**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**