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

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| **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 |  |  |  |
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