Enrolment

Recruiting centre ID	Centre name

A1. Do you have written informed consent for the infant's participation from their parent/legal guardian?

◯ Yes ◯ No

A1.1. Infant's date of birth

yyyy-mm-dd

A2. Has the parent/legal guardian agreed to be interviewed by a member of the research team?

◯ Yes ◯ No

A3. Infant's gestational age at birth (completed weeks)

◯ 22 ◯ 23 ◯ 24
◯ 25 ◯ 26 ◯ 27
◯ 28 ◯ 29 ◯ 30
◯ 31 ◯ 32 ◯ 33
◯ 34 ◯ 35 ◯ 36
◯ 37 ◯ 38 ◯ 39
◯ 40 ◯ 41 ◯ 42
◯ 43 ◯ 44 ◯ 45

A4. Infant's sex

◯ Male ◯ Female ◯ Indeterminate

A5. Infant's weight at birth

(g)

A6. Is this infant one of a multiple pregnancy?

◯ Yes ◯ No

If yes, has a sibling from this pregnancy already been recruited into this study?

◯ Yes ◯ No

Please enter one of their sibling's study numbers

.....

A7. Does the infant have a stoma formed?

◯ Yes ◯ No

A8. Was this stoma formed before the infant was 44 weeks post-conceptual age?

◯ Yes ◯ No

A9. Was this stoma formed as part of a planned treatment pathway, e.g. for anorectal malformation or Hirschsprung's Disease?

◯ Yes ◯ No

Date of enrolment yyyy-mm-dd	Time of enrolment *(hh:mm)*
.....	.....

Stoma Formation

Please complete this form as soon as possible after the infant's stoma is formed.

Any question marked with an * is mandatory

1. Infant's date of birth *

yyyy-mm-dd

2. Date of stoma formation *

yyyy-mm-dd

3. Infant's weight at time of formation *

(g)

4. What is the primary diagnosis requiring stoma formation? *

- ◯ Necrotising enterocolitis (NEC)
- ◯ Spontaneous intestinal perforation
- ◯ Meconium ileus
- ◯ Gastroschisis
- ◯ Intestinal atresia
- ◯ Other
- ◯ Volvulus
- ◯ Milk curd obstruction

Please specify

5. Does the infant have any co-morbidities that mean recruitment to a trial of early vs. late closure at this point would be inappropriate ? *

- ◯ Yes
- ◯ No

If Yes, please give details of these (Please choose all that apply):

Known major syndrome/genetic disorder *

Complex cardiac comorbidity, including any requirement for surgery *

Other major congenital anomaly *

Palliative care pathway for other reason *

Other *

6. Were any of the following operative findings present:

Presence of perforation? *

- ◯ Yes
- ◯ No

Signs of NEC *

- ◯ Yes, localised
- ◯ Yes, diffuse
- ◯ Yes, multifocal
- ◯ No

Evidence of residual NEC distal to the stoma? *

- ◯ Yes
- ◯ No

7. What resection was performed? *

Please tick all that apply

- ☐ Small bowel
- ☐ Ileocaecal valve
- ☐ Colon
- ☐ None

Please confirm type if colon resection was performed

Please tick all that apply

- ☐ Ascending
- ☐ Transverse
- ☐ Descending
- ☐ Sigmoid
- ☐ Rectum

8. What is the site of the active stoma? *

- ◯ Duodenum
- ◯ Jejunum
- ◯ Ileum
- ◯ Colon

Please enter length of small bowel from DJ flexure to active stoma *cm*	**Please confirm if length of small bowel from DJ flexure to active stoma was not measured** ◯ Not measured
Please enter the total length of small bowel remaining *cm*	**Please confirm if total length of small bowel remaining was not measured** ◯ Not measured

Post-operative Clinical Condition

Please complete this form as close as possible to one week after the infant's stoma was formed. It gives an approximate indication of the infant's clinical condition around the time randomisation to a potential trial might be considered.

1. Infant's date of birth *

yyyy-mm-dd

2. Please enter date form completed *

yyyy-mm-dd

3. What is the infant's current weight? *

(g)

4. What is the infant's current level of respiratory support (highest level of the day)? *

- ◯ None
- ◯ Non-invasive support
- ◯ Mechanical ventilation
- ◯ High-Frequency Oscillatory Ventilation (HFOV)

Did the infant receive nitric oxide?

