TOPIC2 CRF completion guidelines

This document provides guidance to support the completion of the TOPIC2 CRF. If you have any queries related to CRF completion that are not covered in this guideline please email topic2@trials.bham.ac.uk.

Contents

General advice

- If any data is unavailable as it cannot be located in the source data then please write in the notes on the online database the data item concerned and that is not known e.g. arrival at theatre time not known
- Time format– all times should be in accordance with the 24hr clock
- Date format- all dates should be recorded in the following format DD/MM/YYYY

Consent and Randomisation Form

Section 4- Randomisation

Reason for lung thoracotomy? *Tick one*	◯ Lung cancer resection	◯ Other indication

- Please bear in mind reason for lung thoracotomy, if patient is having a thoracotomy for a **suspected** lung cancer, lung cancer resection should be selected.
- If patient has metastatic lung cancer and surgery is for curative intent then patient should be randomised as 'lung cancer resection', if not they should be randomised as 'other indication'. If prior to randomisation it is known that the surgery is for cancer metastases to the lung then the patient should be randomised as 'other indication'

Age	◯ <65 years	◯ ≥65 years

- Double check date of birth to ensure correct age randomisation variable is provided

Section 5- Form Completion Details

Principal Investigator Name:	Principal Investigator Signature:

- The principal investigator **does not** need to have signed the form in order to randomise the patient, this can be done post-randomisation.

Patient Completed Booklets

Site Name		Trial Number:					Initials:		

- Please ensure the above details are **always** completed prior to the booklet being given to the patient.
- The day 1 booklet should be completed on the next day following surgery, day 2 on the second day and day 3 on the third day. For example if surgery took place on the 1st, the day 1 booklet should be completed on 2nd, day 2 on 3rd and day 3 on 4th.
- Once the patient has completed a booklet during the baseline and acute phase please double check while with the patient to ensure all answers to all questionnaires have been provided. If there is missing data ask the patient if they intentionally did not answer a question or missed it by accident.
- If the patient is discharged during days 1-3, on the day of discharge ensure patient only completes the discharge booklet.
- If the patient doesn't complete the day 1, 2, 3 or discharge booklet on the relevant day this data cannot be collected retrospectively.

Intervention form

Section 3 - Analgesia

Analgesia data should record analgesia that was given **from pre-medication until the patient leaves recovery.**

- 'Premedication' refers to all analgesics prescribed by the anaesthetic / surgical team administered prior to theatre (the night before or day of surgery).
- Ensure **total doses** of opioids are given for the period from pre-medication until patient leaves recovery.

Section 5- Analgesic Intervention

Name of anaethetist who performed intervention:	

- The anaesthetist that performed the intervention and recorded in the above data item should have completed the competency log prior to performing the intervention.

Was the intervention allocated at randomisation given?	

- If the intervention failed and this was due to insertion difficulties ensure you provide further detail using the following data items:

Any difficulties during performance of analgesic intervention?	Yes If yes please complete the section below
Insertion difficulty encountered: ***Please tick if occurred***	
Bony obstruction	☐
Difficulty in positioning	☐
Multiple attempts at insertion	☐
Vascular puncture	☐
Dural puncture	☐
Other	☐

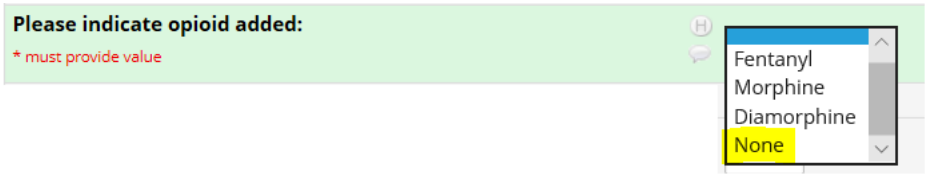
Sections 7 Local Analgesia for PVB and 9 Local Analgesia for TEB

Analgesia data should record analgesia that was given **perioperatively until the patient leaves recovery.**

Rate of infusion: *If rate varies provide rate on leaving recovery*	ml/hr

- If rate of infusion varied please ensure rate on leaving recovery is recorded.

