

**Memorandum**

**Date** April 21, 2023

**From** Felecia Peterson  
Human Research Protection Office

**Subject** CDC IRB Approval of Continuation of Protocol #4167.0, "IND: Use of Diphtheria Antitoxin (DAT) for Suspected Diphtheria Cases (FDA IND #11184)" (Convened)

**To** Kimberly Fox, MD, MPH  
NCIRD/DBD

CDC's IRB has reviewed and approved your request to continue protocol #4167.0 with the removal of the optional blood draw research component for the maximum allowable period of one year. CDC IRB approval will expire on **04/08/2024**. The continuation action was reviewed at a meeting of the convened IRB on 04/20/2023.

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

As a reminder, the IRB must review and approve all human subjects research 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 research 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 research 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 04/08/2024.**

**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) 639-4721 or by e-mail [huma@cdc.gov](mailto:huma@cdc.gov).

cc:  
NCIRD Project Determination (CDC)