Cups or Cash for Girls (CCg) Trial			***Serious Adverse Event Form*** **Sponsor: Liverpool School of Tropical Medicine, lstmgov@lstmed.ac.uk, pv@lstmed.ac.uk**		
Participant ID		**Date of report**	__ __ - __ __ __ - __ __ __ __	**SAE no.**	

Type of report	☐ **Expedited** ☐ **Full**		
SECTION A: PATIENT DETAILS			
Age (years)		**Or date of birth (DD-MMM-YYYY)**	__ __ - __ __ __ - __ __ __ __
Relevant medical history including pre-existing medical conditions			
Informant relationship to participant i.e mother; clinic nurse; teacher; etc		**Contact details of informant (phone number, address etc)**	
SECTION B: SERIOUS ADVERSE EVENT AND INVESTIGATIONS			
Main diagnosis			
Description of event (include details of all signs, symptoms and events that have occurred at the time of the main event)	*In cases of violence, please describe the nature of the violence and the clinical outcome for the patient i.e. any bruises, broken bones, cuts etc. Indicate on the diagram in appendix A the type and location of injuries on the body provided.* *Use continuation sheet if necessary. Tick if continuation sheet used* ☐ *How many pages?*		
Date of onset/occurrence (DD-MMM-YYYY)	__ __ - __ __ __ - __ __ __ __	**Date resolved (DD-MMM-YYYY)** **Or tick if ongoing**	__ __ - __ __ __ - __ __ __ __ ☐

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Record details of investigations/relevant tests/laboratory data (including dates)	Investigation/test	Date	Result

SECTION C: EVENT ASSESSMENT

When completing below please refer to definition guide at the end of this document

Action taken	☐ None	☐ Admitted as inpatient to hospital; name of hospital_____
	☐ Medication given; specify _____	☐ Intervention (cash and/or cup) withdrawn
	☐ Referred to hospital OPD/health facility; name of hospital/health facility _____	☐ Other; Specify_____
Outcome	☐ Resolved	☐ Not resolved
	☐ Resolving/partly resolved	☐ Fatal
	☐ Resolved with sequelae	☐ Unknown
Maximum severity	☐ Mild	☐ Severe ☐ Fatal
	☐ Moderate	☐ Life threatening ☐ Unable to assess

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Seriousness	☐ Death ☐ Life threatening ☐ Hospitalisation ☐ Prolongation of existing hospitalisation ☐ Persistent or significant disability ☐ Other	***If death:*** **Date of death (DD-MMM-YYYY)** __ __ - __ __ __ - __ __ __ __
	If other, specify	***If hospitalisation:*** **Date admitted (DD-MMM-YYYY)** __ __ - __ __ __ - __ __ __ __ **Date discharged (DD-MMM-YYYY)** __ __ - __ __ __ - __ __ __ __

SECTION D: INTERVENTION

Cup ☐	**Cash** ☐	**Cup & Cash** ☐	**Usual practice (control)** ☐

If the event is related to menstrual or vaginal health, complete the following questions:

Was the girl having her monthly period at time of event?	☐ **Yes** ☐ **No**	**Did the girl have an item inserted in her vagina at time of event?**	☐ **Yes** ☐ **No**
If not at time of event, did she have an item inside her vagina on a recent day prior to the event (just removed)?	☐ **Yes** ☐ **No**	**Name of item which was inserted in vagina:**	☐ **Rags** ☐ **Grass** ☐ **Newspaper** ☐ **Foam/bedding** ☐ **Sanitary pads** ☐ **Traditional medicine** ☐ **Cup** ☐ **Tissue paper** ☐ **Cotton wool** ☐ **Other; Specify** _____

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SECTION E: OTHER MEDICINE(S)/SUBSTANCE(S)

Were any other medicines taken up to two weeks prior to the onset of SAE? ☐ Yes ☐ No

If yes, complete a concomitant drugs form and send with this SAE form

Were any traditional medicines taken up to two weeks prior to the onset of SAE? ☐ Yes ☐ No

If yes, give details	

Were any other substances (e.g. alcohol, recreational drugs) taken in the two weeks prior to the onset of SAE? ☐ Yes ☐ No

If yes, give details	

SECTION F: CAUSALITY ASSESSMENT

Using the key below, insert number in the box to indicate causality for each intervention relevant to the patient. If the patient has not received the specified intervention, enter "7".
*If you suspect the event is related to something **other** than the intervention(s), enter the causality in the 'other' box and provide further details on the continuation sheet.*

Causality	1. Certain 2. Probable/likely 3. Possible 4. Unlikely 5. Unrelated 6. Unassessable 7. Not applicable (i.e. participant not receiving the intervention)	Cup ☐ Cash ☐ Other ☐

