TOPKAT

National Institute for Health Research

Total Or Partial Knee Arthroplasty Trial

Study Number | | | | | |

Serious Adverse Event and Participant Death Report Form

- Form to be completed for any related (resulted from administration of any of the research procedures) and unexpected serious adverse event or patient's death for any reason

- All information on hospital readmissions related to the study knee for 'expected' complications as listed in the protocol should be recorded on a TOPKAT readmission form.

Date of report D D / M M / Y Y Y Y

Type of Event (please tick all that apply)

Life threatening ☐

Requires inpatient hospitalisation / prolongation of hospitalisation - ☐
Other than those listed in the protocol as possible 'expected' complications following these procedures.

Results in persistent / significant disability / incapacity ☐

Other medically significant condition ☐

Resulted in death ☐

Date of Event D D / M M / Y Y Y Y

Please state where SAE occurred / was detected

Brief details of SAE

Assessment of whether event was related

Is it reasonably likely that the serious adverse event resulted from administration of any of the research procedures required by the protocol? **Yes** ☐ **No** ☐

If the causal relationship is not clear, please indicate how you came to your decision:

Was the event 'expected'

Your assessment should be based on the possible'expected' complications as listed in the protocol. **Yes (Expected)** ☐ **No (Unexpected)** ☐

Name and position of person making this judgement:

Date of Assessment D D / M M / Y Y Y Y

Any subsequent information:

Name of person initially reporting Adverse / SAE:

Contact Details

Address

Telephone

E-mail