- ◯ Yes
- ◯ No

5. Between the operation and now, how many days has the infant received each of the following ventilation:

High-Frequency Oscillatory Ventilation (HFOV) * *days*	**Mechanical ventilation** * *days*	**Non-invasive support** * *days*

6. Is the infant receiving inotropic support? *

- ◯ Yes
- ◯ No

7. Has the infant received blood products in the last 24 hours? *

- ◯ Yes
- ◯ No

Please indicate which products

Please tick all that apply

- ☐ Packed red cells
- ☐ Fresh frozen plasma (FFP)
- ☐ Cryoprecipitate

Early Intervention

Please complete this intervention form at two time points:

- The "early" intervention point in a potential randomised trial (around six weeks post-stoma formation). If the infant's stoma is closed before this time point, please complete this form for the period immediately before stoma closure

- The "late" intervention point in a potential randomised trial (around twelve weeks post-stoma formation). If the infant's stoma is closed before this time point, please complete this form for the period immediately before stoma closure

If the infant is transferred out of the Trust, or discharged home, or dies before closure is performed, please complete this form, if you have not already completed it for both intervention points.

1. Infant's date of birth *

yyyy-mm-dd

2. Why are you completing this form? *

- ◯ It is six weeks after the infant's stoma was formed
- ◯ It is twelve weeks after the infant's stoma was formed
- ◯ The infant's stoma has been closed before the early intervention point was reached
- ◯ The infant's stoma has been closed before the late intervention point was reached
- ◯ The infant has been transferred out of the Trust
- ◯ The infant has been discharged home
- ◯ The infant has died

3. What is the infant's current level of respiratory support (highest level of the day)? *

- ◯ None
- ◯ Non-invasive support
- ◯ Mechanical ventilation
- ◯ High-Frequency Oscillatory Ventilation (HFOV)

Did the infant receive nitric oxide?

- ◯ Yes
- ◯ No

4. Between the operation and now, how many days has the infant received each of the following ventilation:

High-Frequency Oscillatory Ventilation (HFOV) * *days*	**Mechanical ventilation** * *days*	**Non-invasive support** * *days*

5. In the last week, has the infant received postnatal steroids for chronic lung disease? *

- ◯ Yes
- ◯ No

Cardiovascular status

6. Is the infant receiving inotropic support? *

- ◯ Yes
- ◯ No

Fluids and nutrition

7. Is the infant receiving parenteral nutrition? *

- ◯ Yes
- ◯ No, not required
- ◯ No, inadequate vascular access to allow it

How much?
(ml/kg/day)

8. Is the infant receiving enteral feeds? *

- ◯ Yes
- ◯ No

How much?
(ml/kg/day)

9. What is the infant's current actual weight? *
(g)

10. Is the infant oedematous? *

- ◯ Yes
- ◯ No

11. Has the infant gained or lost weight over the last seven days? *

- ◯ Yes, gained weight
- ◯ Yes, lost weight
- ◯ No

12. What is the stoma's average output over five days? *

(ml/kg/day)

.....

13. Is the stoma recycling distally? *

- ◯ Yes
- ◯ No

14. Are any of the following stoma problems present? *

Please tick all that apply

- ☐ Prolapse
- ☐ Stenosis
- ☐ Retraction
- ☐ Leaking bags
- ☐ Skin problems
- ☐ None of the above

Infection

15. Is the infant receiving antibiotics? *

- ◯ Yes
- ◯ No

15.1 Has there been a positive blood culture in the last two weeks?

- ◯ Yes
- ◯ No

16. Is this infant currently being treated for a new episode of NEC? *

- ◯ Yes
- ◯ No

» Other

17. What was the infant's last conjugated bilirubin level? *

umol/L

.....

Late Intervention

Please complete this intervention form at two time points:

- The "early" intervention point in a potential randomised trial (around six weeks post-stoma formation). If the infant's stoma is closed before this time point, please complete this form for the period immediately before stoma closure

- The "late" intervention point in a potential randomised trial (around twelve weeks post-stoma formation). If the infant's stoma is closed before this time point, please complete this form for the period immediately before stoma closure

If the infant is transferred out of the Trust, or discharged home, or dies before closure is performed, please complete this form, if you have not already completed it for both intervention points.

