Appendix (1): Examples of the ESTEEM study consent forms

esteem

UTIN: ☐☐|☐☐☐☐

Barts Health NHS
NHS Trust

Barts and The London
School of Medicine and Dentistry

PARTICIPANT CONSENT FORM

Title of project: Effect of simple, targeted diet in pregnant women with metabolic risk factors on pre-eclampsia (ESTEEM): A randomised trial

Please initial each box to confirm consent

1.	I confirm that I have read and understood the information sheet dated 17th July 2014 version 2.0 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 decide not to continue I understand that any collected data will be analysed, unless I specify otherwise.	
4.	I understand that the information and samples collected will be used for medical research only, including academic publications. I will be given a Unique Trial Identification Number (UTIN) in order to ensure that me and my baby's data are anonymous.	
5.	I understand that my healthcare professional will provide a copy of my consent form and personal information about me and my pregnancy, in confidence, to the central organisers at the Women's Health Research Unit at Queen Mary University London for use in the ESTEEM trial in accordance with the data protection act.	
6.	I understand that the information held by the NHS may be used to keep in touch with me and to follow up the health status of me and my baby and that I may be contacted by the research team in the future to be invited to take part in future studies. I agree to be contacted for these purposes	
7.	I understand that relevant sections of me or my baby's medical notes and data collected during the study may be looked at by individuals from the research team, 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 records.	
8.	After entering the study, if I am found not to be at risk of pre-eclampsia, I give permission for my medical records to be accessed to obtain my delivery outcome data	
9.	I agree to my GP being informed of my participation in the ESTEEM trial.	
10.	I understand what is involved in the ESTEEM trial and agree to participate.	

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

Name of participant	Signature	Date
Name of person taking consent	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 patient can understand.

Name of interpreter	Signature	Date

1 copy for Patient, 1 for hospital medical notes and original to be kept in ESTEEM Investigator Site File

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CONSENT TO DONATION AND STORAGE OF TISSUE SAMPLES FOR FUTURE MEDICAL RESEARCH

Patient details (or affix pre-printed label)

Patient's full name:	Name of Investigator: Professor Shakila Thangaratinam
Date of birth:	Research Ethics Committee Ref: 14/EE/1048
Hospital number (or other identifier):	Description of tissue/sample to be taken: **Umbilical cord blood sample**

Tissue collected as part of the present research project and/or procedure may be stored and used by the Barts Health NHS Trust, Queen Mary's School of Medicine and Dentistry, and approved external research organisations for future medical research.

Samples used for research may contain personal information but all such information will be anonymised at the end of any project, when the results are published, and you will not receive the results of any future research project. All staff undertaking future studies will abide by the Data Protection Act 1998 with any medical information relating to you being kept confidential. The tissue may be given to external research organisations for approved medical research but tissue will not be sold, although costs will be recovered without any financial benefit to either you or to the researcher. All tissue will be disposed of lawfully when it is no longer required.

	Patient Initials
I understand that additional tissue (described above) will be taken during my treatment / investigation and will not be used for diagnostic purposes. I agree that this additional tissue will be stored in a Research Tissue Bank for future research.	☐
I accept that I have given my consent voluntarily to the storage of this additional tissue and that I am free to withdraw my consent at any time and the tissue to be destroyed.	☐
I agree that the tissue may be used for future genetic research but not for research that involves reproductive cloning, or be tested for inherited diseases (other than diabetes, obesity or cardiovascular disease) without my express consent.	☐
I agree that my health records may be used by authorised members of staff who are not directly involved in my clinical care and my hospital number is written above.	☐
I agree for cord blood samples taken from me to be stored for use in future ethically approved research	☐

If you have any preferences or exclusions for use of the donated tissue, or any other comments, please include them here:

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

1 copy for Patient, 1 for hospital medical notes and original to be kept in ESTEEM Investigator Site File