Intervention form *continued*



- If opioid wasn't added ensure 'none' is recorded.

Top-ups PVB:
Please provide the total cumulative dose of local anaesthetic and opioid used to top-up local anaesthetic block. These are additional to single shot injections and loading catheters
If different strengths of the same local anaesthetic used, please average to derive a total dose e.g. 5ml 0.25% and 5ml 0.5% = 10ml 0.375%.
Top-ups TEB:
Please provide the total cumulative dose of local anaesthetic and opioid used to top-up local anaesthetic block. These are additional to loading bolus.
If different strengths of the same local anaesthetic used, please average to derive a total dose e.g. 5ml 0.25% and 5ml 0.5% = 10ml 0.375%.

Section 8 – TEB Details

- Please record as higher level of inter-vertebral space e.g. T4/5 insertion level should be recorded as T4.

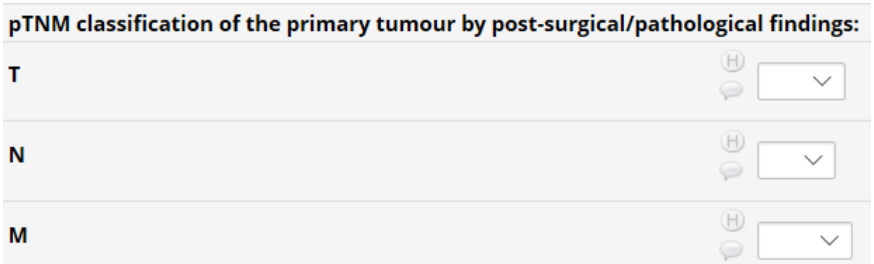
Operations Details form

Section 2- Operation Type

- If lobectomy/bilobectomy performed ensure lobe(s) are specified.

Section 4- Histology

- Staging should be taken from the pathology report after surgical resection.



- If there are more than one type of tumour pathology, please report the higher TNM.

Acute Phase Day 0 Post-recovery form

All data should be taken **from period post recovery until midnight on day of surgery**

Section 2- Management of the Local Anaesthetic Block

Was additional, unplanned involvement of the pain team required to address pain management? * must provide value	if yes indicate if block was optimised below

- The pain team is healthcare staff other than doctors.
- If patient is in pain and pain team is called anything outside of routine visit would count as additional/unplanned, this includes block management for hypotension, paraesthesia or motor weakness in arms or legs.
- If there was pain team involvement please specify whether block was optimised using the below data item:

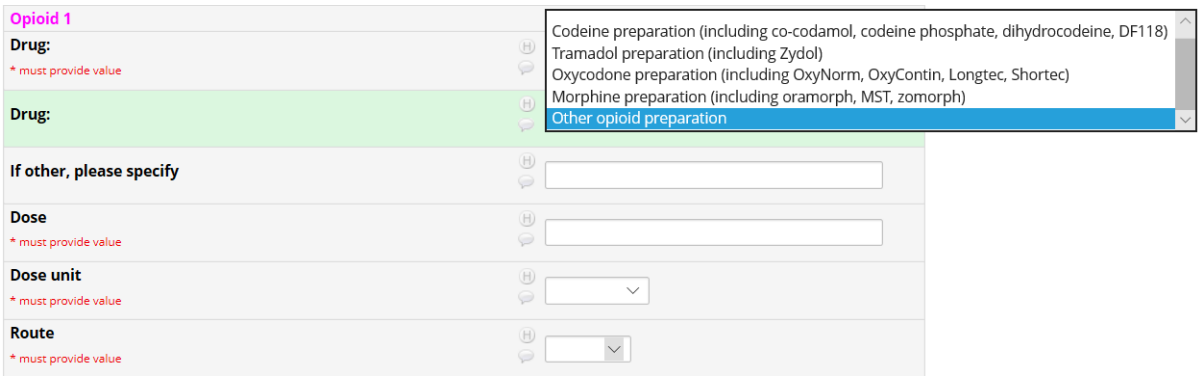
Optimise block? * must provide value	E.g. addition of bolus, increase in rate
Was additional, unplanned involvement of an anaesthetist/other doctor required to address pain management? * must provide value	if yes indicate reason below

