UIN: ☐☐☐|☐☐☐

INFORMED CONSENT FORM – STUDY PARTICIPANT

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 participant information sheet dated _____ version ___ for 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 participation is voluntary and that if I take part, I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3.	If in the course of the study I change my mind about taking part, I understand that any data already collected will be analysed.	
4.	I understand that if I lose the capacity to consent at any point during the study, no additional tests will be conducted for research purposes. In such a case, I agree for the researchers to use any previously collected research data and any further data collected as part of routine clinical practice.	
5.	I understand that the information and blood samples collected will be used for medical research only, including academic publications, and data about me may be shared anonymously with other researchers. I will be given a Unique Identification Number (UIN) in order to ensure that my data remain confidential.	
6.	I understand that the information held by the NHS may be used to keep in touch with me and to follow up my health status, and that I may be contacted by the research team in the future to be invited to take part in future studies. I understand that I do not have to take part in any future research if I did not wish to.	
7.	I understand that relevant sections of my 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 taking part in this research. I give permission for these individuals to have access to my medical records.	
8.	I agree to my GP being informed of my participation in the ACROBAT study.	
9.	I understand what is involved in the ACROBAT study and agree to participate. I allow the hospital collect de-identified routine data about me.	
10.	**Optional:** I agree for the research team to collect additional data and analyse leftover blood samples.	
11.	**Optional:** I agree to be contacted by a researcher from Queen Mary University of London about taking part in an interview about my experience of being included in this study.	

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

_____	_____	_____
Name of participant	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 can understand.

_____	_____	_____
Name of interpreter	Signature	Date

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