Adverse Event (AE) Tracking Log

Investigator Name:	Study Title/Number:	Site Number:
Subject ID:	Adverse Events: ☐ None	

Adverse Event	Start Date mm/dd/yyyy	Stop Date* mm/dd/yyyy	Type of AE	Severity of Event	Relationship of Event	Action Taken	Outcome	**Date Report Sent to HRPP	PI Initials/Date
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		
			☐ Expected ☐ **Un**expected	☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening or Disabling ☐ Death	☐ Unrelated ☐ Unlikely ☐ Possible ☐ Probable ☐ Definite	☐ None ☐ Medication ☐ Procedure ☐ Hospitalization ☐ Other	☐ Recovered ☐ Improved ☐ Ongoing ☐ Death ☐ Unknown		

* All events should be resolved or noted as unresolved at the time of subjects discontinuation in the study (i.e. study complete or subject withdrawal)
** Report all adverse events in accordance with HRPP Guidelines.

Delegation of Responsibility Log

Instructions: Use this log to document all study personnel and their specific responsibilities, signatures, and dates of obligation during the study.

Investigator Name:	**Study Title/Number:**	**Site Number:**

Print Name	Signature	Initials	Dates of Responsibility*		Delegated Responsibilities**	PI Initial/Date
			Start	End		

*Start date should be the date of IRB approval of study personnel.

**Enter number(s) that corresponds to the responsibilities: (1) obtain informed consent (2) source document completion (3) case report form (CRF) completion (4) assess inclusion and exclusion criteria (5) physical examination (6) obtain medical history (7) obtain medication history (8) administer investigational drug (IP) (9) dispense IP (10) laboratory specimen collection/shipment (12) adverse event inquiry and reporting (13) Other _____

I certify that the above individuals are appropriately trained, have read the Protocol and pertinent sections of the relevant regulations, and are authorized to perform the above study-related tasks/procedures. Although I have delegated significant trial-related duties, as the principal investigator, I still maintain full responsibility for this trial.

Investigator Signature: _____ **Date:** _____

Device Accountability Log

Investigator Name:	Study Title/Number:	Site Number:
Device Name:		

Date Received	Model #	Serial #	Lot No.	Participant ID	Date(s) Used	Indicate: Returned, Destroyed, Repaired	Date Returned, Destroyed, Repaired	Study Staff Initials	Comments

Investigational Product Accountability Log: Subject Record

Investigator Name:	Study Title/Number:	Site Number:
Name of Drug:		

Date	Subject ID Number	Subject's Initials	Dose	Quantity Dispensed and/or Received	Balance Forward / Balance	Lot No.	Recorder's Initials
21 Mar 2018	115	XYZ	100mg	50 tabs	200 / 150	39999	ABC

Pre-Screening and Enrollment Log

Instructions: Use this log to list participants screened and include those who failed screening and those who are enrolled.

Investigator Name:	Protocol:	Site Number:

Participant ID	Date of Consent	Version of Consent	Date Screened	Eligible for Enrollment? (Y/N)	Ineligibility Reason (if applicable)

Protocol Deviation Log

Investigator Name:	**Study Title/Number:**	**Site Number:**

Ref No.	Subject ID	Date of Deviation	Date Identified	Deviation Description	Dev. Type[1]	Resulted in AE? (Y/N)	Did subject continue in study? (Y/N)	Meets IRB reporting requirements? (Y/N)	IRB Reporting Date
1									
2									
3									
4									
5									
6									
7									

[1]**Deviation Type**: enter appropriate deviation code: (A) – consent procedures; (B) – inclusion/exclusion criteria; (C) – concomitant medication (D) – laboratory assessments/procedures; (E) – study procedures; (F) – serious adverse event reporting/unanticipated adverse device event (G) – randomization procedures/study drug dosing; (H) – visit schedule; (I) – efficacy ratings; (J) – other (specify)

Specimen Accountability Log

Investigator Name:	Study Title/Number:	Site Number:

Subject Identifier	Description of Specimen	Date and Time of Collection	Visit Number	Storage Location	Date and Time of Shipping/ Release	Name of Person Specimen Released to	Initials

Staff Training Log

This log is designed to be study specific. You may customize this log to be the training record for an individual in the study team.

Name of Individual	Training (Manual of Operating Procedures, Standard Operating Procedures, Study Initiation Visit etc.)	Date of Training	Initials of Supervisor / PI

Study Monitoring/Site Visit Log

Record of all external and internal study reviews

Investigator Name:	Study Title/Number:	Site Number:

Date	Name	Signature	Purpose of Visit