- If patient is in pain and an anaesthetist/other doctor is called anything outside of routine visit would count as additional/unplanned, this includes block management for complications such as hypotension, paraesthesia or motor weakness in arms or legs .
- If above is selected 'yes' then ensure answers are provided to the below data items:

Optimise block? * must provide value	E.g. addition of bolus, increase in rate
Resite block? * must provide value	E.g. reinsertion of the same block or insertion of new block. If yes complete below.
What was the re-sited block? * must provide value	
If other, please specify	

Acute Phase Day 0 Post-recovery form *continued*

Section 3 - Analgesia



- For opioid doses ensure total cumulative dose of each is recorded. This includes opioids administered of the same preparation type and route, doses should be combined to give a total cumulative dose e.g. if 10mg Longtech was given BD followed by 4 x 10mg PRN doses of Shortec this should be recorded as 'oxycodone preparation' and dose 60mg.

- PCA opioid if pump is re-set please ensure that the overall cumulative total is provided reflecting totals provided by both pumps.

Acute Phase Up to Day 3 form

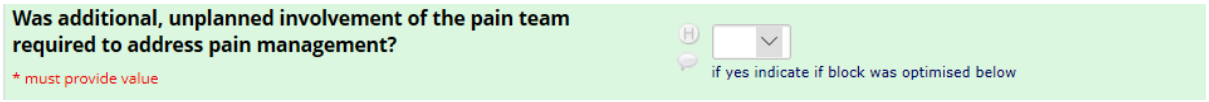
Day 1 starts at midnight on day of surgery (day 0) i.e. midnight at start of day 1 until the next midnight. Day 2 starts at the midnight of day 1 until the next midnight. Day 3 starts at the midnight of day 2 until the next midnight.

Section 2 – Post-operative Ward Care

- If the patient was located on more than one ward type on a given day only the ward type the patient was present on at midnight going into the day needs to be recorded. E.g. Day 1 - patient located on HDU from midnight to 2pm and then at 2pm – next midnight located on general ward, day 1 location would be HDU.

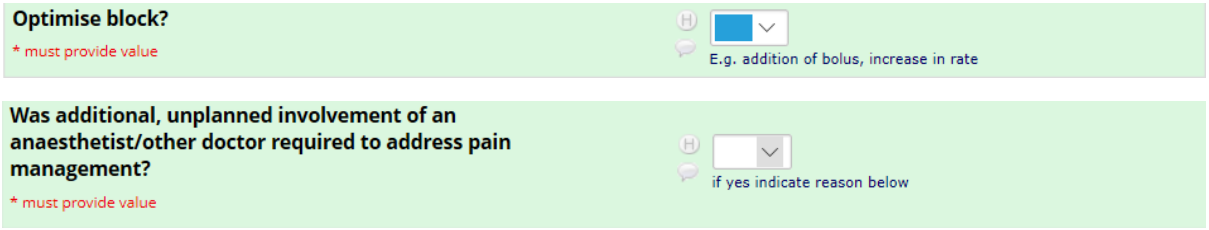
Section 3 – Management of Local Anaesthetic Block During Days 1-3

- This should cover the period from midnight at the start of day 1 to end of day 3.