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SECTION F: CAUSALITY ASSESSMENT *(continued)*		
If the answer to the above is 1, 2 or 3 for any intervention, complete the following assesments ***FOR THE RELEVANT INTERVENTION ONLY***		
Action taken due to adverse event	1. Intervention/other withdrawn 2. Intervention/other withheld 3. None 4. Not applicable 5. Unknown	Cup ☐ Cash ☐ Other ☐
De-challenge	1. Improved when intervention/other stopped 2. No improvement when intervention/other stopped 3. Not applicable (no de-challenge undertaken) 4. Unknown	Cup ☐ Cash ☐ Other ☐
History with suspected intervention/other	1. Not used before 2. Used before, this event **did not** occur 3. Used before, this event **did** occur 4. Unknown	Cup ☐ Cash ☐ Other ☐

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SECTION G: REPORTER DETAILS			
Reporter Name		**Reporter Position**	
Reporter Signature		**Date (DD-MMM-YYYY)**	__ __ - __ __ __ - __ __ __ __
SECTION H: PRINCIPAL INVESTIGATOR RECEIPT			
PI Name			
PI Signature		**Date (DD-MMM-YYYY)**	__ __ - __ __ __ - __ __ __ __

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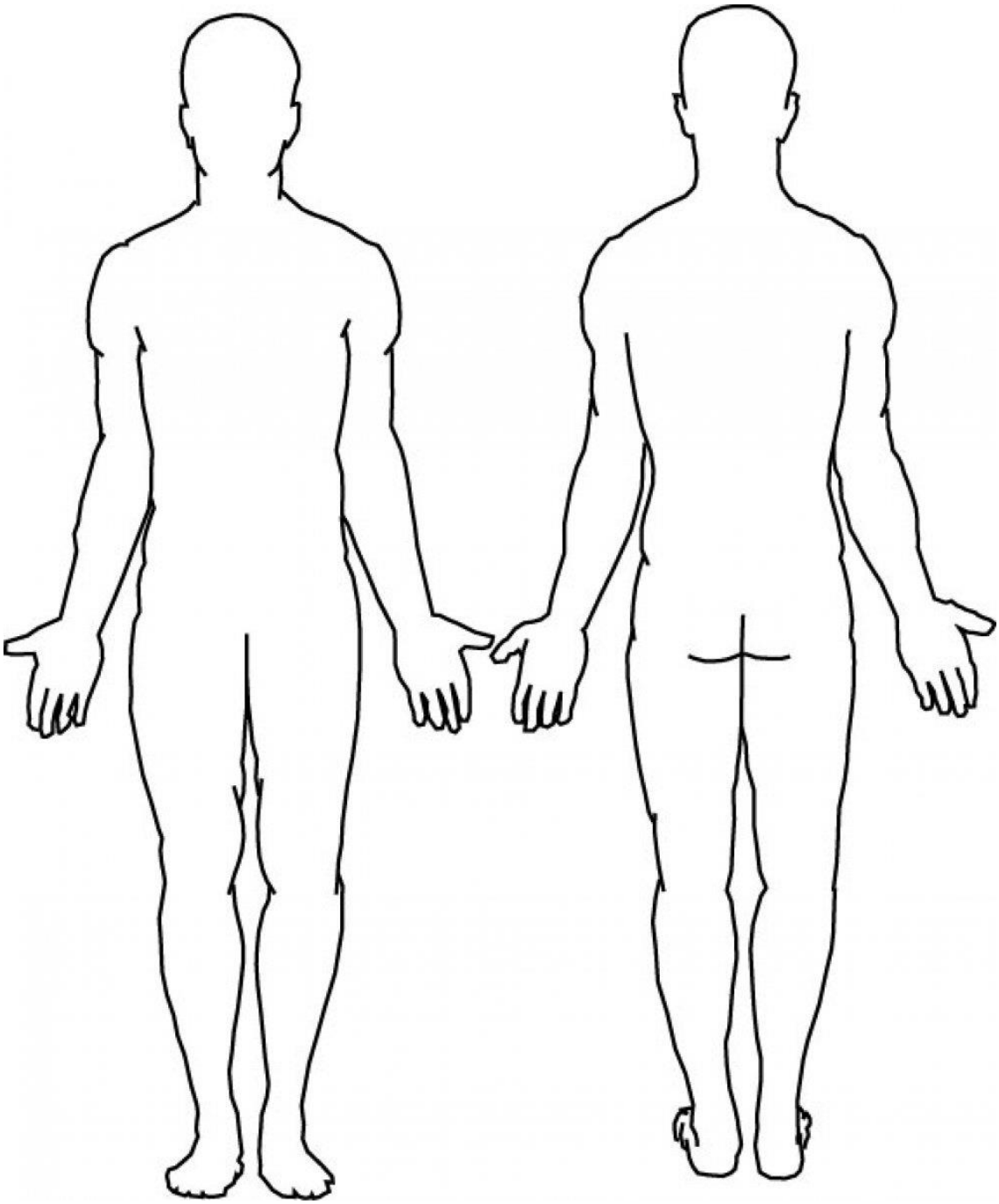
Appendix A. Body diagram – if appropriate, please indicate location of illness, infection, or injuries

APPENDIX A. BODY DIAGRAM
Please indicate with an arrow and words the location, and the type of illness, infection, or injuries on the diagram below (includes severe pain or bleeding)



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APPENDIX B. CONTINUATION SHEET