

 **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 periodProvide 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*)*