**UHL Medical Device Deficiency Report Form**

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| EudraCT number: | |  |
| Sponsor number: | |  |
| Protocol title: | |  |
| Site: | |  |
| Subject number: | |  |
| Device: | |  |
| **Device details** | | |
| Describe the nature of the device, its normal (label) applications and its application in the Clinical Investigation if different: | | |
| **Event details** | | |
| Date of deficiency: | |  |
| Description of deficiency | | |
| Please indicate if the deficiency concerns identity, quality, durability, reliability, safety or performance of the device. | | |
| Please indicate if the deficiency is due to malfunction, use error or inadequate labelling. | | |
| **Action taken** | | |
|  | | |
| **Additional information** | | |
| Name and contact details of person reporting and role |  | |
| Date of report: |  | |
| PI signature: |  | |
| Date received by Sponsor: |  | |
| Action: | | |