UIN: ☐☐☐|☐☐☐

INFORMED CONSENT FORM – PARENT/GUARDIAN OF PARTICIPANTS UNDER 16 YEARS OF AGE

The effect of early cryoprecipitate transfusion versus standard care in women who develop severe postpartum haemorrhage: A pilot cluster randomised trial

(ACROBAT: Administering CRyoprecipitate in Obstetric Bleeding At an earlier Time)

REC Reference number: 18/LO/2062
Local principal investigator name: _____

		Please initial box
1.	I confirm that I have read and understood the parent/guardian information sheet dated _____ version ____ the above study. I have had the opportunity to consider the information, ask questions about the study and have had these answered satisfactorily.	
2.	I understand that my daughter's participation is voluntary and that if I agree for her to take part, we are free to withdraw at any time, without giving a reason and without my daughter's medical care or legal rights being affected.	
3.	If in the course of the study my daughter or I change our minds about taking part, I understand that any data already collected will be analysed.	
4.	I understand that the information collected will be used for medical research only, including academic publications, and data about my daughter may be shared anonymously with other researchers. If we give consent, my daughter will be given a Unique Identification Number (UIN) in order to ensure that her data remains confidential.	
5.	I understand that relevant sections of my daughter's medical notes and data collected during the study may be looked at by individuals from the research team, sponsor (Queen Mary University of London), regulatory authorities or the NHS Trust, where it is relevant to my daughter taking part in this research. I give permission for these individuals to have access to my daughter's medical records.	
6.	I agree to our GP being informed of my daughter's participation in the ACROBAT study.	
7.	I understand what is involved in the ACROBAT study and agree for my daughter to participate. I allow the hospital to transfer de-identified, routinely collected data about my daughter's hospital treatment to the study organisers.	

You will be provided with a copy of this signed consent form.

_____	_____
Name of participant under 16 years	Relationship of legal representative to participant

_____	_____	_____
Name of parent/guardian	Signature	Date
_____	_____	_____
Name of researcher	Signature	Date

Statement of interpreter (where appropriate): I have interpreted the information above to the best of my ability and in a way in which the participant's legal representative can understand.

_____	_____	_____
Name of interpreter	Signature	Date

1 copy for parent/guardian, 1 for participant's medical notes, original to be kept in Investigator Site File.