

**SERIOUS**

**ADVERSE EVENT REPORT**

**FORM**

**FORM 3.1**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Principal Investigator: | Protocol No.: | IRB Reference No:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | - |  |  |  |  | - |  |  |

  |
| Study Title: |
|  |
|  |
|  |
|  |
|  |
| Name of the study medicine/device: |

|  |  |
| --- | --- |
|  | initial |
|  |
|  | Follow-up |

 Report Date:   | Onset date: |
| Sponsor: | Date of first use: |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Subject’s initial/number: | Age: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | MALE |  |  | FAMALE |

 |
| Subject’s history: | Laboratory findings: |
| SAE: | Treatment: |
|  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | resolved |  | On-going |

Outcome: |
| Seriousness:  |  Relation to 🔾 Drug 🔾 Study |
|

|  |
| --- |
|  |
|  | Death |
|  |
|  | Life Threatening |
|  |
|  | Hospitalization -🔾 initial 🔾 prolong |
|  |
|  | Disability / Incapacity |
|  |
|  | Congenital Anomaly |
|  |
|  | Other |

 |

|  |
| --- |
|  |
|  | Not related |
|  |
|  | Possibly |
|  |
|  | Probably |
|  |
|  | Definitely related |
|  |
|  | Unknown |

 |
| Changes of the protocol recommended? Changes to the informed consent form recommended? |

|  |  |  |  |
| --- | --- | --- | --- |
|  | No |  | Yes , attach proposal |
|  |
|  | No |  | Yes , attach proposal |

 |
|  Reviewed by: Date: Comment: Action: |
|  |
|  |