1. Infant's date of birth *

yyyy-mm-dd

2. Why are you completing this form? *

- ◯ It is six weeks after the infant's stoma was formed
- ◯ It is twelve weeks after the infant's stoma was formed
- ◯ The infant's stoma has been closed before the early intervention point was reached
- ◯ The infant's stoma has been closed before the late intervention point was reached
- ◯ The infant has been transferred out of the Trust
- ◯ The infant has been discharged home
- ◯ The infant has died

3. What is the infant's current level of respiratory support (highest level of the day)? *

- ◯ None
- ◯ Non-invasive support
- ◯ Mechanical ventilation
- ◯ High-Frequency Oscillatory Ventilation (HFOV)

Did the infant receive nitric oxide?

- ◯ Yes
- ◯ No

4. Between the operation and now, how many days has the infant received each of the following ventilation:

High-Frequency Oscillatory Ventilation (HFOV) * *days*	**Mechanical ventilation** * *days*	**Non-invasive support** * *days*
.....	.....	.....

5. In the last week, has the infant received postnatal steroids for chronic lung disease? *

- ◯ Yes
- ◯ No

Cardiovascular status

6. Is the infant receiving inotropic support? *

- ◯ Yes
- ◯ No

Fluids and nutrition

7. Is the infant receiving parenteral nutrition? *

- ◯ Yes
- ◯ No, not required
- ◯ No, inadequate vascular access to allow it

How much?
(ml/kg/day)
.....

8. Is the infant receiving enteral feeds? *

- ◯ Yes
- ◯ No

How much?
(ml/kg/day)
.....

9. What is the infant's current actual weight? *
(g)
.....

10. Is the infant oedematous? *

- ◯ Yes
- ◯ No

11. Has the infant gained or lost weight over the last seven days? *

- ◯ Yes, gained weight
- ◯ Yes, lost weight
- ◯ No

12. What is the stoma's average output over five days? *

(ml/kg/day)

.....

13. Is the stoma recycling distally? *

- ◯ Yes
- ◯ No

14. Are any of the following stoma problems present? *

Please tick all that apply

- ☐ Prolapse
- ☐ Stenosis
- ☐ Retraction
- ☐ Leaking bags
- ☐ Skin problems
- ☐ None of the above

Infection

15. Is the infant receiving antibiotics? *

- ◯ Yes
- ◯ No

15.1 Has there been a positive blood culture in the last two weeks?

- ◯ Yes
- ◯ No

16. Is this infant currently being treated for a new episode of NEC? *

- ◯ Yes
- ◯ No

» Other

17. What was the infant's last conjugated bilirubin level? *

umol/L

.....

Stoma Closure/Reversal Form

If the infant's stoma is closed/reversed, please complete this form 30 days after reversal.

1. Infant's date of birth *

yyyy-mm-dd

2. Date of closure/reversal *

yyyy-mm-dd

3. Infant's weight at time of surgery *

(g)

4. Was closing the stoma at this time point planned? *

- ◯ Yes
- ◯ No

4.1. Was it: *

- ◯ Expedited
- ◯ Delayed

4.2. What was the principal reason for this? *

- ◯ Clinical
- ◯ Social/family (e.g. a requirement for safe discharge)
- ◯ Logistical (e.g. theatre list, NICU cot availability, surgeon/anaesthetist availability)
- ◯ Other

Please specify

Outcomes post-closure

5. Please indicate whether any of the following complications occurred within 30 days of closure/reversal *

Please tick all that apply

- ☐ Anastomotic leak
- ☐ Anastomotic stricture
- ☐ Local wound problems e.g. infection, dehiscence
- ☐ Adhesive bowel obstruction

- [ ] Unplanned return to theatre
- [ ] Other
- [ ] None of the above
- [ ] Prolonged feed intolerance / ileus

Please specify

Text entered in Other complication which was reviewed and resulting in Other being recoded to a different complication

6. When did the infant achieve full enteral feeds post-operatively? *

yyyy-mm-dd

7. Is the infant: *

- ◯ Still an inpatient
- ◯ Discharged home
- ◯ Transferred to another Trust
- ◯ Died

Please enter date transferred to another Trust

yyyy-mm-dd

Please enter date discharged home

yyyy-mm-dd

Please enter date of death

yyyy-mm-dd

8. What was the infant's duration of invasive ventilation post-operatively?

days

Or

- ◯ Infant is still ventilated
- ◯ Infant was transferred to another Trust ventilated