

Participant trial number: _____

Please add following participant randomisation

Site: _____



ABA-feed STUDY

PARTICIPANT CONSENT FORM

Chief Investigator: **Prof Kate Jolly**

Please initial inside each box

| | | |
|----------|---|-------------------------|
| 1 | I confirm that I have read and understood the information sheet, dated __/__/____ version ____ for the ABA-feed study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. | <i>Woman's initials</i> |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used. | <i>Woman's initials</i> |
| 3 | I agree for my contact details to be passed onto the ABA-feed infant feeding team and for details about when I give birth to be passed to the research team and to the ABA-feed infant feeding team. | <i>Woman's initials</i> |
| 4 | I understand that my local research team will provide a copy of my consent form, which identifies me by name, and personal information about my progress, in confidence, to the study organisers at the University of Birmingham where my data will be stored for use in the ABA-feed study. I agree to the transfer and storage of this data. | <i>Woman's initials</i> |
| 5 | I understand that relevant sections of my and my baby's medical notes (including those from my NHS maternity provider), any infant feeding support records collected by the ABA-feed infant feeding team and information collected during the study may be looked at by regulatory bodies, individuals from the University of Birmingham and the ABA-feed research team, where it is relevant to my taking part in this research. The Sponsor may appoint a third party to access my identifiable data. I give permission for these individuals to have access to my medical and research records. | <i>Woman's initials</i> |
| 6 | Information collected that identifies me by name and date of birth and includes my contact details (contact details form), will be transferred from where it is collected and securely stored at the <i>University of Birmingham</i> and my NHS maternity care provider. I agree to the transfer and storage of this information and that my NHS provider will contact the trial provider and inform them if I no longer wish to participate. | <i>Woman's initials</i> |
| 7 | I understand that the study researchers may contact me for follow up by letter, telephone, SMS text message or email to remind me to complete the questionnaires or to ask me questions. | <i>Woman's initials</i> |
| 8 | I agree to my study number and mobile telephone number being passed to a private company (Textlocal) who will send me text messages to follow-up how my baby and I are doing. I understand that my study number, telephone number and responses will be encrypted whilst being stored by Textlocal and my data will not be used by them for any other purpose. Once my responses have been transferred from Textlocal to the study database held at the University of Birmingham I understand that Textlocal will securely delete all of my and my baby's data that they hold. I understand that if I travel outside of the European Economic Union (EEA) then any text message sent to me may pass through a non-EEA server. | <i>Woman's initials</i> |
| 9 | I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised. | <i>Woman's initials</i> |

| | | |
|-----------|---|-------------------------|
| 10 | I agree to take part in the ABA-feed study. | <i>Woman's initials</i> |
| 11 | I consent to my anonymised data being stored for use in future ethically approved research. (optional) | <i>Woman's initials</i> |
| 12 | I agree that the research team can contact my GP when my baby is 12 months old to request information about any general practice consultations or hospital admissions my baby or I have had during my baby's first year of life. (optional) | <i>Woman's initials</i> |
| 13 | I agree to be approached in the future to ask how my baby and I are getting on. (optional) | <i>Woman's initials</i> |

Name of Participant

Date

Signature

Name of Person taking Consent

Date

Signature

Please tick if this consent was given remotely over the phone or via video call?

When completed: 1 for participant, 1 for hand held maternity record, 1 for Investigator Site File, 1 for UoB Trials Unit