## University of Leicester Sponsored Multi Centre CTIMP
### Serious Adverse Event Listing Table

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<th>Date of SAE</th>
<th>Type of Report 1-4</th>
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<th>Expectedness Expected/unexpected</th>
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Chief Investigator Name ----------------------------------------------- Signature ----------------------------------------------- Date-----------------------------

All SAEs that are not resolved at time of SAE line listing submission must be included on subsequent line listings until resolution confirmed.
CTIMP Line Listing Guidance

1 Study site: list site name/number - If numbers utilised ensure that the Sponsor is provided with a listing of corresponding site names.
2 Date of SAE: Provide date of SAE
3 Type of report: List relevant number in column
   1 – Initial
   2 - Follow up
   3 - Final
   4 - Initial and Final
4 Subject Study ID: Provide details of subject's unique study Identification Number. Note: No personal identifiable data must be used.
5 Brief description of event: Provide brief description of event and subsequent investigations/actions
6 Serious Criteria: List relevant number in column
   1 - Resulted in Death
   2 - Life Threatening
   3 - In-patient Hospitalisation/prolongation of existing hospitalisation
   4 - Persistent or significant disability/incapacity
   5 - Congenital anomaly/birth defect
   6 - Other
7 Causality: record Related or Unrelated
8 Expectedness: record Expected or Unexpected

Where an event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting - Inform the Sponsor Immediately.

9 Outcome of event
   1 - Resolved
   2 - Resolved with Sequelae
   3 - Ongoing
   4 - Unknown at Present
   5 - Fatal

Where an event is Fatal, the Sponsor will require further information with regards to cause of death.

10 Date of resolution: All SAES must be followed up until resolution