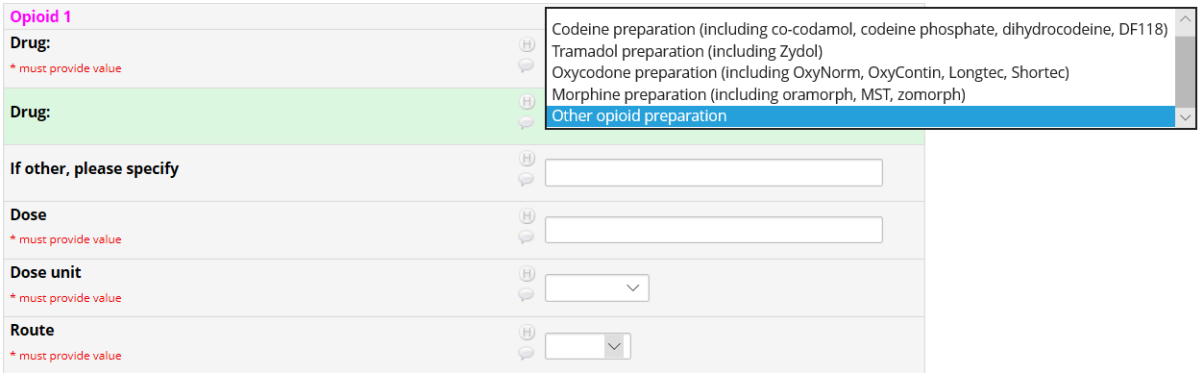
- The pain team is healthcare staff other than doctors .
- If patient is in pain and pain team is called anything outside of routine visit would count as additional/unplanned, this includes block management for hypotension, paraesthesia or motor weakness in arms or legs.

- If there was pain team involvement please specify whether block was optimised using the below data item.



- If patient is in pain and an anaesthetist/other doctor is called anything outside of routine visit would count as additional/unplanned, this includes block management for complications such as hypotension, paraesthesia or motor weakness in arms or legs.
- If above is selected 'yes' then ensure answers are provided to the below data items:

Section 4- Post-operative Analgesia



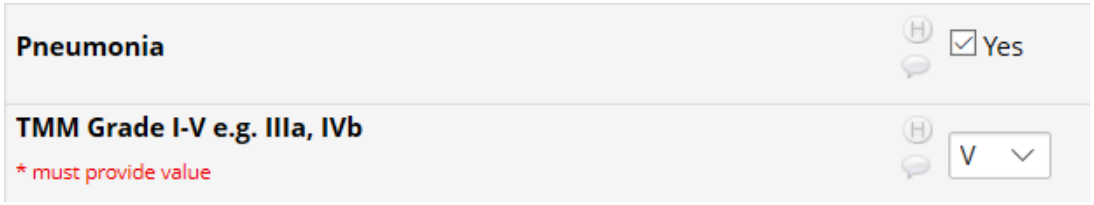
- For opioid doses ensure total cumulative dose of each is recorded. This includes opioids administered on a given day of the same preparation type and route, doses should be combined to give a total cumulative dose e.g. if 10mg Longtec was given BD followed by 4 x 10mg PRN doses of Shortec on day 1 this should be recorded as day 1 opioid 'oxycodone preparation' and dose 60mg.

- PCA opioid if pump is re-set please ensure that the overall cumulative total is provided reflecting totals provided by both pumps.

Section 5 – Complications

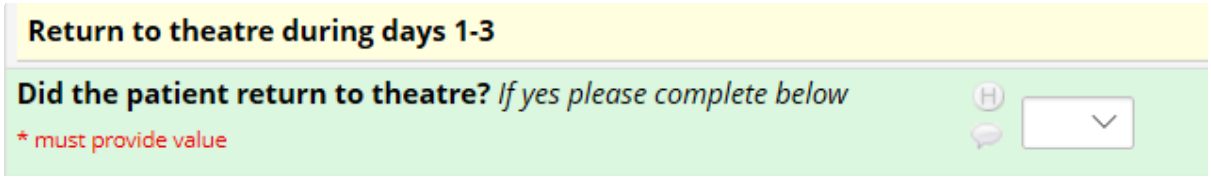
Record complications encountered covering period from recovery to the end of day 3

