Case Report Form (CRF)

Record ID	_____
Study ID	_____
Date of randomization	_____ (YY-MM-DD)
Group assignment	◯ A ◯ B (A or B)
Start date of intervention	_____
Intervention interrupted Note if intervention has been interrupted during study intervention period. Add description for interrupting intervention. If numerous interruptions: add 1, 2, 3 and so on before every interruption period	_____
Infection during pregnancy	◯ Yes ◯ No
Antenatal antibiotics	◯ Yes ◯ No (Note Yes if mother has been given antibiotics during pregnancy)
Stool sample at baseline	◯ Yes ◯ No (As soon as possible after inclusion/randomization)
Stool sample at 14 (+/- 2 days)	◯ Yes ◯ No
Stool sample at 34 weeks gestational age (+/- 2 days)	◯ Yes ◯ No
Stool sample at 12 months corrected age	◯ Yes ◯ No
Comments Add potential comments to data entery in CRF	_____

Case Report Form (CRF) - sub cohort

Study ID	_____
Bolus feeds	◯ Yes ◯ No
Period of treatment with bolus feeds Document as YY-MM-DD - YY-MM-DD. Or document if the patients has always been given bolus feeds.	_____
Continious feeds	◯ Yes ◯ No
Period of treatment with continious feeds Document as YY-MM-DD - YY-MM-DD. Or document if the patients has always been given continious feeds.	_____
Interruptions of enteral feeds for >8 hours	_____

Verification of NEC

Study ID

_____

Episode 1
Abdominal sympthoms

_____
(Description)

INCLUDE DATE OF EVENT

Episode 1
Radiological findings

_____
(Description)

INCLUDE DATE OF EVENT

Episode 1
Differential diagnoses

_____
(SIP, malrotation, volvulus, other?)

Episode 1
Operation with NEC findings

◯ Yes
◯ No

Episode 1
Verified NEC

◯ Yes
◯ No

Episode 2
Abdominal sympthoms

_____

INCLUDE DATE OF EVENT

Episode 2
Radiological findings

_____

INCLUDE DATE OF EVENT

Episode 2
Differential diagnoses

_____

Episode 2
Operation with NEC findings

◯ Yes
◯ No

Episode 2
Verified NEC

◯ Yes
◯ No

Episode 3
Abdominal sympthoms

INCLUDE DATE OF EVENT

Episode 3
Radiological findings

INCLUDE DATE OF EVENT

Episode 3
Differential diagnoses

Episode 3
Operation with NEC findings
◯ Yes
◯ No

Episode 3
Verified NEC
◯ Yes
◯ No

Episode 4
Abdominal sympthoms

INCLUDE DATE OF EVENT

Episode 4
Radiological findings

INCLUDE DATE OF EVENT

Episode 4
Differential diagnoses

Episode 4
Operation with NEC findings
◯ Yes
◯ No

Episode 4
Verified NEC
◯ Yes
◯ No

Episode 5
Abdominal sympthoms

INCLUDE DATE OF EVENT

Episode 5
Radiological findings

_____

INCLUDE DATE OF EVENT

Episode 5
Differential diagnoses

_____

Episode 5
Operation with NEC findings

◯ Yes
◯ No

Episode 5
Verified NEC

◯ Yes
◯ No

Comments

Use for comments or for documenting more potential NEC episodes

_____

INCLUDE DATE OF EVENT

Verification of Sepsis

Study ID	_____
Sepsis episode 1 LPK < 5 or > 20 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 1 TPK < 100 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 1 CRP > 15 mg/L	◯ Yes ◯ No
Verified sepsis Incidence of sepsis is defined as culture proven sepsis including positive blood, urin - and/or urin, clinical impairment and laboratory inflammatory response were at least one of the three above is confirmed	◯ Yes ◯ No
Sepsis episode 2 LPK < 5 or > 20 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 2 TPK < 100 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 2 CRP > 15 mg/L	◯ Yes ◯ No
Sepsis episode 2 Verified sepsis Incidence of sepsis is defined as culture proven sepsis including positive blood, urin - and/or urin, clinical impairment and laboratory inflammatory response were at least one of the three above is confirmed	◯ Yes ◯ No
Sepsis episode 3 LPK < 5 or > 20 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 3 TPK < 100 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 3 CRP > 15 mg/L	◯ Yes ◯ No

Sepsis episode 3 Verified sepsis Incidence of sepsis is defined as culture proven sepsis including positive blood, urin - and/or urin, clinical impairment and laboratory inflammatory response were at least one of the three above is confirmed	◯ Yes ◯ No
Sepsis episode 4 LPK < 5 or > 20 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 4 TPK < 100 (x109 cells/L)	◯ Yes ◯ No
Sepsis episode 4 CRP > 15 mg/L	◯ Yes ◯ No
Sepsis episode 4 Verified sepsis Incidence of sepsis is defined as culture proven sepsis including positive blood, urin - and/or urin, clinical impairment and laboratory inflammatory response were at least one of the three above is confirmed	◯ Yes ◯ No

Reporting Serious Adverese Events (SAE)

Study ID

_____

Death

◯ Yes
◯ No

_____

Verified NEC

◯ Yes
◯ No

_____

Verified sepsis

◯ Yes
◯ No

_____

RDS

◯ Yes
◯ No

_____

BPD

◯ Yes
◯ No

_____

PDA

◯ Yes
◯ No

_____

PPHN

◯ Yes
◯ No

_____

IVH

◯ Yes
◯ No

_____

Hydrocephalus	◯ Yes ◯ No
	_____
ROP	◯ Yes ◯ No
	_____
Gastrointestinal diagnoses (volvulus, illeus, SIP, malrotation, other)	_____ (description)
	_____
Comments	_____

Reporting Suspected unexpected serious adverse event (SUSAR)

Study ID

_____

Patients name

_____
(First and second name)

Patients Social Security Number

_____
(Personnummer/reservnummer)

Date of event (SUSAR)

_____

Time of event (if appliable)

_____

Place of event

_____

Description of event
DO NOT ADD INFORMATION ABOUT GROUP ALLOCATION EVEN IF CODE BREAKING HAS ACCOURED

_____

Screening Log

Date of screening	_____
Gestational age	_____ (Week + day (For example 26+3))
Meets inclusion criteria	◯ Yes ◯ No
If previous answers was "No". Please add description why inclusion criterias were not meet.	_____
Included in PEPS-trial	◯ Yes ◯ No
If previous answers was "No" even though inclusion criteria were met. Add description why the patient was not included. For example: parents did not give consent	_____
STUDY ID If included (N-NNN)	_____
Other information	_____ (if appliable)

Patient Identification Log

STUDY ID	_____ (Add study id (N-NNN))
Full Name	_____ (First name and last name)
Social Security Number	_____ ("personnummer eller reservnummer")
Date of randomization	_____ (YY-MM-DD)
Group allocation	◯ A ◯ B
Including hospital	◯ Karolinska UH Solna ◯ Karolinska UH Huddinge ◯ Linköping UH ◯ Lund UH ◯ Sahlgrenska UH ◯ Umeå UH ◯ Uppsala UH ◯ Aarhus UH ◯ Copenhagen UH ◯ Glostrup UH ◯ Odense UH ◯ Aalborg