- Preterm infants can be recruited up to 3 months post EDD, either in-person at the recruiting site, or remotely after transfer to another hospital. Preterm infants cannot be consented after discharge home.
- HIE infants can be recruited up to EDD plus 28 days, either in-person at the recruiting site, or remotely after transfer to another hospital, or after discharge home.

Who can take consent?

- Any healthcare professional may obtain consent for the DOLFIN study, however they must have undertaken GCP training as per local trust policy, DOLFIN study-specific training, and be delegated to take consent on the **DOLFIN Site Delegation Log**.

The final assessment of eligibility of the infant for DOLFIN must be confirmed by a delegated individual, as per the **DOLFIN Site Delegation Log**, and documented in the infant's medical records

Who can give consent?

Where possible, both parents should be involved in the consent process, however, only parents with legal parental responsibility for the infant can sign to consent to the study.
Legal parental responsibility is defined as either:

- Birth mother
- Father/partner who meets one of the following criteria:
  - Married or in a civil partnership with the child's birth mother
  - Listed on the birth certificate; has a parental responsibility agreement with the mother; has a parental responsibility order from a court

One parent with legal responsibility is permitted to give informed consent on behalf of the infant, **however, if the mother does not provide the original consent, maternal consent must be requested as soon as practically possible for maternal data collection purposes**.

Parent questionnaires contain some maternal outcomes and it is preferable that the mother completes them. However it is possible for another care giver to complete them if required (preferably the same person each time).

Where the mother is under 16 years of age, they may be approached for consent by the clinical team, if they are determined to be competent according to the Fraser Guidelines.

If a parent's capacity to give informed, voluntary consent is in doubt, their infant should not be recruited.

Where there is a disagreement amongst parents regarding the infant's participation, the infant should not be recruited.

Approaching families

- Once infants have been identified (see **Guidance Sheet 1 - Screening & Eligibility**), the clinical team should approach parents to discuss the study and request consent.
- Parents should be provided with the relevant **Parent Information Leaflet (PIL)** (preterm or HIE) and given time to read and discuss it with the clinical team. The PIL may be provided as a hardcopy leaflet, or as an electronic copy via email.
- The **DOLFIN Summary PIL** and **DOLFIN Easy Read PIL** may be used as supplementary documents to support consent discussions but consent must be taken on the basis of the main study PILs.
- Remote consent may be taken according to remote consenting guidance for eligible infants where in-person consent is not possible, for example if an infant has been discharged home (HIE infants) or transferred to a continuing care site (preterm or HIE infants) before consent can be taken.
- For preterm infants, consent (and randomisation) can be taken up to 3 months post EDD and prior to discharge home. Preterm infants can be consented in-person at the recruiting site, or remotely after transfer to another hospital. Preterm infants cannot be consented after discharge home.
- For HIE infants, consent (and randomisation) can be taken up to EDD plus 28 days. Please ensure site staff and parents are aware of the date after which the infant can no longer be enrolled in the study. Infants in the HIE stratum may be consented in person at the recruiting site, or remotely after transfer to another hospital or after discharge home.
- Consent can be obtained even if the infant has not yet reached full feeds and so will not commence supplement straight away. This is to ensure that infants do not become ineligible before they are consented and randomised. Infants must be both consented and randomised to be enrolled on the study. See **Guidance Sheet 3 – Randomisation**.

This project was funded by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. (Project number NIHR 130925).

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Key points to discuss with parents:

- Ensure parents are aware that participation is voluntary and that they can change their consent at any time without giving a reason. If they decide not to participate, it will not affect their baby's current or future NHS treatment and care.
- Babies born very early or who have difficulties around birth have a higher risk of problems with neurological child development than babies born close to their due date.
- The study aims to find out if adding a daily nutrient supplement to a baby's usual milk or weaning food can help improve their neurological child development (such as how they think, communicate, play and interact with others).
- The treatment supplement contains nutrients needed for healthy brain development, within Recommended Daily Amounts. The control supplement contains most of the same nutrients as the treatment supplement but in much smaller amounts.
- A small UK study using the same supplement showed it was safe, and that it may improve neurological child development, but we need to find out more.
- Nutritional supplements are often given to babies and there are no additional risks involved with taking part in the study. Whilst there may not be any direct benefit in taking part, participation may help improve future care for babies.