- For complications data refer to protocol appendices C, D and E.
- **Any complication occurring during period from intervention to end of day 3 that meets SAE definition and is a protocol defined expected event (see protocol section 9.8.1) should be recorded on this form rather than using an SAE form. Any complication that meets SAE definition and is NOT a protocol defined event should reported via SAE form.**
  PLEASE NOTE: an event only needs to be recorded on either the acute up to day 3 form or acute day 4 to discharge form depending on the date the event became serious, it does not need to be recorded on both.
- If a complication is grade V then a trial exit/change of status form should be completed and the event reported as an SAE according to the previous statement.



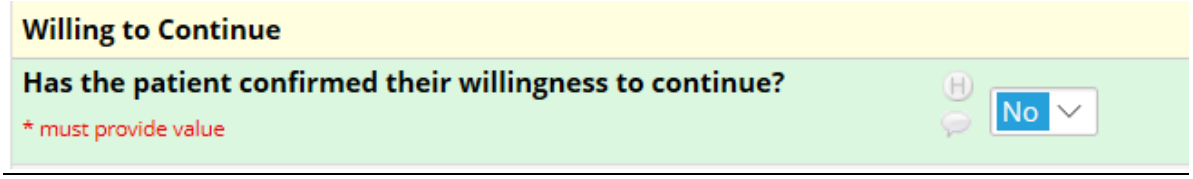
Section 6- Return to theatre during days 1-3

- This should cover the period from midnight at the start of day 1 to end of day 3



Section 9 – Willing to Continue

- If the patient is no longer willing to continue in the trial a trial exit/change of status form should be completed

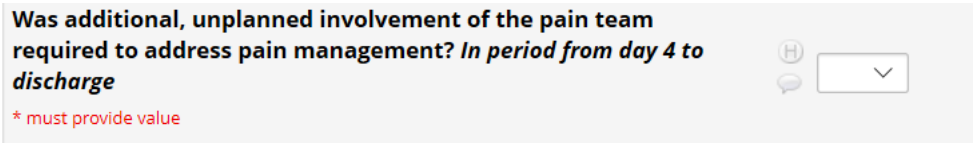


Acute Phase Days 4-Discharge Form

Section 2- Post-operative Care

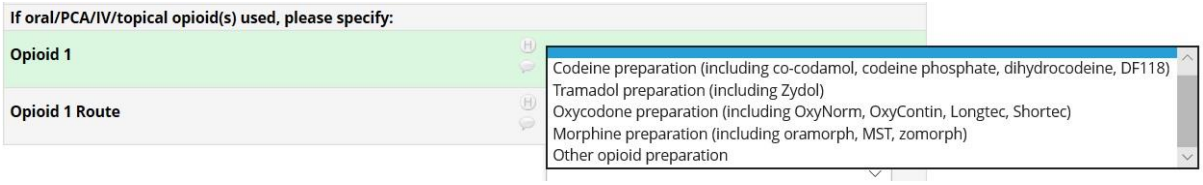
- For ward locations use same principle as days 1-3 form in that if patient was located on more than one ward type on a given day include the location patient was on at midnight into overall count. E.g. if patient was located on HDU at midnight until 4pm on day 4 and then at 4pm – the next midnight located on general ward and then discharged on day 5. Number of days on HDU would be 1 day and number of days on general ward would be 1 day.

Section 2- Post-operative care



- This should cover period from start of day 4 to discharge.
- The pain team is healthcare staff other than doctors.
- If patient is in pain and pain team is called anything outside of routine visit would count as additional/unplanned, this includes block management for hypotension, paraesthesia or motor weakness in arms or legs.

