|  |  |  |
| --- | --- | --- |
| **PROTOCOL TITLE:** | | |
| **PROTOCOL NO.:** | **PRINCIPAL INVESTIGATOR:** | **SITE NAME:** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial participant ID** | **SAE** | **Onset Date** | **Date site was first aware of SAE** | **Date SAE was reported to Sponsor / CRO** | **Initial (I) or Follow-up (F) SAE Report** | **IRB submission Date** | **HSA Submission Date**  **(if applicable)** | **Comments** |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |
|  |  |  |  |  | I  F |  |  |  |