# Guidance Sheet 12:

# Change of Consent

Once an infant has been randomised and a study number allocated, they are entered into the study.

Parents have the right to change their consent for the trial at any time.

If a parent wishes to **permanently discontinue the supplement** for their infant, but otherwise does not want to change their infant's participation in the trial, with respect to other aspects of consent (e.g. study data collection, receipt of study updates) **only** the **Discontinuation of Supplement Form** needs to be completed. This form is to record permanent discontinuation. A temporary discontinuation of supplement is recorded on the **DOLFIN Dosing Log**

If a parent wishes to change their consent, this should be recorded on the **DOLFIN Change of Consent Form**. Parents can opt to change their consent to the following aspects of the study:

- Receiving the 24 month questionnaire
- Receiving other follow-up questionnaires
- Allowing for data to be collected from an infant's medical records
- Receiving study updates
- Sharing data with national databases
- Taking part in follow-up studies

Data collected up to point of change of consent will be used in the trial.

**It is important to notify the DOLFIN study team as soon as possible after becoming aware of any change of consent.**

## Key points:

- **If there is a permanent or temporary discontinuation or interruption of supplementation by parent or clinician this does not constitute a withdrawal or change of consent if they are not changing other aspects of consent (e.g. data collection)**
- If an infant dies, a change of consent form does not need to be completed. This is collected on the **DOLFIN Transfer/Discharge form**.
- Parents who wish to discontinue trial supplementation should be asked if they are still happy to complete data collection and give permission for the trial team to complete data collection using medical records. **A Change of Consent Form only needs to be completed if they are not happy for data collection to continue.**
- If known please include reason for change of consent. However, parents should not feel pressured to give a reason for a change in consent or to discuss it more than they would like.

GUIDANCE SHEET 12

## Process for Change of Consent

When a parent expresses a wish to change consent, please undertake the following steps:

- If deemed appropriate and to ensure informed decision-making, the clinical team should make time to discuss any potential concerns or misconceptions related to change of consent. If the clinical team would like support answering parent questions, please contact the DOLFIN study team.
- Reassure parents that any change of consent in the study will not affect their infant's ongoing clinical care or their care in hospital.
- Complete the **DOLFIN Change of Consent Form**, recording where possible the reasons for change of consent.
- If a parent notifies the DOLFIN study team that they wish to change their consent, the DOLFIN study team will notify the site team and ask the site to follow up with the parent if appropriate and complete the **DOLFIN Change of Consent Form**.
- A **Change of Consent Form** should be completed as soon as possible after a parent notifies the site of DOLFIN study team so that any required changes can be made, for example planned messages to parents for questionnaires or supplement deliveries. You can start completing the form even if you do not have all the information, additional information can be added at a later date (just close the form instead of marking as complete). The DOLFIN study team receive an automatic notification if a **Change of Consent Form** has been started. If you think there may be a delay in recording the necessary information on the **DOLFIN Change of Consent Form** please notify the DOLFIN study team of any change of consent by phone or email.

GUIDANCE SHEET 12

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