ADVERSE EVENT (AE) REPORT FORM

This form captures adverse events of a single participant throughout the study.

STUDY TITLE					
PROTOCOL NO.		PATIENT ID		DATE	
SITE				SITE NUMBER	

ADVERSE EVENT	START DATE dd-mm-yyyy	STOP DATE dd-mm-yyyy	SEVERITY	RELATIONSHIP	ACTION TAKEN	OUTCOME OF AE	EXPECTED (Y/N)	*SAE (Y/N)

Participant had no adverse events (to be completed at the end of study): ☐ NONE

**Fill out SAE form if Yes is answered.*

Print Name of Principal Investigator	*Signature of Principal Investigator*	*Date*

Adverse Event (AE) Report Form Key

CODE	SEVERITY	RELATIONSHIP	ACTION TAKEN	OUTCOME OF AE
00		Not related	None	
01	Mild	Unlikely related	Does modification	Resolved
02	Moderate	Possibly related	Medical intervention	Recovered with minor sequelae
03	Severe	Probably related	Hospitalization	Recovered with major sequelae
04	Life-threatening	Definitely related	Intervention discontinued	Ongoing treatment
05			Other, describe	Condition worsening
06				Death
07				Unknown

DISCLAIMER

Any articles, templates, or information provided by Smartsheet on the website are for reference only. While we strive to keep the information up to date and correct, we make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability, or availability with respect to the website or the information, articles, templates, or related graphics contained on the website. Any reliance you place on such information is therefore strictly at your own risk.

This template is provided as a sample only. This template is in no way meant as legal or compliance advice. Users of the template must determine what information is necessary and needed to accomplish their objectives.