Withdrawals and Discontinuation

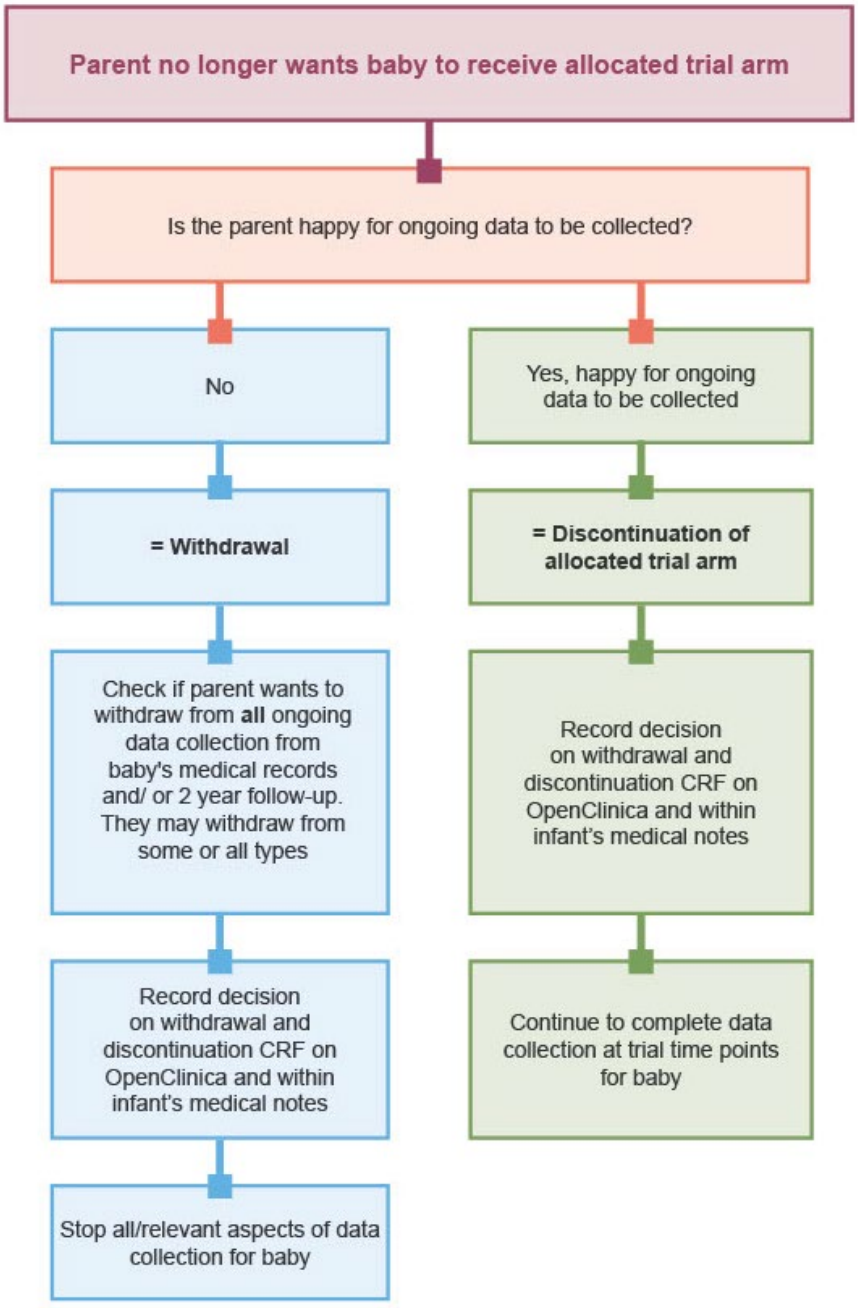
BASE

GUIDANCE SHEET

Once an infant has been randomised into the study, at any point and for any reason, a parent/carer can request to withdraw from the study.

Parents/carers can either withdraw from study data collection and/or discontinuation of the allocated treatment arm.

Please use the flowchart below to distinguish between a withdrawal and a discontinuation and follow the appropriate steps.



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Withdrawal/ Discontinuation process, hints and tips

1. If deemed appropriate, the clinical team should make time to discuss any potential concerns or misconceptions related to the withdrawal

2. Record the decision on the Withdrawal and Discontinuation eCRF on OpenClinica and within the infant's medical notes. If an infant withdraws while at a continuing care site, the continuing care site should inform the recruiting site and they will complete the eCRF.

3. The following events **do not** constitute a withdrawal:

    - If an infant allocated to no sodium bicarbonate receives sodium bicarbonate.
        - This will be captured on daily dosing log and then can be monitored by study team.
    - Decision to discontinue permanently from the allocated trial arm by treating clinician because baby was found to be ineligible after randomisation.
    - If an infant is transferred to an unapproved continuing care site.

The withdrawal form does not need to be completed in any of these situations.

GUIDANCE SHEET