Taking part

- Their baby will have an equal chance of being in either study group; treatment supplement or control supplement. Parents cannot choose which supplement their baby will receive.
- Joining the study involves parents giving the supplement daily to their baby until 12 months post estimated date of delivery (EDD).
- Parents will be asked to complete questionnaires at randomisation, discharge home, and 3, 6, 12, 18 and 24 months post EDD.
- Parents are asked to provide information about whether they have given the supplement or not. This can be done using the study app, a link sent via text or email, or by completing a paper diary.
- Parents are asked to submit monthly weights to ensure correct dosing. Sites will contact parents once a month for the first 6 months to check dosing. Parents can request for this to be more or less frequent.
- We will keep all data safe and secure, and follow all privacy rules, including the General Data Protection Regulation (GDPR) and the Data Protection Act. It will not be possible to identity participants from any presentation, report or publication that may arise from this study.

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Completing DOLFIN Consent Form

Written informed consent **must** be obtained using **the DOLFIN Consent Form** (for in-person consent) or the **DOLFIN Remote Consent Form** (for remote consent) before an infant can be randomised to DOLFIN or any study procedures take place.

In-person consent using paper DOLFIN Consent Form

The **DOLFIN Consent Form** must be signed and dated by the parent(s) and the healthcare professional taking consent.

- Please complete the consent form in block capitals. Ensure all boxes are initialled and completed, the writing is clearly legible, and details have transferred through all three copies of the form.
- Parents should initial (not tick) each box before signing and dating the form (do not complete in advance).
- The dates for the parent/s and healthcare professional signatures must be the same. Parents must not be given a consent form to sign at a later date.
- For parents, if someone other than the mother signs the consent form, a counter-signature from the mother should be obtained as soon as practically possible for maternal data collection purposes.
- Points 11, 12, 13, and 14 on the **DOLFIN Consent Form**, which relate to measuring whether there are long term neurological development effects from giving the supplement, are optional and whilst we would like parents to agree due to their importance, they are not mandatory for taking part in the DOLFIN study.
- Separate consent forms will be required for twins, triplets etc. Please make this clear on the consent form e.g. FIRST NAME (TWIN 1), LAST NAME.

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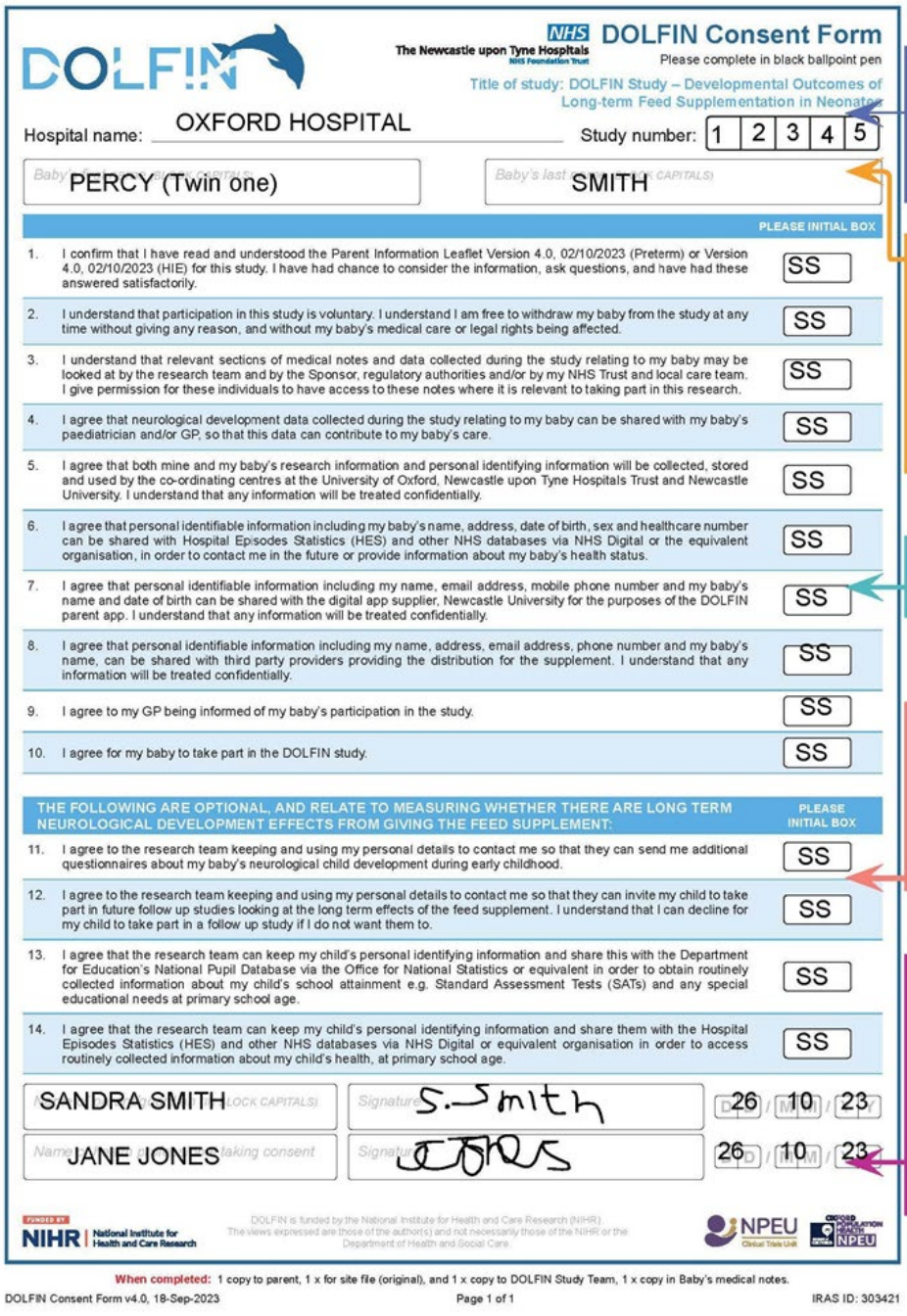
DOLFIN Consent Form



