Serious Adverse Event Reporting Form

Section 1 - Site Details

Site Name: _____ Name of PI: _____

Section 2 - Patient Details

Trial Number: ☐☐☐☐

Patient Gender: *Please tick one* ◯ Male ◯ Female

Patient Initials: *First, Middle, Last* ☐☐☐

Section 3 - Report Type

Report type: ◯ Initial Report ◯ Follow-up Report

SAE number: *Enter once provided by BCTU and ensure this is recorded on any follow up forms*
☐☐☐☐☐☐

If "Follow-up" has the new information changed the causality assessment by the PI: ◯ No ◯ Yes

Is this the final report? ◯ No ◯ Yes

Section 4 - Event Information

Signs and symptoms:

_____

_____

_____

_____

Section 5 - Event Diagnosis

Diagnosis:

_____

_____

_____

Event Severity: ◯ Mild ◯ Moderate ◯ Severe ◯ Life Threatening ◯ Fatal

Section 6 - Seriousness of Event (Each Yes/No question requires a response)

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:

_____

Please continue to next page

Trial Number: ☐☐☐☐ | Initials: *First, Middle, Last* ☐☐☐

Section 7 - Details of Event

Date of Onset: *E.g. 31-Jan-2017*
D D - M M M - Y Y Y Y

Date Became Serious: *E.g. 31-Jan-2017*
D D - M M M - Y Y Y Y

Date Became Aware: D D - M M M - Y Y Y Y

Event is Ongoing: *Tick one* ◯ No ◯ Yes

If 'No', Date Resolved: *E.g. 31-Jan-2017*
D D - M M M - Y Y Y Y

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

Concomitant Medication Table

Drug Name	Dose (including units)	Start Date (dd/mmm/yyyy)	Ongoing No (tick if applicable)	Ongoing Yes (tick if applicable)	Stop Date (dd/mm/yyyy)

Section 9 - Causality Assessment *to be completed by the PI or delegated clinician only*

Is the event related to the trial intervention? ◯ No ◯ Yes

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

List any underlying comorbidities or investigations etc. that may be relevant: *Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only*

Section 10 - Details of Person Reporting

Name of Person Reporting:

Job Title of Person Reporting:

Signature of Person Reporting: *Must appear on delegation log*

Date of Signature: *E.g. 31-Jan-2017*
D D - M M M - Y Y Y Y

Date Reported: *E.g. 31-Jan-2017* D D - M M M - Y Y Y Y

Signature of Principal Investigator or Medically Qualified Delegate:

Date of PI/Delegate Signature: *E.g. 31-Jan-2017* D D - M M M - Y Y Y Y

Return this form to the TOPIC 2 Trial Office by faxing to 0121 415 9135 or scan and email to topic2@trials.bham.ac.uk

Trial Number:	Initials: *First, Middle, Last*

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	

Section 13 - Office Use Only

SAE Reference Number:	
Date Reported to REC: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y	N/A
Date Reported to Sponsor: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y	N/A