



FEED1
FLUIDS EXCLUSIVELY
ENTERAL FROM DAY 1

eCRF Paper Gut Sign form

This additional form is to be used as an aide memoire only, it does not replace the electronic CRF (MACRO).

All paper workbooks and additional forms should be retained in the Investigator Site File as they represent Source Data.

Mother's Initials:

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(If only two initials are given then please separate with a hyphen)

Infant ID:

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Sponsor: University Hospitals of Derby and Burton NHS Foundation Trust

CRF Version: Final Version 1.0

**PLEASE ATTACH THIS COMPLETED FORM TO THE INFANT
WORKBOOK**

Mother's Initials:

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Infant ID:

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**Definitions - Necrotising enterocolitis:**

NEC may be diagnosed at surgery, at post-mortem examination or clinically and radiologically using the following criteria:

At least one of the following clinical signs present:

Bilious gastric aspirate or emesis, Abdominal distension, Occult or gross blood in stool (no fissure)

and at least one of the following radiological features:

Pneumatosis intestinalis, Hepato-biliary gas, Pneumoperitoneum

Infants who satisfy the definition of NEC above but are found at surgery or post-mortem examination for that episode to have a "Focal Intestinal Perforation" should be coded as having "Focal Gastrointestinal Perforation", not as having NEC.

Bell stage	Systemic	Gastro-intestinal	Radiographic
Stage IIA (Definite NEC: mildly ill)	Increased desaturations and/or bradycardia Temperature instability Lethargy	Increased pre-feed gastric aspirate Definite abdominal distension Possible abdominal tenderness Possibly bloody stools	Pneumatosis intestinalis
Stage IIB (Definite NEC: moderately ill)	As IIA with platelets <100 x 10 ¹² and/or metabolic acidosis: base excess <-8 meq/l	Abdominal distension with definite tenderness Possible abdominal wall oedema and/or erythema	As IIA with portal vein gas Possible ascites
Stage IIIA (Advanced NEC: bowel intact)	As IIB plus mixed acidosis: pH <7.2 DIC neutropaenia <1x10 ⁹ /l Severe apnoea Hypotension requiring inotropes	Generalised peritonitis with severe tenderness with abdominal wall induration	As IIA with definite ascites
Stage IIIB (Advanced NEC: bowel perforated)	As IIIA	As IIIA	As IIIA with pneumoperitoneum

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Gut Signs													
Start date = the day abdominal concerns were raised and infant was put nil by mouth End date = the date enteral feeding was restarted													
Start of episode (dd-mmm-yyyy)	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td> <td> </td><td> </td><td> </td><td> </td> <td> </td><td> </td><td> </td><td> </td> </tr> </table>												
End of episode (dd-mmm-yyyy)	<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td> <td> </td><td> </td><td> </td><td> </td> <td> </td><td> </td><td> </td><td> </td> </tr> </table>												
Final diagnosis													
Dysmotility, meconium or milk plug:	Yes <input type="checkbox"/> No <input type="checkbox"/>												
Septic ileus:	Yes <input type="checkbox"/> No <input type="checkbox"/>												
Focal intestinal perforation (no NEC):	Yes <input type="checkbox"/> No <input type="checkbox"/>												
Necrotising enterocolitis: <i>(Bell stage 2 or 3)</i>	Yes* <input type="checkbox"/> No <input type="checkbox"/>												
*If yes, please specify stage:	Suspected NEC not fulfilling criteria for stage II <input type="checkbox"/> Stage II A or B: Definite NEC <input type="checkbox"/> Stage III A: Advanced NEC, no perforation <input type="checkbox"/> Stage III B: Advanced NEC, with perforation <input type="checkbox"/>												

Continued overleaf

Mother's Initials:

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Infant ID:

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*How was NEC diagnosed? (select all that apply)											
Clinically and radiologically:	Yes <input type="checkbox"/> No <input type="checkbox"/>										
Surgery:	Yes* <input type="checkbox"/> No <input type="checkbox"/>										
*If, Yes please indicate date of surgery (dd-mmm-yyyy)	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>										
If yes, please specify stage:	Peritoneal drain or paracentesis: <input type="checkbox"/> Laparotomy: <input type="checkbox"/> Bowel resection: <input type="checkbox"/> Stoma: <input type="checkbox"/> Other: <input type="checkbox"/>										
*please specify											
Post Mortem:	Yes <input type="checkbox"/> No <input type="checkbox"/>										
If, Yes please indicate date of post mortem (dd-mmm-yyyy)	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table>										
Other diagnosis:	Yes* <input type="checkbox"/> No <input type="checkbox"/>										
*please specify											

Please note the PI will be required to login to Macro database to assess and sign off each Gut Sign episode reported.