DOLFIN

The Newcastle upon Tyne Hospitals NHS Foundation Trust

NHS DOLFIN Consent Form

Please complete in black ballpoint pen

Title of study: DOLFIN Study – Developmental Outcomes of Long-term Feed Supplementation in Neonates

Hospital name: OXFORD HOSPITAL

Study number: 1 2 3 4 5

Baby's first name (BLOCK CAPITALS): PERCY (Twin one)

Baby's last name (BLOCK CAPITALS): SMITH

		PLEASE INITIAL BOX
1.	I confirm that I have read and understood the Parent Information Leaflet Version 4.0, 02/10/2023 (Preterm) or Version 4.0, 02/10/2023 (HIE) for this study. I have had chance to consider the information, ask questions, and have had these answered satisfactorily.	SS
2.	I understand that participation in this study is voluntary. I understand I am free to withdraw my baby from the study at any time without giving any reason, and without my baby's medical care or legal rights being affected.	SS
3.	I understand that relevant sections of medical notes and data collected during the study relating to my baby may be looked at by the research team and by the Sponsor, regulatory authorities and/or by my NHS Trust and local care team. I give permission for these individuals to have access to these notes where it is relevant to taking part in this research.	SS
4.	I agree that neurological development data collected during the study relating to my baby can be shared with my baby's paediatrician and/or GP, so that this data can contribute to my baby's care.	SS
5.	I agree that both mine and my baby's research information and personal identifying information will be collected, stored and used by the co-ordinating centres at the University of Oxford, Newcastle upon Tyne Hospitals Trust and Newcastle University. I understand that any information will be treated confidentially.	SS
6.	I agree that personal identifiable information including my baby's name, address, date of birth, sex and healthcare number can be shared with Hospital Episodes Statistics (HES) and other NHS databases via NHS Digital or the equivalent organisation, in order to contact me in the future or provide information about my baby's health status.	SS
7.	I agree that personal identifiable information including my name, email address, mobile phone number and my baby's name and date of birth can be shared with the digital app supplier, Newcastle University for the purposes of the DOLFIN parent app. I understand that any information will be treated confidentially.	SS
8.	I agree that personal identifiable information including my name, address, email address, phone number and my baby's name, can be shared with third party providers providing the distribution for the supplement. I understand that any information will be treated confidentially.	SS
9.	I agree to my GP being informed of my baby's participation in the study.	SS
10.	I agree for my baby to take part in the DOLFIN study.	SS

