Adverse Event/Device Effect Record

For UoL Sponsored Medical Device Studies

| **Event Number** | **Adverse event/ Device Effect Description** | **Start Date**  (DD/MMM/YYYY) | **End Date**  (DD/MMM/YYYY) | **Relationship to Procedure\***  (\*key below) | **Relationship to Device** (\*key below) | **SAE or Device Deficiency?**  (Yes/No) | **Expectedness**  **Assessment**  (1=Expected  2=Unexpected) | **Outcome**  (‡key below) |
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**\***1=not related, 2=unlikely, 3=possibly related, 4=probably, **5=**causal relationship

‡ 1=Resolved, 2= Resolved with sequelae, 3=ongoing, 4=Fatal, 5=Unknown