

**SAE ASSESSMENT**

**FORM**

**FORM 3.4**

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| **IRB REFERENCE NO.** |  |
| **PROTOCOL NO. & TITLE** |  |
| **Site of reported SAE** | **Type of SAE****(Number)** |   On-site SAEs |
| **On-site****(Site in the country)** | **Off – Site****(Site in foreign countries)** | **SUGAR** | **Non-****SUGAR** | **Date of SAE** | **Date reported****To REC** | **Date Presented in REC meeting** | **Relation to Investigational New Drug** | **Action taken** | **Reviewed By** |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
|   🞎 |   🞎 |   🞎 |   🞎 |  |  |  |  |  |  |
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