THE FOLLOWING ARE OPTIONAL, AND RELATE TO MEASURING WHETHER THERE ARE LONG TERM NEUROLOGICAL DEVELOPMENT EFFECTS FROM GIVING THE FEED SUPPLEMENT:		PLEASE INITIAL BOX
11.	I agree to the research team keeping and using my personal details to contact me so that they can send me additional questionnaires about my baby's neurological child development during early childhood.	SS
12.	I agree to the research team keeping and using my personal details to contact me so that they can invite my child to take part in future follow up studies looking at the long term effects of the feed supplement. I understand that I can decline for my child to take part in a follow up study if I do not want them to.	SS
13.	I agree that the research team can keep my child's personal identifying information and share this with the Department for Education's National Pupil Database via the Office for National Statistics or equivalent in order to obtain routinely collected information about my child's school attainment e.g. Standard Assessment Tests (SATs) and any special educational needs at primary school age.	SS
14.	I agree that the research team can keep my child's personal identifying information and share them with the Hospital Episodes Statistics (HES) and other NHS databases via NHS Digital or equivalent organisation in order to access routinely collected information about my child's health, at primary school age.	SS

Name of person taking consent (BLOCK CAPITALS)	Signature	Date (DD / MM / YY)
SANDRA SMITH	S. Smith	26 / 10 / 23
JANE JONES	J Jones	26 / 10 / 23

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NPEU Clinical Trials Unit | Oxford Population Health NPEU

When completed: 1 copy to parent, 1 x for site file (original), and 1 x copy to DOLFIN Study Team, 1 x copy in Baby's medical notes.

DOLFIN Consent Form v4.0, 18-Sep-2023 Page 1 of 1 IRAS ID: 303421

After consent, obtain a study number from the Randomisation website and write study number here

Differentiate between multiples (for example, infants can be named as TWIN ONE, TWIN TWO). Where first name is not yet confirmed, write down as Baby

Initial the boxes, not tick

This is optional consent and can be left blank if they do not wish to be contacted in the future

Both the parent providing consent and the health professional taking consent must sign the form. Both signatures should be on the same date.

GUIDANCE SHEET 2

This project was funded by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. (Project number NIHR 130925).

Remote consent using DOLFIN Remote Consent Form

Consent may be obtained remotely (via telephone or video call) for eligible infants if in-person consent is not possible, for example if an infant has been discharged home or transferred to another hospital before consent can be taken.

- Remote consent should be of the same standard as in-person consent as outlined above.
- The health professional taking remote consent must complete the identity checks and confirm the parent's name and address, and the infant's name, address and date of birth. It must be documented in the medical notes that a parent with legal parental responsibility consented to the ID checks during the consent process. The health care professional must ensure that the parent has verbally agreed to each consent item **by initialling the boxes with their own initials** (not the parent's initials).
- Please complete the consent form in block capitals. Ensure all boxes are initialled and completed, the writing is clearly legible, and details have transferred through all three copies of the form.
- The health professional taking consent should initial (not tick) each box before signing and dating the form (*do not complete in advance*).
- For parents, if someone other than the mother gives consent, confirmation of consent from the mother should be obtained as soon as practically possible for maternal data collection. For remote consent where the father has consented, confirmation of consent from the mother should be sought and documented.
- Points 11, 12, 13, and 14 on the **DOLFIN Consent Form**, which relate to measuring whether there are long term neurological development effects from giving the supplement, are optional and while we would like parents to agree due to their importance, they are not mandatory for taking part in the DOLFIN study.
- Separate consent forms will be required for twins, triplets etc. Please make this clear on the consent form e.g. FIRST NAME (TWIN 1), LAST NAME.

