



The **C**erclage **S**uture **T**ype for an **I**nsufficient **C**ervix and its effect on **H**ealth outcomes (C-STICH)

CRF7: C-STICH Serious Adverse Event Reporting Form

Please use this CRF to report any **SERIOUS ADVERSE EVENTS (SAEs)** occurring at any time following the day of consent and randomisation until the defined end of the trial (as per section 10.3 of the trial protocol). Any unresolved SAEs need to be followed up until they are resolved.

Patient's trial number:

Patient's Date of Birth (MMM-YYYY): -

Centre _____

SAE Details:

SAE Type:	IN	FU
Is this an Initial (IN) or follow up (FU) report?	<input type="checkbox"/>	<input type="checkbox"/>
	YES	NO
Is this the final report?	<input type="checkbox"/>	<input type="checkbox"/>

Reason for reporting (<i>Please tick one box only</i>):		
Maternal Death	<input type="checkbox"/>	Date of death: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Life-threatening Event	<input type="checkbox"/>	
In-patient hospitalisation or prolongation of existing hospitalisation	<input type="checkbox"/>	
Persistent or significant disability / incapacity	<input type="checkbox"/>	
Other pertinent medical reason for reporting?	<input type="checkbox"/>	
If 'Other', please specify: -		

Four empty boxes for patient trial number

SAE Details Continued:

SAE Description:

Date Event Started:

Date Event Resolved:

DD - MMM - YYYY date format boxes

DD - MMM - YYYY date format boxes

Details of SAE (Please attach copies of relevant but anonymised (containing Trial Number only) reports):

Multiple horizontal lines for SAE details

Causality Assessment (please tick one box

- Unrelated to fitted suture thread
- Possibly related to fitted suture thread
- Probably related to fitted suture thread
- Definitely related to fitted suture thread

Please give reasons if you consider the event to be treatment related:

Two dotted lines for providing reasons

Action taken due to SAE (please tick one box only)

- None
- Placement of cerclage delayed
- Cerclage removed
- Other

If 'Other', please specify:

Horizontal line for specifying 'Other' action

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Some information about you:

Your Name: _____ Position: _____ Telephone No: _____

Your name must appear on the delegation log for reporting SAEs

Investigator's Name: _____ Investigator's Signature: _____

(If not the person completing the form)

Today's Date:

D	D
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M	M	M
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Y	Y	Y	Y
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THANK YOU FOR COMPLETING THIS FORM

Please send this form by fax to the C-STICH Trial Office on **0121 415 9136**

Or via email to cstich@trials.bham.ac.uk - if emailing, include 'SAE' in the email subject

SAE Status—BCTU USE ONLY

SAE Reference Number:

Date Reported to BCTU?

D	D
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M	M	M
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Y	Y	Y	Y
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Date Reported to CI?

D	D
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M	M	M
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Y	Y	Y	Y
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Date reply received from CI?

D	D
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M	M	M
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Y	Y	Y	Y
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Does the CI consider the event to be related and unexpected?

*Yes No

***Related**—that is, it resulted from the research material; **Unexpected**—the type of event is not listed in the protocol as an expected occurrence.

CI Comments: _____

Signature: _____

If 'unexpected' and 'related' expedite to the REC.

Date reported to Main REC?

D	D
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M	M	M
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Y	Y	Y	Y
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