# Adverse Event/Device Effect Record

For UoL Sponsored Medical Device Studies

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<tr>
<th>Subject ID</th>
<th>Subject Initials</th>
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<tr>
<th>Adverse event/ Device Effect Description</th>
<th>Start Date (DD/MMM/YYYY)</th>
<th>End Date (DD/MMM/YYYY)</th>
<th>Relationship to Procedure: 1=not related OR 2=unlikely OR 3=possible OR 4=probable OR 5=causal relationship</th>
<th>Relationship to Device: 1=not related OR 2=unlikely OR 3=possible OR 4=probable OR 5=causal relationship</th>
<th>SAE or Device Deficiency? Y/N</th>
<th>Expectedness Assessment: 1=Expected 2=Unexpected</th>
<th>Outcome: 1=Resolved 2=Resolved with sequelae 3=Ongoing 4=Fatal 5=Unknown</th>
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SOP S-1043 Appendix 2 Adverse Event/Adverse Effect Record V1.1 Sep 2021