The Cerclage Suture Type for an Insufficient Cervix and its effect on Health 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): MMM - YYYY

Centre_____

SAE Details:

SAE Type:	**IN**	**FU**
Is this an Initial (IN) or follow up (FU) report?	☐	☐
	YES	**NO**
Is this the final report?	☐	☐

Reason for reporting (*Please tick one box only*):		
Maternal Death	☐	Date of death: DD - MMM - YYYY
Life-threatening Event	☐	
In-patient hospitalisation or prolongation of existing hospitalisation	☐	
Persistent or significant disability / incapacity	☐	
Other pertinent medical reason for reporting?	☐	

If 'Other', please specify: -

_____

_____

_____

_____

SAE Details Continued:

SAE Description:

Date Event Started: Date Event Resolved:

D D - M M M - Y Y Y Y D D - M M M - Y Y Y Y

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

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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:

……

……

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

None ☐

Placement of cerclage delayed ☐

Cerclage removed ☐

Other ☐

If 'Other', please specify:

_____

SAE Details Continued:

Concomitant Medication?: **Yes** ☐ **No** ☐ *If 'YES', please complete below:*

Drug	Start date DD-MMM-YYYY	Tick if Continuing?	Or, specify stop date DD-MMM-YYYY	Dose (mg)	Indication
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			
		☐			

Outcome of SAE: **Fatal** ☐ **Recovered** ☐ **Continuing** ☐

If continuing, please describe the latest outcome at the time of faxing the initial report:

_____

_____

_____

_____

_____

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 - M M M - Y Y Y Y

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 - M M M - Y Y Y Y

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

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

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 - M M M - Y Y Y Y