Clarification Memorandum # 1 for:

IMPAACT 2008
Phase I/II Multisite, Randomized, Controlled Study of Monoclonal Antibody VRC01 with Combination Antiretroviral Therapy to Promote Clearance of HIV-1-Infected Cells in Infants

Version 2.0, dated 29 May 2017

DAIDS ES # 20735
IND # 133,017 Held By DAIDS

Clarification Memorandum Date: 26 April 2018

Summary of Clarifications and Rationale

This Clarification Memorandum (CM) clarifies that the current version of the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events should be used to grade adverse events. In addition, this CM corrects a typographical error: "malnutrition" had inadvertently been retained in protocol Section 7.3.3 due to a cut-and-paste error; malnutrition is now removed from this listing.

Implementation

This CM has been approved by the NIAID and NICHD Medical Officers. Institutional Review Board/Ethics Committee (IRB/EC) approval of this CM is not required by the study sponsor prior to implementation. However, sites may submit this CM to the responsible IRBs/ECs for their information or, if required by the IRBs/ECs, for their approval prior to implementation.

The content of the CM does not impact the sample informed consent forms for the study or the benefit-to-risk ratio for study participants. This CM should be maintained in each site's essential documents file for IMPAACT 2008. It is the responsibility of the Investigator of Record to ensure that all study staff are made aware of this CM.

The modifications included in this CM are listed below in order of appearance in the protocol and will be incorporated into the next protocol amendment as specified below. Additions to the text are indicated in bold; deletions are indicated by strike-through.

1. Protocol Section 7.3.3 is updated to specify use of the current Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events and to correct a typographical error, as follows:

   For infants in both study arms, adverse events will be graded according to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (DAIDS AE Grading Table), **Corrected** Version 2.1, dated ~~March~~ **July** 2017, which is available on the RSC website: http://rsc.tech-res.com/clinical-research-sites/safety-reporting/daids-grading-tables

   The only exceptions to the above apply to grading of axillary measured fever~~,~~ **and** injection site pain/tenderness~~, and malnutrition~~, which will be graded as follows […] *[see protocol Section 7.3.3]*