



Memorandum

Date May 6, 2019

From LaShonda Roberson, DHSc, MPH
LCDR, USPHS
Lead IRB Administrator, Human Research Protection Office

Subject CDC IRB Approval of Continuation of Protocol #5032.0, " IND: Intravenous Artesunate for Treatment of Severe Malaria in the United States" (Convened)

To Kathrine Tan, MD, MPH
CGH/DPDM

CDC's IRB S has reviewed and approved your request to continue protocol #5032.0 for the maximum allowable period of one year. CDC IRB approval will expire on **12/10/2019**. The continuation action was reviewed at a meeting of the convened IRB on 12/03/2018. This is a response protocol treatment, and the IRB has determined that this is not a research activity under 45 CFR 46. The protocol was reviewed by the IRB in accordance with 21 CFR 50 and 56. The IRB approved the inclusion of children in the program in accordance with 21 CFR 50.52 and determined that the assent of children 7-17 years of age is not a necessary condition for proceeding with clinical treatment and data collection in accordance with 50.55(c)(2). The IRB also determined that the permission of one parent is sufficient based on 50.55(e)(1).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all treatment protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. **To avoid lapses in approval of your protocol and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 12/10/2019.**

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or by e-mail @ huma@cdc.gov.

cc:

CGH Human Subjects

Thomas Spira, MD