**Serious Adverse Event Reporting Form – Non CTIMP only**

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| **Study Information**  |
| **Study Title & Protocol No:**  |
| **Chief Investigator Name:**  |
| **Site Name & Number:** |
| **Principal Investigator Name:**  |
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| **Participant Information** |
| **Participant’s Initials:** | .............................. | **[ ]  Male** | **[ ]  Female** |
| **Participant’s Study Number:** | .............................. |  |  |

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| **Report Type**  |
| **Report Type:** *(tick one)* | [ ]  Initial [ ]  Follow-up Report (FU Report number: …………) |
| *(Follow-up report should be submitted until resolution or specified in the protocol.* *Please use a new SAE Report form for FU reporting and only report new or changed information.)* |
| **Is this the final report** *(no further updates expected)***? [ ]** Yes[ ]  No |
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| **Serious Adverse Event Information** |
| *(A summary of signs and symptoms including vital signs, diagnosis, treatment of event, concurrent treatment and other relevant medical history)***Describe event:** |
| *(If more space is required, please continue on page 3)* |
| **Start Date of SAE:** *(DD/MM/YYYY)*  | *.…..…. / ……… / …….……* | **Location:** |
| **Stop Date of SAE:** *(DD/MM/YYYY)*  | *.…..…. / ……… / …….……* | [ ]  Or Ongoing  |
| **Date the site becoming aware of SAE:** *(DD/MM/YYYY)*  | *…..…..…. / ……….… / ………….……* |
| ***Please complete this form with all currently available information and submit it*** ***as soon as possible after becoming aware of the SAE.*****PLEASE EMAIL FORM TO: papworth.safety-reporting@nhs.net** |

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| **Seriousness of Adverse Event** |
| **Criteria for definition as SAE:***(tick all that apply)*[ ]  Death [ ]  Life threatening [ ]  Hospitalisation[ ]  Prolongation of existing hospitalisation  |  [ ]  Disability or incapacity [ ]  Congenital abnormality/birth defect[ ]  Other important medical event  |
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| **Medical Assessment of Serious Adverse Event***to be completed by medically qualified PI or suitable delegate only* |
| **Severity of event:** *(Assign the severity of the SAE* *based on the most severe symptom.)*   | [ ]  Mild [ ]  Moderate [ ]  Severe |
| **Is the event related to the participant’s involvement in the study?**[ ]  Definitely (related) [ ]  Probably (related) [ ]  Possibly (related) [ ]  Unlikely (unrelated) [ ]  Unrelated (unrelated) **Name / Signature / Date of medically qualified person making decision:**  …………………….…………………/……….….…………….……………/…………...………….…..….…………. (DD/MM/YYYY) |
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| **Outcome of Serious Adverse Event** |
| **Is the event expected per protocol?**   |  | [ ]  Expected [ ]  Unexpected [ ]  Not applicable  |
| **Outcome of SAE at the time of reporting:***(tick one)*  | [ ]  Resolved [ ]  Resolved with sequelae [ ]  Ongoing [ ]  Death  |
| **If death**, give date (DD/MM/YYYY): .*…....…. / …..…….… / ………..….……*Cause of death: ................................................................................................................................ ............................................................................................................................................................ ............................................................................................................................................................  |

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| **Additional sheet** |
| *(continued from previous pages / can be left blank)* |
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| **Details of Reporter and Principal Investigator** |
| Name of person completing report: Position: Contact no: Signature and Date (DD/MM/YYYY): |
| Name of Principal Investigator authorising report: Signature and Date (DD/MM/YYYY): |

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| **Sponsor Internal Use Only**  |
| **1. Is the event related?** [ ]  Related [ ]  Unrelated**2. Is the event expected?** [ ]  Expected [ ]  Unexpected [ ]  Not applicable **3. Is the event related and unexpected?** [ ]  Yes [ ]  No**If yes**, please follow reporting requirements for REC if applicable. **Date of reporting to REC:** *(DD/MM/YYYY)* |
| **Comments:***(to be completed if further information is required or queries are raised about the event).* |
| Name of sponsor representative conducting the review:Signature of sponsor: Date of signature (DD/MM/YYYY):  |