File A7. Adverse event questionnaire.

Record ID		
Subjet ID		
Date of Notification		
Event Description (From AE Trainer Form)		
Chronicity?	○ Single Occurrence ○ Intermittent ○ Persistent	
Severity?	○ Mild ○ Moderate ○ Severe	
Event Outcome?	○ Recovered or Resolved ○ Recovering or Resolving ○ Not Recovered or Resolved ○ Recovered or Resolved with Sequelae ○ Death Related to Adverse Event ○ Unknown	
Start Date (Onset)		
Was the event ongoing at the end of study?	○ Yes ○ No	
Section 1		
What phase of the study is the participant in?	○ Screening ○ Intervention ○ Post Intervention	
Was new medication prescribed? (If YES, update Participant Medications	○ Yes ○ No	
Section 2		
Is this a Serious adverse event using the below criteria for Serious adverse event (Determine whether any of the following apply)		
Death (Complete Death Report Document)	○ Yes	○ No
Life Threatening Event	○ Yes	○ No
Hospitalization	○ Yes	○ No
Permanent Disability or capacity?	○ Yes	○ No
Clinically Significant lab or test result that requires medical intervention?	○ Yes	○ No
Any other adverse event that, in opinion of PI, might have resulted in a Serious Adverse Event if medical intervention had not been initiated	○ Yes	○ No
If Death, Enter Date		
Section 3: Serious Adverse Event Summary		
Participant Medications		
Participant Current Medical Complications:		

Hospitalization:	○ Yes ○ No
Admit Date	
Discharge Date	
Diagnosis	
Section 4- To be completed by site PI or during executive call (If there are questions from the site PI about relatedness)	
What is the causal relationship between the adverse A. Definite - an event that follows a reasonable event and the assessment or intervention procedures? (Check only one that applies)	○ Definitive- and event that follows a reasonable event and the temporal sequence from administration of the study intervention, follows a known or expected response ○ pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure ○ Possible - An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors. ○ Unknown - Relationship for which no evaluation can be made. ○ Not Related - an event for which sufficient information exists to indicate that the cause is unrelated to the study intervention.
Section 5- To be completed if it has been determined that relatedness has been determined to be DEFINITE or POSSIBLE	
Was the Adverse Event an 'expected'event associated with the intervention with the intervention and listed in the protocol / i.e., transient foot pain, muscle soreness	○ Yes ○ No
Specify the unlisted event:	
Was the Adverse Event list in the informed consent?	○ Yes

	○ No
Specify the unlisted event:	
Should a change in protocol be consider to reduce or eliminate risk to study participants?	○ Yes ○ No
Provide rationale:	
Should this event be reported to the IRB? In general, IRB's only require information to be reported that is both: • unexpected and serious adverse events that are definitely related to the intervention.	○ Yes ○ No
Intervention Action?	○ Reduce Dose ○ Temporarily Stopped ○ Permanently Stopped ○ Changed Modality ○ None
Section 6: Serious Adverse Event Follow Up (Ongoing SAE)	
Date of Follow up	
Follow Up Number	