

**Memorandum**

Date April 7, 2020

From James Cope, Ph.D., Chief, Human Research Protection Office, Centers for Disease Control & Prevention (CDC)

Subject CDC IRB Protocol #4167, Use of Diphtheria Antitoxin (DAT) for Suspected Diphtheria Cases under Expanded Access Investigational New Drug application (BB-IND 11184)

To Healthcare providers and affiliated hospitals or local institutional review boards

This memorandum is intended to provide clarification regarding CDC Institutional Review Board's (IRB) review of the IND protocol for equine-based DAT, an investigational antitoxin, for the treatment of patients with suspected diphtheria in the United States under CDC-sponsored BB-IND 11184.

To facilitate timely, nationwide access to DAT for treatment purposes only (i.e., non-research) and ease the logistical and regulatory burden of individual hospitals from having to procure DAT, develop an IND treatment protocol, obtain FDA permission, and comply with FDA's IND regulations, including IRB approval per 21 CFR Parts 50 and 56, CDC holds an active IND filed with FDA that permits CDC's distribution and use of investigational DAT for treatment of patients with suspected diphtheria in the United States. The CDC-sponsored BB-IND 11184 has been FDA-authorized since December 19, 2003, with continued IND annual report reviews, and CDC IRB serves as a central IRB for continuing review and approval of the DAT IND protocol (CDC IRB Protocol #4167) to help reduce the administrative burden on local IRBs and allow timely access for DAT treatment. Therefore, hospitals may elect to use CDC IRB's approval for this protocol in place of local IRB review per local hospital's or institution's policy with internal documentation as applicable. However, CDC IRB will not be providing IRB authorization agreements for investigational drugs that CDC provides solely for treatment (i.e., non-research purposes) due to lack of comparable FDA-approved alternatives.

CDC IRB determined that use of DAT as described in Protocol #4167 does not constitute human subjects research because it is provided for treatment purposes only (45 CFR 46.102(1)) and therefore, does not need to be reviewed for compliance with 45 CFR 46. Each hospital that receives DAT for treatment of suspected diphtheria under BB-IND 11184 may elect to use the CDC IRB approval to meet FDA's regulatory requirements for IRB review (21 CFR Parts 50, 56, and 312). Hospitals that may be precluded by local law or institutional policy from relying on another IRB, or those hospitals that otherwise decide to perform their own IRB review regardless of the central IRB review, should consider the following factors in their review:

- This IND protocol may be utilized for the administration of investigational DAT to all patients with suspected diphtheria, including vulnerable populations. Vulnerable populations including but not limited to pediatrics, pregnant and nursing women, and prisoners may be treated under this IND protocol.
- CDC IRB and program staff will not be able to respond to specific issues and concerns arising from local IRB review. Hospitals that choose to perform their own IRB review rather than utilizing the central IRB review mechanism should be aware that CDC is unable to accommodate requests for changes to this IND protocol (CDC IRB Protocol #4167).

Additionally, since this IND protocol for DAT is solely for treatment use and determined as non-research, Federalwide Assurance is also not applicable.

If you have any additional questions about any aspects of the protocol, you can contact the CDC Diphtheria Duty Officer through the CDC Emergency Operations Center (EOC) at 770-488-7100.

Enclosure: CDC IRB Approval Memo for CDC IRB Protocol #4167