SCORE Manual Summary of Changes

Section	Current	New	Rationale
Appendix Source Documentation Requirements V4.0	All toxicities and/or signs and symptoms, whether assessed by a clinician or reported by the participant, must be documented in the participant research record along with an assessment of the grading and clinical significance. This documentation must include: • Signature/date of the individual completing the grading and clinical significance assessment • A numerical grade that corresponds to the DAIDS AE Grading Table; or • A written description for those toxicities and/or signs and symptoms that do not appear in the table, which corresponds to the DAIDS AE Grading Table's definitions CRS staff are <u>not</u> required to record grades in participant research records for non- reportable AEs that are not clinically significant (NCS); however, staff need to document they assessed the event and determined it was NCS.	All toxicities and/or signs and symptoms, whether assessed by a clinician or reported by the participant, must be documented in the participant research record <u>along with grading of the severity of the AE</u>. <u>In addition, for laboratory results an assessment of clinical significance must be documented in the participant's research record.</u> This documentation must include: • Signature/date of the individual completing the grading and clinical significance assessment. • A numerical grade that corresponds to the DAIDS AE Grading Table; or • A written description for those toxicities and/or signs and symptoms that do not appear in the table, which corresponds to the DAIDS AE Grading Table's definitions, <u>CRS staff are required to document and grade all AEs in participant research records to determine reportability of the AEs.</u>	Clarified requirement for the assessment of clinical significance and grading of severity for toxicities signs/symptoms. Clarified requirements for assessing clinical significance for laboratory results.

Informed Consent of Participants V4.0	***Parameters and Considerations for Consenting Participants*** To ensure a thorough and compliant consenting process, the person(s) obtaining informed consent should adhere to the following mandates and best practices: Introduce themselves and provide information about the CRS. Speak plainly in a language understood by participants that facilitates their understanding of the clinical research and allows them to make an informed decision on whether to participate in the clinical research. Consider using an approved script to explain the clinical research for consistency. Provide information about the clinical research, pathology, and any general information that may help participants understand why they were invited to participate in the clinical research. Present the ICF and/or recruitment materials properly and ensure that participants understand the form's contents by: ▪ Reviewing all ICF elements with potential participants in detail. ▪ Never coercing or attempting to improperly influence a potential participant to enroll in the clinical research.	***Parameters for Consenting Participants*** To ensure a thorough and compliant consenting process, the person(s) obtaining informed consent <u>adheres to the following practices:</u> Introduce themselves and provide information about the CRS. Speak plainly in a language understood by participants that facilitates their understanding of the clinical research and allows them to make an informed decision on whether to participate in the clinical research. Provide information about the clinical research, pathology, and any general information that may help participants understand why they were invited to participate in the clinical research trial.* *<u>*Consider using an approved script to explain the clinical research for consistency*</u>. Present the ICF and/or recruitment materials and ensure that participants understand the form contents by: ▪ Reviewing all ICF elements in detail with potential participants. ▪ Allowing participants ample time to read the ICF and other recruitment materials on their own and ask questions about any information in the ICF.	Updated section name Edited section to clarify the timing and sequence for assessing and documenting assessment of participant understanding during the informed consent process.

	▪ Allowing participants ample time to read the ICF and other recruitment materials on their own and ask questions about any information in the ICF. To facilitate this process, consider: - Providing potential participants an unsigned, approved ICF and/or recruitment material before the consenting visit, so they have time to read the form and consult with others, as needed, before deciding to participate in the clinical research. - Assessing whether participants understood the ICF information presented to them, documenting this assessment of understanding in the source documents (e.g., participant research record, study-required assessment of understanding form, etc.), and clarifying any misunderstandings before applicable parties sign the ICF. Before any study-specific procedures are conducted, including screening: Participant and the person obtaining consent must sign and date the consent forms.	**To facilitate this process, consider providing potential participants an unsigned, approved copy of ICF and/or recruitment materials before the consenting visit so they have time to read the form and consult with others as needed, before deciding to participate in the clinical research.* Never coerce or attempt to improperly influence a potential participant to enroll in the clinical research. Before any study-specific procedures (including screening) are conducted: ● Assess whether participants understood the ICF information presented to them, document this assessment of understanding in the source documents (e.g., participant research record, study-provided assessment of understanding form/questionnaire, etc.) and answer any questions, address any concerns, and clarify any misunderstandings before all applicable parties sign the ICF.	

Site Visits 2.0	No less than 15 business days before the planned site visit, the CRS staff will receive a PVL and an Announced Work Order (AWO) through the Clinical Site Monitoring (CSM) System.	No less than 20 business days before the planned site visit, the CRS staff will receive a PVL and a Site Visit Work Order (SVWO) through the Clinical Site Monitoring (CSM) System.	Aligned terminology from Announced Work Order to Site Visit Work Order. Updated timeframe for release of the Site Visit Work Order from 15 to 20 days prior to scheduled visit to align with current processes.