Section 3- Post-operative analgesia

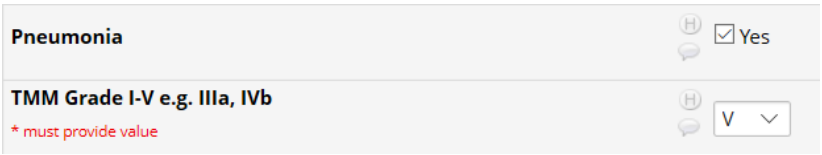


- If multiple opioids of the same preparation type and route are given e.g. oral oxycontin and oxynorm this only needs to be recorded once as 'oxycodone preparation' and route 'oral'

Section 4- Post-operative symptoms and complications

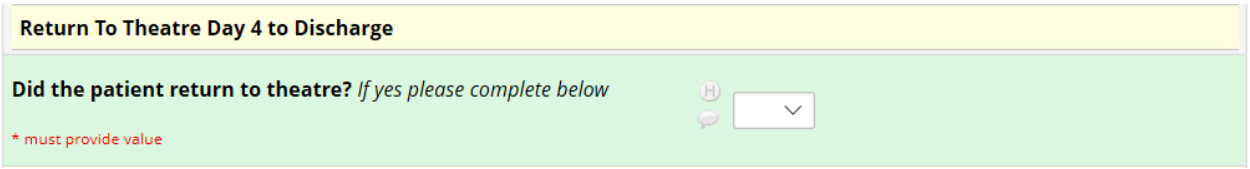
Record complications encountered covering period from start of day 4 to discharge

- For complications data refer to protocol appendices C, D and E.
- **Any complication occurring during period from start of day 4 to discharge that meets SAE definition and is a protocol defined expected event (see protocol section 9.8.1) should be recorded on this form rather than using an SAE form. Any complication that meets SAE definition and is NOT a protocol defined event should reported via SAE form**
  PLEASE NOTE: an event only needs to be recorded on either the acute up to day 3 form or acute day 4 to discharge form depending on the date the event became serious, it does not need to be recorded on both.
- If a complication is grade V then a trial exit/change of status form should be completed and the event reported as an SAE according to the previous statement



Acute Phase Days 4-Discharge Form continued

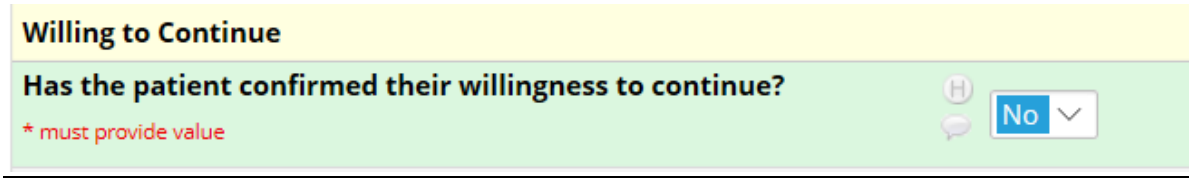
Section 5- Return to theatre day 4 to discharge



- This should cover period from start of day 4 to discharge.

Section 7 – Willing to Continue

- If the patient is no longer willing to continue in the trial a trial exit/change of status form should be completed



Healthcare Contacts Form

This data should be collected by direct interview with the patient via telephone call or seeing them at a routine clinical visit. Site staff should complete the form **not** the patient

3 month follow up covers the period from discharge to the 3 month contact. 6 month follow up covers the period from 3 month contact to 6 month contact. 12 month follow up covers the period from 6 month contact to 12 month contact

- For sections that require number of visits, number of investigations performed, number of days, overall cost (for medications) if any of the data items are not applicable **please record as '0'**

Section 3 – A+E visits

- If patient had a life threatening event and this either occurred within 30 days of intervention OR occurred more than 30 days from intervention and investigator evaluates as related to intervention then this **should be reported as an SAE**

Section 4 – Hospital Admissions

- If patient has a hospital admission that is not pre-planned and this either occurred within 30 days of intervention OR occurred more than 30 days from intervention and investigator evaluates as related to intervention then this **should be reported as an SAE**