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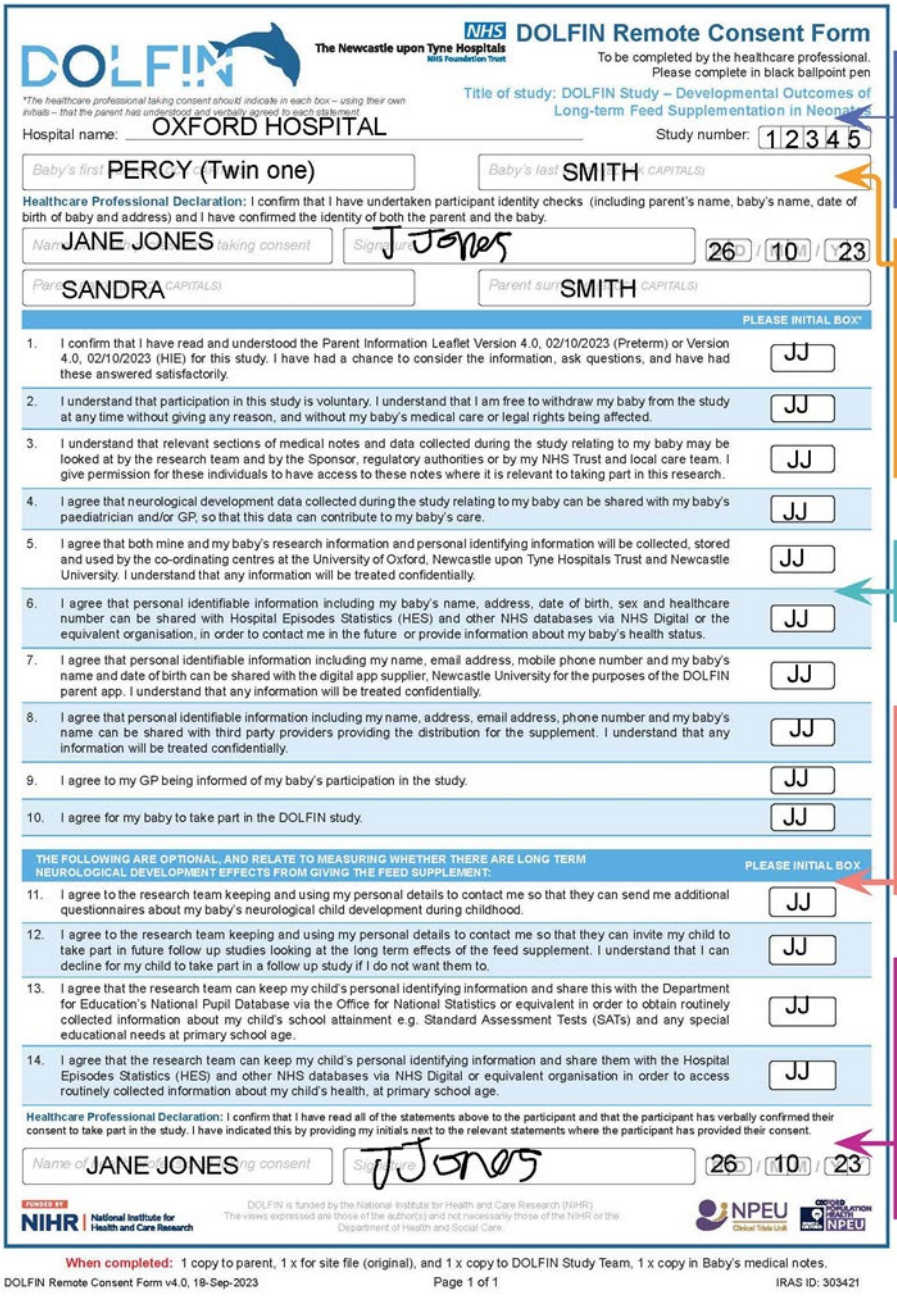
DOLFIN Remote Consent Form



DOLFIN

The Newcastle upon Tyne Hospitals NHS Foundation Trust

NHS DOLFIN Remote Consent Form

To be completed by the healthcare professional. Please complete in black ballpoint pen

*The healthcare professional taking consent should indicate in each box – using their own initials – that the parent has understood and verbally agreed to each statement

Title of study: DOLFIN Study – Developmental Outcomes of Long-term Feed Supplementation in Neonates

Hospital name: OXFORD HOSPITAL

Study number: 1 2 3 4 5

Baby's first name (CAPITALS): PERCY (Twin one)

Baby's last name (CAPITALS): SMITH

Healthcare Professional Declaration: I confirm that I have undertaken participant identity checks (including parent's name, baby's name, date of birth of baby and address) and I have confirmed the identity of both the parent and the baby.

