**TEMPLATE FOR REPORTING SERIOUS ADVERSE EVENTS (SAEs) FOR SAMRC HREC-APPROVED PROTOCOLS**

**PROTOCOL NUMBER:**

**PROTOCOL TITLE:**

**DATE OF INITIAL APPROVAL:**

**NAME OF PI / INVESTIGATOR:**

**SITE NAME:**

**STUDY PRODUCT (if applicable):**

|  |  |
| --- | --- |
| **Participant ID, age, date of enrolment** | **Date and description of event; relationship to product/study activities** |
|  |  |
|  |  |
| **Outstanding / next steps (Y/N)** | **Description** *(For example, medical records to be retrieved, more information to be obtained, etc.)* |
|  |  |