STOP-ACEi – SERIOUS ADVERSE EVENT (SAE) FORM

- Please report any SERIOUS ADVERSE EVENTS occurring over the 36 month study period, by sending a completed copy of this form to the STOP-ACEi Trial Office in line with the reporting timeframes and definitions stated in STOP-ACEi Protocol, Section 10. If in doubt, report within 24 hours of being made aware of the event.
- All reports must be reviewed, signed and dated by the Principal Investigator (or delegated doctor) within 7 days of site's awareness of the event.
- To send an SAE report, e-mail the **anonymised** report to the trial mailbox at stopacei@trials.bham.ac.uk
- Reports should identify the participant by their trial ID number and partial date of birth ONLY. Do NOT include the patient's name, address, NHS number, hospital number, GP name/address, discharge address, next of kin details etc.

STOP-ACEi Trial Number:	☐☐☐☐	Month & year of Birth:	☐☐/☐☐☐☐
Responsible study clinician:		Hospital Name:	
Participant Gender:	Female ☐ Male ☐	Trial arm:	Continue ☐ Discontinue ☐
Report type:	Initial Report ☐	Follow-up Report ☐	Final Report ☐

Report Type Please refer to Protocol section 10

☐ SAE that is expected for the trial population and is listed in Protocol section 10.6.2. **Report within 30 days**.	→For 30 day reports, please give the event code from Protocol section 10.6.2: ☐☐
☐ SAE that is related to the trial intervention, or any reportable SAE that is not listed in Protocol section 10.6.2. **Report within 24 hours**.	

Seriousness of event (provide a response to each question)	**No**	**Yes**	**Details**
Death	☐	☐	→If Yes, date of death (DD/MMM/YYYY, e.g. 01-Jun-2018) ☐☐/☐☐☐/☐☐☐☐ Cause of death category: ☐ 1 – Cancer, 2 – Cardiovascular, 3 – Cerebrovascular, 4 – Renal, 5 – Hepatic, 6 – Respiratory, 7 – Neurodegenerative, 8 – Accidental (death not caused by disease), 9 – Other, please specify: ……
Life threatening event	☐	☐	
In-patient hospitalisation or prolongation of existing hospitalisation	☐	☐	→If Yes, ☐ Initial ☐ Prolonged →If Yes, number of days spent in hospital as result of the SAE ☐☐☐
Persistent or significant disability/incapacity	☐	☐	
Congenital abnormality or birth defect	☐	☐	
Other pertinent medical reason for reporting?	☐	☐	→If Yes, please specify: …… ……

Date Event Started (DD/MMM/YYYY, e.g. 01-Mar-2018)	☐☐/☐☐☐/☐☐☐☐
Date site became aware of event (DD/MMM/YYYY)	☐☐/☐☐☐/☐☐☐☐ **PTO**

STOP-ACEi Trial Number:	☐☐☐☐

Serious adverse event description: narrative / signs and symptoms. Please attach copies of relevant reports. Where investigations or lab tests are appended, please ensure patient identifiers are replaced with trial number only.

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Details of relevant medical history. If none, please indicate 'nil relevant'.

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Concomitant Medication. Please provide details of medication/s the patient was taking prior to the event which are relevant to the SAE. You do not need to list irrelevant medications**:**

Drug Name (give generic name)	Start date (DD/MMM/YYYY)	Tick if continuing or specify stop date (DD/MMM/YYYY)		Dose	Unit	Freq-uency	Route
				Please refer to coded list on Page 4			
____________	___/_____/____	☐	___/_____/____				
____________	___/_____/____	☐	___/_____/____				
____________	___/_____/____	☐	___/_____/____				
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____________	___/_____/____	☐	___/_____/____				

What was the final outcome of the event?

Resolved no sequelae ☐	→If Resolved, date of resolution: ☐☐/☐☐☐/☐☐☐☐
Resolved with sequelae ☐	→If Resolved, date of resolution: ☐☐/☐☐☐/☐☐☐☐ →Specific sequelae: ....
Continuing ☐	→If Continuing, please provide date of resolution on follow-up/final SAE form
Fatal ☐	

PTO

STOP-ACEi Trial Number:	☐☐☐☐

Trial intervention causality assessment. The assessment of causality must be provided by a clinician.

For the control arm (continue ACEi/ARB), is the SAE related to the particular ACEi and/or ARB the participant is taking?
For the experimental arm (discontinue ACEi/ARB), is the SAE related to the withdrawal of ACEi/ARB treatment?

Date of randomisation: (DD/MMM/YYYY)	Date last dose of ACEi/ARB taken: (DD/MMM/YYYY)	Causality Assessment. Please tick one option only.
__/_____/____	__/_____/____	☐ Unrelated to trial intervention ☐ Unlikely to be related to trial intervention } unrelated ☐ Possibly related to trial intervention ☐ Probably related to trial intervention ☐ Definitely related to trial intervention } related

Action taken due to SAE. Please tick one option only.	Please give reasons for the causality assessment provided above. If unrelated, please provide an alternative cause:
☐ ACEi/ARB stopped or (if on discontinue arm) ACEi/ARB re-started. ☐ ACEi/ARB Dose reduced ☐ ACEi/ARB Dose increased ☐ No change to ACEi/ARB use ☐ Unknown ☐ N/A , i.e. because participant not on trial treatment or has died.	…… …… …… …… ……

If treatment was altered, did the reaction abate after drug changes? No ☐ Yes ☐

Event Clinical Coding

Once resolved, the event should be coded using CTCAE v5.0, which can be found at www.birmingham.ac.uk/STOP-ACEi/CTCAE. The coded event should meet at least one of the criteria for seriousness (see page 1).

CTCAE term code: ☐☐☐ - ☐☐☐	If other, specify: ……

CTCAE grade: Please tick one option only

☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade 5

Details of person reporting (you must have signed the site delegation log)

Name of Person Reporting:	Signature of Person Reporting:
……	……
Position: ……	Date of signature: ☐☐/☐☐☐/☐☐☐☐
Telephone Number:	Email Address:
Fax Number: (state N/A if not used)	Date of first reporting:_____/_____/_____

Principal Investigator sign off

I confirm that I have reviewed this report and have assessed the seriousness, causality and clinical coding of this event.

Signature: ……	Date of signature: ☐☐/☐☐☐/☐☐☐☐

Coded Reference Lists

CTCAE Event Term Coding

The event should be coded using CTCAE v5.0, which can be found at www.birmingham.ac.uk/STOP-ACEi/CTCAE

Or via the following QR code:

Concomitant Medication Codes (Units, Route, Frequency)

Unit Codes		**Route Code**		**Frequency Code**	
1	mg	1	Intraarterial	1	Twice a day
2	µg	2	Intraperitoneal	2	Three times a day
3	g	3	Intravenous	3	Four times a day
4	puffs	4	Oral	4	Hourly
5	units	5	Respiratory (inhalation)	5	4 hourly
6	ml	6	Subcutaneous	6	Daily
7	mg/ml	7	Topical	7	Alternate days
8	mg/kg	8	Suppository	8	As desired
9	µg/ml	9	Intraocular	9	If necessary
10	AUC	10	Intramuscular	10	Slow release
97	Other, **specify**	97	Other, **specify**	97	Other, **specify**
99	Not known	99	Not known	99	Not known