Name of person taking consent (CAPITALS): JANE JONES

Signature: J Jones

Date (DD / MM / YY): 26 / 10 / 23

Parent's first name (CAPITALS): SANDRA

Parent surname (CAPITALS): SMITH

		PLEASE INITIAL BOX*
1.	I confirm that I have read and understood the Parent Information Leaflet Version 4.0, 02/10/2023 (Preterm) or Version 4.0, 02/10/2023 (HIE) for this study. I have had a chance to consider the information, ask questions, and have had these answered satisfactorily.	JJ
2.	I understand that participation in this study is voluntary. I understand that I am free to withdraw my baby from the study at any time without giving any reason, and without my baby's medical care or legal rights being affected.	JJ
3.	I understand that relevant sections of medical notes and data collected during the study relating to my baby may be looked at by the research team and by the Sponsor, regulatory authorities or by my NHS Trust and local care team. I give permission for these individuals to have access to these notes where it is relevant to taking part in this research.	JJ
4.	I agree that neurological development data collected during the study relating to my baby can be shared with my baby's paediatrician and/or GP, so that this data can contribute to my baby's care.	JJ
5.	I agree that both mine and my baby's research information and personal identifying information will be collected, stored and used by the co-ordinating centres at the University of Oxford, Newcastle upon Tyne Hospitals Trust and Newcastle University. I understand that any information will be treated confidentially.	JJ
6.	I agree that personal identifiable information including my baby's name, address, date of birth, sex and healthcare number can be shared with Hospital Episodes Statistics (HES) and other NHS databases via NHS Digital or the equivalent organisation, in order to contact me in the future or provide information about my baby's health status.	JJ
7.	I agree that personal identifiable information including my name, email address, mobile phone number and my baby's name and date of birth can be shared with the digital app supplier, Newcastle University for the purposes of the DOLFIN parent app. I understand that any information will be treated confidentially.	JJ
8.	I agree that personal identifiable information including my name, address, email address, phone number and my baby's name can be shared with third party providers providing the distribution for the supplement. I understand that any information will be treated confidentially.	JJ
9.	I agree to my GP being informed of my baby's participation in the study.	JJ
10.	I agree for my baby to take part in the DOLFIN study.	JJ
	THE FOLLOWING ARE OPTIONAL, AND RELATE TO MEASURING WHETHER THERE ARE LONG TERM NEUROLOGICAL DEVELOPMENT EFFECTS FROM GIVING THE FEED SUPPLEMENT:	**PLEASE INITIAL BOX**
11.	I agree to the research team keeping and using my personal details to contact me so that they can send me additional questionnaires about my baby's neurological child development during childhood.	JJ
12.	I agree to the research team keeping and using my personal details to contact me so that they can invite my child to take part in future follow up studies looking at the long term effects of the feed supplement. I understand that I can decline for my child to take part in a follow up study if I do not want them to.	JJ
13.	I agree that the research team can keep my child's personal identifying information and share this with the Department for Education's National Pupil Database via the Office for National Statistics or equivalent in order to obtain routinely collected information about my child's school attainment e.g. Standard Assessment Tests (SATs) and any special educational needs at primary school age.	JJ
14.	I agree that the research team can keep my child's personal identifying information and share them with the Hospital Episodes Statistics (HES) and other NHS databases via NHS Digital or equivalent organisation in order to access routinely collected information about my child's health, at primary school age.	JJ

Healthcare Professional Declaration: I confirm that I have read all of the statements above to the participant and that the participant has verbally confirmed their consent to take part in the study. I have indicated this by providing my initials next to the relevant statements where the participant has provided their consent.

Name of person taking consent: JANE JONES

Signature: J Jones

Date (DD / MM / YY): 26 / 10 / 23

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NPEU Clinical Trials Unit | Oxford Population Health NPEU

When completed: 1 copy to parent, 1 x for site file (original), and 1 x copy to DOLFIN Study Team, 1 x copy in Baby's medical notes.

DOLFIN Remote Consent Form v4.0, 18-Sep-2023 Page 1 of 1 IRAS ID: 303421

After consent, obtain a study number from the Randomisation website and write study number here

Differentiate between multiples (for example, infants can be named as TWIN ONE, TWIN TWO). Where first name is not yet confirmed, write down as Baby

Initial the boxes, not tick

This is optional consent and can be left blank if they do not wish to be contacted in the future

Only the health professional taking consent signs the form. Parents do not need to countersign the form

GUIDANCE SHEET 2

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Filing Documentation

After randomisation please add the participant study ID to the consent form.

There will be three carbon copies of the completed consent form.

- The original paper copy should be retained in the site folder and an electronic copy saved to the **electronic Investigator Site File (eISF)**.
- One copy should be provided to the parents, either as hard copy or electronically via email.
- One copy should be filed in the infant's medical notes.

Once complete, a clear scanned copy of the original should be sent to the DOLFIN study team via the NPEU CTU secure file transfer system. Training and access to this system will be provided to sites as required.

Change of Consent

- If a parent wishes to change their consent to any or all parts of data collection for the trial, this should be recorded on the **DOLFIN Change of Consent Form**. See **Guidance Sheet 12 - Change of Consent**.
- If a parent wants to **permanently** discontinue their baby receiving the supplement, this should be recorded on the **Supplement Discontinuation Form**. Data collection can continue (and is still useful to the trial) even if supplement has been permanently discontinued, if the parent continues to consent to this.

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