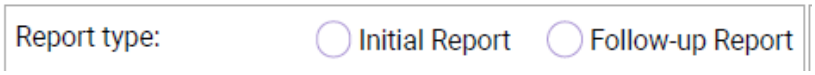
Section 10- Willing to Continue

- If the patient is no longer willing to continue in the trial a trial exit/change of status form should be completed

Serious Adverse Event Form

Ensure the event meets the reporting period for the trial: Serious adverse events should be reported from date of intervention until 30 days after the intervention. Note, protocol defined expected events that meet the SAE criteria during the patient's post-thoracotomy stay are reported in the acute data set **not** via an SAE form. All events that meet the definition of serious and judged to be at least possibly related to the intervention must still be reported in an expedited manner irrespective of how long after the intervention the event occurred.

Section 3- Report Type



- The first report submitted to the trial office should be marked as initial report and any subsequent reports marked as follow-up report

- Once an SAE no. has been provided by the trial office ensure it is recorded on the initial report and any subsequent follow up reports.

- When all information on the report is complete ensure 'is this the final report?' is marked as 'yes'

Section 5- Event Diagnosis and 9 Causality Assessment

- Event severity and relatedness should be confirmed by the PI or medically qualified delegate by signing the report however this **does not** need to done in order to submit the initial report. If you are unable to obtain it immediately still submit the report.

Serious Adverse Event Form *continued*

Section 6- Seriousness of Event

Death: *If yes please complete an Trial Exit/Change of Status Form*		◯ No ◯ Yes
Date of death: D D - M M M - Y Y Y Y	Cause of death: _____	
Life Threatening Event		◯ No ◯ Yes
In-patient Hospitalisation or Prolongation of Existing Hospitalisation:		◯ No ◯ Yes
If 'Yes', Initial or Prolonged? ◯ Initial ◯ Prolonged	If 'Yes', Date of Discharge: *e.g. 31-Jan-2017* D D - M M M - Y Y Y Y	
Persistent or Significant Disability/Incapacity:		◯ No ◯ Yes
Congenital Anomaly or Birth Defect:		◯ No ◯ Yes
Other Medical Reason For Reporting:		◯ No ◯ Yes
If 'Yes', Please Specify: _____		

- If the patient suffered an event that lead to their post thoracotomy stay being extended then this should be recorded as 'prolonged'

Section 8- Concomitant Medications

Has the patient taken any other drugs which may interact with the intervention or influence the SAE? *If yes record in below table* ◯ No ◯ Yes

- Ensure only drugs which may have interacted with intervention or influenced the SAE are recorded. **Do not** just record all drugs the patient is currently taking.
- When recording any relevant drugs ensure generic names rather than brand names are used where possible.

Section 9- Causality Assessment

If the event is unrelated, please provide details of an alternative explanation for the event: _____

- The above data item does not need to be completed in order to submit the initial SAE report to the trial office, if you are unable to ascertain this information immediately it can be provided as a follow up report.

Section 10- Details of Person Reporting

Signature of Principal Investigator or Medically Qualified Delegate: _____

- Signature of PI or medically qualified delegate **is not required** in order to submit the initial report to the trial office. If you are unable to obtain it immediately still submit the report.

Serious Adverse Event Form *continued*

Section 11- To Be Completed by Chief Investigator or Named Delegate

Section 11 - To Be Completed By Chief Investigator or Named Delegate	
Review of relatedness to the intervention by Chief Investigator or delegate:	◯ Related ◯ Unrelated
Assessment of expectedness with reference to the Protocol by Chief Investigator or delegate:	◯ Expected ◯ Unexpected
Is the event related and unexpected? *Serious related and unexpected events require reporting to the REC and sponsor*	◯ No ◯ Yes

Section 12 - Signatures	
In signing this form the Investigator or delegate confirms the Causality and Expectedness of the event	
Name of CI or Delegate:	Signature of CI or Delegate:
Date of CI or Delegate Signature: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y	

- The above is for completion by the CI or their delegate, it **should not** be completed by site.