**ACMS-IRB LOCAL SERIOUS ADVERSE EVENT (SAE) REPORTING FORM**

*All sections must be completed.*

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| **ACMS IRB Reference No:** | | **Protocol Title:** | | |
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| **Subject Identifier:** | **Subject Gender:** | | **Location where the SAE occurred:** | **Date of Adverse Event:** |
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| **Brief Description of the Event:**  (In the space below, please use (3 – 6) keywords, e.g. Liver Failure, to concisely describe the event.) | | | | |
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| **Description of the Event:**  (In the space below, please provide a detailed description of the event and subsequent treatment, if any. Reference to supporting documents is not an acceptable substitute. Additional documents describing the event may be attached (please remove all personal identifiers before submitting additional documents). | | | | |
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| **Description of the Outcome of the Event:**  (In the space below, please provide a detailed description of any intervention or process that occurred. **Do not leave blank**. If outcome is unknown, state so.) | | | | |
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| **Outcome of SAE at the time of this report (Check one):** |
| Resolved  Unresolved\* Unable to assess  Death. Cause of death: |
| \*If the serious adverse event is unresolved (i.e. if additional treatment or follow-up of the SAE is necessary, please note that a follow-up report must be submitted when the event resolves. |
| **Expectedness [Nature] (Check one):** |
| Expected Unexpected |
| Expected (Anticipated) Adverse Events: These are risks or events reported in the Investigator’s Brochure (IB) and listed in the consent document. The ACMS IRB will consider an adverse event as “anticipated” or “expected” only if it is discussed in the protocol and included in the consent document.  Unexpected (Unanticipated) Adverse Events: These are any unexpected untoward event or medical occurrence in a participant that is not consistent with the known, predicted possible effects of the protocol. An unexpected adverse event can therefore be any unanticipated, unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the research that was not listed in the protocol, consent document or IB. This includes adverse drug reactions, the nature of severity of which is not consistent with the applicable product information (e.g. IB for an unapproved investigational product or product insert/summary of product characteristics for an approved product) and any experience that suggests a significant hazard, contraindication or side effect. In addition to this definition, the ACMS IRB will interpret any adverse event not included in the Consent Document as a risk to be “unanticipated” or “unexpected”. |

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| **Relatedness [Causality] (Check one):**  **Only “Related” SAE (definitely/ probably/ possibly) needs to be reported to ACMS IRB. Unrelated SAE does not need to be reported to ACMS IRB. “Related” means there is a reasonable possibility that the even occurred as a result of participation in the research.** | | | |
| Definitely Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable and there is no other cause to explain the event (or a rechallenge is positive). | | |
| Probably Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable and the event is more likely to be explained by the medicinal product than by another cause. | | |
| Possibly Related | Where a temporal (timely) relationship of the onset of the event, relative to the administration of the product is reasonable, but the event could have been due to an equally likely cause. | | |
| Determining Cause:  The investigator must make an independent determination as to whether the SAE was thought to be related to study participation) i.e. study intervention, test article administration, study procedures) | | | |
| **Please explain the rationale for the determination of relatedness (causality) in the space below.:** | | | |
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| **Classification of SAE (Check all that apply):**  At least one should be checked for this form to be used | | | |
| Results in death  Is life-threatening  Requires inpatient hospitalisation or prolongation of existing hospitalisation  Results in persistent or significant disability/incapacity  Is a congenital anomaly/birth defect  Transmission of a communicable disease  Misidentification or mix-up of any type of human biological material, gamete or embryo  Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above | | | |
| **Significant New Finding:**  Should currently enrolled subjects be notified or re-consented or the past subjects be informed about this adverse event? | | | Yes  No |
| If “No”, explain your rationale: | | | |
| If “Yes”, please explain and describe the mechanism to be employed: | | | |
| **Consent document:**  If the occurrence of the event is consistent with information included in the current, IRB-approved consent document and is the frequency and/or severity of the event consistent with available published information (IRB-approved protocol IB)? | | | Yes \*\*  No |
| \*\*If your answer is “Yes”, please state where the information can be found (e.g. consent document/protocol/IB; Section X, Page Y, etc): | | | |
| **Amendments to protocol and/or consent document:**  Should the protocol and/or consent document be revised? | | | Yes #   No@ |
| **#If your answer is “Yes”, please submit the amendments for ACMS IRB approval, prior to the enrolment of any new subjects.** | | | |
| **@If your answer is “No”, please explain the rationale for your decision.** | | | |
| **Principal Investigator’s Certification:**  I have thoroughly reviewed the details of this serious adverse event and the information above accurately reflects my conclusions. | | | |
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| **Name and Signature** | | **Date** | |