



Attn: DAIDS Networks and DAIDS Staff

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DAIDS, Office for Policy in Clinical Research Operations (OPCRO)

Date: February 28, 2025

Re: Clarification to the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events, Corrected version 2.1, July 2017

DAIDS has developed a clarification for the DAIDS AE Grading Table (GT) to address the Executive order issued in January 2025, titled *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.

The clarification updates the language in footnote No. 16 on page 29 of the GT for the hemoglobin parameter, which previously referenced 'transgender'. For ease of reference, the revised language has been incorporated directly into the body of the GT.

Please note that the current version number (corrected version 2.1) and the publication date (July 2017) for the GT remain unchanged. Therefore, while this clarified GT may be used for protocols in development, there is no requirement to change any references to the GT (i.e., title, version, date) in approved protocols. Importantly, this clarification has no impact on the actual grading for the hemoglobin parameter.

Below is the updated language:

Footnote No. 16: For participants ≥ 13 years of age, hemoglobin is graded based on the predominant sex hormone present in the body, whether endogenous or exogenous, for at least 6 consecutive months.

The clarified GT is now posted on the RSC NIAID website at <https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-event-grading-tables>.

SPT is grateful to DAIDS staff for their thoughtful contributions to the clarification.