of IV artesunate") on how to prepare IV artesunate.	
2*.	Provide IV AS protocol and remaining report forms (Appendix I, II, II, V) to treating physician before IV AS is administered.	
3.	Complete and return Investigational Drug Accountability and Return Form (Appendix VI) to CDC by fax at 404-639-3717 within 14 days of receipt of IV AS by pharmacy. If IV AS is not administered to the patient, unopened and unused product should be returned. **Use 6-digit QARS# for Participant ID.**	

Treating Physician Responsibility		**Check (X) when complete**
1*.	Read IV AS Protocol	
2*.	Complete Appendix V (Informed Consent/Parental Permission Form) **and** FDA Form 1572 **BEFORE** IV AS administration: • Appendix V: Informed Consent/Parental Permission Form. Informed consent **must** be obtained from patient, legal guardian or other legally authorized representative, and witnessed by the physician or other healthcare provider before administering IV AS.	
3*.	Complete IV AS IND report form **BEFORE, DURING, AND AFTER** artesuante administration (**Use 6-digit QARS# for Participant ID**): • Appendix I (Demographics), II (Treatment Plan), III (Adverse Events Form)	
4*.	Monitor for post-artesunate delayed hemolysis† starting one week after initial dose for up to 4 weeks. Weekly lab evaluation should include hemoglobin, reticulocyte count, haptoglobin, lactate dehydrogenase (LDH), and total bilirubin.	

Appendices I, II, III &V, FDA Form 1572, and treating physician's CV must be completed and returned to CDC within 14 days of IV AS administration. Fax these report forms directly to CDC at 404-471-8035. ***Please include QARS#/Participant ID on coversheet of fax. QARS# is found on lower right-hand corner of packing slip.***

*Please note that these tasks should be completed immediately.

†Post-artesunate delayed hemolysis is a nonrecurring event characterized by a 10% or greater decrease in hemoglobin levels in the setting of a haptoglobin level <0.1 g/L and an increase of LDH levels to >390 U/L, or an increase of ≥10% over baseline at least 7 days after initiation of parenteral artesunate treatment.