

Summary

Change of Consent and Discontinuation of Medication are independent and are managed through different data collection forms. **Please read this Guidance Sheet before having any Change of Consent or Discontinuation of Medication discussions with parents.**

Discontinuation of medication

A parent may choose to **permanently discontinue administration** of the TOAST medication to their infant, at any point and for any reason. The infant's surgeon or clinical team may also decide to permanently discontinue administration of the TOAST medication if they feel it is in the infant's best interest.

Any permanent discontinuation is documented on the Discontinuation of Medication Form (OpenClinica).

Even if the TOAST medication is discontinued, data collection will continue as normal. **A Change of Consent Form only needs to be completed if the parents are not happy for data collection to continue / want to withdraw consent for an aspect of their infant's involvement in TOAST Study** (other than administration of the medication).

If the parent does not otherwise want to change their infant's participation in the study (e.g. as regards study data collection, completion of questionnaires) this is NOT a change of consent. **Collecting data about babies who have permanently discontinued the medication is still beneficial to TOAST Study.**

Missed Doses

TOAST is a pragmatic study; if any number of doses of TOAST medication or placebo are missed then this will not constitute a formal discontinuation of medication or change of consent status for the study. Data on adherence to the TOAST medication will be collected via the TOAST app.

Transfers & Continuing Care Sites

Where an infant is transferred or readmitted to a hospital which is not currently set up as a continuing care site, the TOAST medication can be paused and no Discontinuation of Medication or Change of Consent form needs to be completed. Please refer to **TOAST Guidance Sheet 12: Transfers and Continuing Care Sites.**

Change of Consent

Change of Consent refers to a situation where a parent states that they wish to alter or withdraw the consent they have previously given. Parents can withdraw their consent for specific aspects of the study and retain consent for all other aspects. Parents have the right to change their consent for the study at any time and do not need to provide a reason for doing so.

Do not complete the Change of Consent form if:

- The TOAST medication has been permanently discontinued. In this circumstance, a Change of Consent form should not be completed - please complete a Discontinuation of Medication form on OpenClinica.

- There has been loss of contact with a family. A change of consent cannot be made without a communication from a parent (e.g. email, phone, instant message, face-to-face discussion) confirming their request to change consent. If parents cannot be contacted then their original consent remains valid.
- The infant has died. Please inform the TOAST Study team immediately if this has happened and document this on the Transfer/Discharge CRF. Please refer to **TOAST Guidance Sheet 8: Case Report Forms**.

It is important to get specific information about what the parent is happy to continue with, and what they do not want to continue with. A discussion with parents to confirm their wishes regarding the different change of consent options is always preferred. Please complete the Change of Consent CRF **together with the parent** if they express their wish to withdraw from aspects of the study.

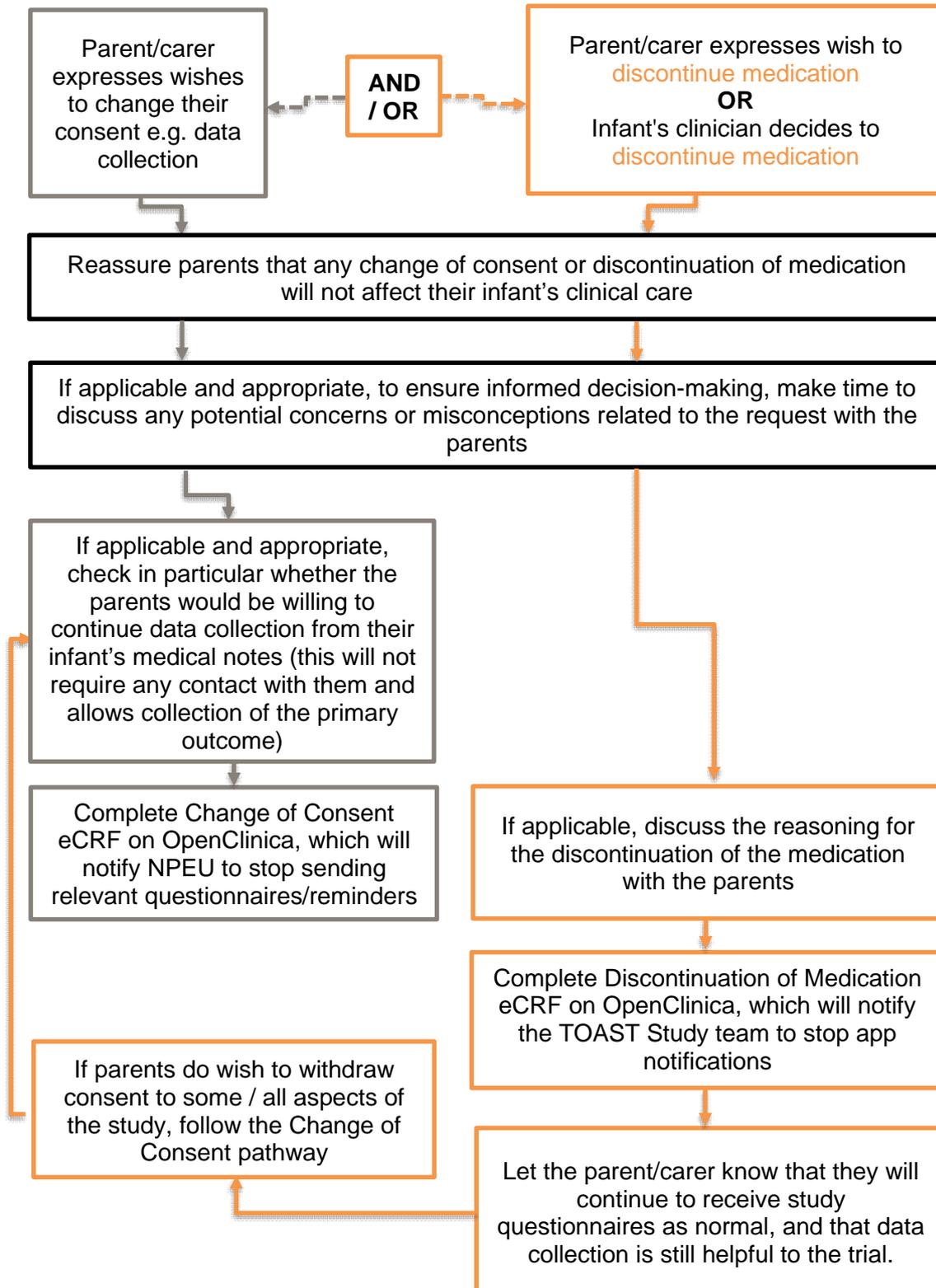
Parents can change their consent to the following:

- Receiving follow-up questionnaires
- **Birth mother only:** completing questionnaires specified for the infant's mother
- Allowing for data to be collected from their infant's medical records
- Receiving study updates
- Their contact details being kept for future contact by NPEU
- Their contact details being kept so their infant can be invited to take part in future studies

The relevant CRF (Discontinuation of Medication or Change of Consent) should be completed as soon as possible after you hear of a request to change / discontinue involvement in TOAST Study. You can start completing the form even if you do not have all the information and additional information can be added at a later date (just close the form instead of marking it as complete).

Please contact the TOAST Study team if there will be a delay in completing any aspects of the Discontinuation of Medication or Change of Consent CRFs.

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