Event Tracking Log

Use this log to document events or incidences that **DO NOT require prompt IRB reporting**. Please consult this document to determine events that do or do not require prompt reporting. Add additional rows as necessary. Study teams are responsible for maintaining one continuous log within the overall regulatory binder that reflects all reportable events that have occurred in the study. **Please do not enter any participant identifiable data in the log.**

| **Definition** | **Types** | **Examples of Events that Do Not Require Prompt Reporting** |
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| Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. | Adverse Event (AE) | * Non-life-threatening reactions not mentioned as possible risks in the Consent
* Accidental Injuries
* Any other unexpected and related or possibly related (as determined by the PI) event that is normally not considered serious

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| Failure to adhere to federal, state, or local regulations governing research, organizational policies, or determinations made by the IRB. | (Minor) Non-Compliance | * Lapse in IRB Approval (without continuation of activities)
* Failure to respond to IRB inquiries
* Engagement of new study personnel without IRB approval
* Change in PI without IRB Approval (without continuation of activities)
* Engagement of new study site without IRB approval
* Fail to maintain copies of regulatory approvals and documents
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| Minor Consent/HIPAA Issues | * Use of outdated/expired consent form
* Missing original signature page
* Missing subject signature, printed name, or date
* Missing consenter signature, printed name, or date
* Copy of consent not provided to subject
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| Unplanned excursion, either intentionally or non-intentionally, from the protocol, by either the study team or the subject, that is not implemented or intended as a systematic change. | Minor Protocol Deviation | * Exceeding approved sample size/enrollment goal
* Study Visit outside of visit window
* Error resulting in drug dosage higher than approved but with no side effects
* Failure of subject to return study medication/device
* Failure to follow study protocol (no effect on subject safety)
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| Any information including anything that falls into the RNI categories listed above that is discovered either by the study team or the IRB in the course of post-approval monitoring. | PAM Findings  |  |

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