**UHL Sponsored Multi Centre CTIMP**

**Appendix 6**

**Serious Adverse Event Listing Table**

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| **Sponsor Number:** |  | **Chief Investigator:** | **Reporting Period:**  |
| **Study Title:** |  |

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| **1****Study Centre** | **2****Date of SAE** | **3****Type of Report****1-4** | **4****Subject Study ID** | **5****Brief Description of Event** | **6****Serious****Criteria****1-6** | **7****Causality****Related/****unrelated** | **8****Expectedness****Expected/****unexpected** | **9****Outcome****1-5** | **10****Date of Resolution** |
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Chief Investigator (Printed 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 hospitalization

 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 further information will be required with regards to cause of death for the Sponsor.

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