**UHL Sponsored Multi Centre**

**Serious Adverse Event/Serious Adverse Device Effect Line Listing Table**

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| **Sponsor Number:** |  | **Principal Investigator:** |
| **Study Title:** |  | **Study Site Name:** |

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| **Date of event** | **Relationship to Procedure?****1 =Not related****2 = Unlikely****3=Possible****4=Probable****5=Causal relationship** | **Serious** **Criteria****1 = Led to a death****2 = Life threatening****3 = In patient hospitalization/prolongation of hospitalization** **4= permanent impairment of body structure/ function****5 = medical/surgical intervention to prevent life threatening illness/injury****6 = led to foetal distress/death or birth defect** | **Patient Study ID** | **Brief Description of Event**  | **Relationship to Device?****1 =Not related****2 = Unlikely****3=Possible****4=Probable****5=Causal relationship** | **Expectedness assessment****1 = Expected****2 =Unexpected** | **Outcome****1 =Resolved****2 =Resolved with sequalae****3 =Ongoing****4 =Fatal****5 =Unknown** | **Date of event resolution**  |
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**If the serious adverse device effect is related and unexpected, it is an Unexpected Serious Adverse Device Effect (USADE) and requires expedited reporting as per SOP S-1041**