|  |  |
| --- | --- |
| **Name of staff/researcher** |  |
| **Completed by (initials)** | |  |  |  | | --- | --- | --- | |  |  |  | |
| **Completed by (role) (Tick one option)** | Care-home manager ☐  Care-home staff ☐  Trial Manager ☐  Other ☐ |
| **Today’s date** | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | |
| **Event identified by** |  |
| **Start date of event (onset date)** | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | |
| **Description of the event**  **Please do not include any information on participant/care home allocation here** |  |
| **Location of event** | In care home ☐  Other ☐ |
|  |  |
| **Status (Tick one option)** | Resolved (not on-going) ☐  Resolved with sequelae (not on-going) ☐  On-going – not at study end ☐  On-going – at study end ☐  Fatal (not on-going) ☐ **Complete withdrawal form**  Unknown ☐ |
| **Severity (Tick one option)** | Mild ☐  Moderate ☐  Severe ☐ |
| **End date of event** | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | |
| **Date Chief Investigator notified** | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | / |  |  | / |  |  |  |  | |
|  |  |
| **Event linked to trial participation?**  **(Relationship to study) (Tick one option)** | Definitely ☐  Likely ☐  Possibly ☐  Unlikely ☐  Not related ☐ |
| **Seriousness of event (Tick all that apply)** | Not serious ☐  Serious:  Results in death (Complete withdrawal form) ☐  Is life-threatening ☐  Requires hospitalisation/prolongation of existing hospitalisation ☐  Persistent/significant disability/incapability ☐  Important Medical Event (IME) ☐ |
| **Expectedness (Tick one option)** | Expected ☐  Unexpected ☐ |
| **Signature of person completing form** |  |
| **Status of participant (Tick one option)** | Continuing in trial ☐  Withdrawn (intervention), follow up continuing ☐  Withdrawn (intervention and follow-up) ☐ |

**Please return to CI within 24 hours of becoming aware of the event**. Any change of condition or other follow up information should be provided as soon as it is available or at least within 24 hours of the information becoming available. Events should be followed up until the event has resolved or a final outcome has been reached