

**KSU IRB Timelines for local (country specific/on site) events:**

* **All ‘Fatal’ or ‘Life Threatening’** **Un**expected Serious Adverse Event (SUSARs): Initial Reporting, within 24 hoursof the investigator awareness of event followed by a complete report **in additional 7 days. (**Requires immediate/expedited reporting**).**
* **All other Unexpected SAEs, SUSARs:** Initial Reportingwithin 24 hoursof the investigator awareness of event followed by a complete report **in additional 15 days**. **(**Requires immediate/expedited reporting**).**
* **Post Study Event**: In similar timelines as per category of the event. (May or may not require expedited reporting).
* All other **Expected SAEs** *and* **Non-Serious** Adverse Events: If Does Not require reporting, then collection, documentation and filing required in Investigator Site File for the purpose of checked at compliance monitoring by IRB, sponsor or competent authority.

1. **Study Information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Institute/Department NA ☐ | Sponsor NA ☐ |  | IRB no. |  |
| Study Title | |  | | |
| Study Drug/Device (Number/ID) | |  | | |
| Blinded Study Agent | |  | | |
| Principal investigator | |  | | |
| Email | |  | Phone |  |

1. **Report Information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date of Report: |  | Date Sponsor Notified (NA: ☐) |  | SAE Onset Date: |  |
| Report #: |  | Expedited Reporting |  | SAE Stop Date/NA: |  |
| Report Type | ☐ Initial Report Initial Report Date:  ☐ Follow-up Report Follow Up Report Date: | | | | |
| Adverse Event Category | ☐ Unexpected Serious Adverse Event/Reaction(SUSAR) ☐ Fatal or Life Threatening SAE/SUSAR  ☐ Unexpected Non-Serious AE  ☐ Expected Serious Adverse Event (SAE ☐ Expected Non-Serious AE | | | | |
| Event Outcome | ☐ Resolved (date:      ) ☐ Stabilized (date:       ) ☐ Resolving  ☐ Ongoing\* ☐ Not Resolved  ☐ Fatal: Date       ☐ Resolved with Sequelae; *State Sequelae*  \*NOTE: If the SAE is ongoing, a follow-up report must be submitted when the SAE is resolved or stabilized.  . IN case of Fatal or Life Threatening SAE/SUSAR, a complete detailed report should be submitted within 7 days of initial report submission. | | | | |

1. **Subject Information**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Subject Initials / ID |  | Age **☐**or  Date Of Birth **☐** |  | | Gender | **☐ Male** **☐ Female** |
| Is the subject still an active participant in this study? | | ☐ **YES** ☐ **NO** | | If no, date discontinued: | | |
| Reason of removal of participant from study: | | ☐**Patient Consent** Withdrawal ☐ Death ☐ Protocol Criteria  ☐PI Decision ☐ Lost to Follow Up | | | | |

1. **Serious Adverse Event Information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Submitted AE**  **AE** | | | | | |
| **☐** AE | **☐** SAE | **☐** SuspectedUnexpected SAE (SUSAR) | **☐** Investigational New Drug (IND) Safety Report from sponsor dated:  **☐** Source of New Information (Safety Report**)** | | |
| **Was the event Serious?** | | | | | ☐ **YES** ☐ **NO** |
| **SAE Term (Medical**):  (PI can state CIOMS defined terms **OR** Can use his/her advised term (used in practice); Sign/symptoms NOT allowed | | | | |  |
| **SAE resulted in: Please select one or more from the list below.** | | | | | |
| ☐ Death | | | | ☐ Hospitalization | |
| ☐ Life threatening | | | | ☐ Congenital anomaly / Birth defect | |
| ☐ Persistent or significant disability / incapacity | | | | ☐ Medically important | |
| ☐ Required immediate intervention | | | | ☐ Other (specify): | |

1. **SUSAR Information**

|  |  |
| --- | --- |
| SUSAR Description | |
| **Was the event Unanticipated?** | ☐ **YES** ☐ **NO**  **If YES, please check ONE,** *Or* **MORE, of the following:** |
| ☐ Unanticipated because the event is not identified in specificity or severity in relevant study product documents (e.g. investigator’s brochure, device manual) | |
| ☐ Unanticipated because the event is not identified in specificity or severity as a risk in the informed consent form | |
| ☐ Other (specify): Please check the list of examples of ‘Unanticipated events’ from the IRB SOP & Handbook. | |
| **Study Drug/Investigational Product (IP) status: PI Action Taken** | |
| ☐ Continued ☐ Discontinued permanently, Date of Discontinue: | |
| ☐ Hold, Date of hold:       (Temporary hold allowed in protocol **ONLY** not affecting the subject’s clinical status/outcome). | |
| ☐ Restarted, Date of restart: | |
| ☐ Alternative treatment/dug given (as standard treatment/mentioned in protocol) during hold period  Provide name on the medication list below in AE management rows, mentioning as ‘**study alternative treatment/drug.’** | |

1. **Concomitant Medication Taken by subject during study**

|  |  |
| --- | --- |
| CONCOMITANT MEDICATIONS (Please use more pages according to the medication). Provide dose, route, duration, start & stop date. | |
| 1 |  |
| 2 |  |
| 3 |  |
| 4 |  |

1. **PI Action taken for AE Management**

|  |  |
| --- | --- |
| PI Action taken for AE management for Diagnosis (Including all lab, radiology and investigational work up (medical/operative/invasive) |  |
| PI Action taken for AE management for treatment (medical/operative) |  |
| Significant findings of All investigations (Radiology, Labs, Invasive). | |
| Laboratory Work up Reports |  |
| Radiology Work up Reports |  |
| Invasive work up report |  |
| Other |  |

1. **Medication list (If any in AE management)**

|  |  |
| --- | --- |
| MEDICATIONS (Please use more pages according to the medication). Provide dose, route, duration, start & stop date. | |
| 1 |  |
| 2 |  |
| 3 |  |
| 4 |  |

1. **Surgical Intervention (if any, for AE management)**

|  |  |
| --- | --- |
| Surgical procedure |  |
| Date of surgery |  |
| Surgeon specialty *(do not provide surgeon’s name if not part of the study team)* |  |

|  |  |  |
| --- | --- | --- |
| **REC USE ONLY** | Report phoned in on: |  |
| PI contacted by: | Telephoned report taken by: |  |
| PI contacted on: | Report received on: |  |

|  |
| --- |
| **Was the event related to the study product?** |
| ☐ Definitely Related |
| ☐ Probably Related |
| ☐ Possibly Related |
| ☐ Unknown Relationship |

1. **Recommendations (not more than 500 words)**

|  |  |
| --- | --- |
| Do you recommend a change to the protocol?  (If **YES**, please attach recommended changes.) | ☐ **YES** ☐ **NO** |
| Do you recommend a change to the informed consent form? | ☐ **YES** ☐ **NO**  ☐ **YES** ☐ **NO** |
| If **YES**, please specify the recommended place for using the modified consent form:  Please attach a tracked consent form and sponsor approval, if applicable. If sponsor does not agree with recommended changes, please include sponsor rationale.) | At the site ☐  study-wide ☐  NA: ☐ |

1. **Reporter and Principal Investigator’s (PI) Signatures**

|  |  |
| --- | --- |
| Printed Name of Reporter: | Printed Name of PI: |
| Signature of Reporter: | Signature of PI: |
| Date: | Date: |

*For more information, please visit the website of the Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm\_Policies*)*