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

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

|  |  |  |
| --- | --- | --- |
| **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 | | |
|  | | |
| **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** | | |

|  |  |  |
| --- | --- | --- |
|  | | |
| **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 |
|  | | |
| **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) | | |
|  | | |
| **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: ................................................................................................................................  ............................................................................................................................................................  ............................................................................................................................................................ | | |

|  |
| --- |
| **Additional sheet** |
| *(continued from previous pages / can be left blank)* |
|  |
| **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): |

|  |
| --- |
| **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): |