NHS Blood and Transplant

PlaNeT-2 - Form 13a

Final Version 1.00
11May2011

Trial Number | | | | | | |

Neonate Initials | | | |

If multiple births; birth order | | of | |

MAJOR / SEVERE BLEED

Complete form at time of major or severe bleed as defined in the protocol and use 1 form per bleed
Record episodes occuring from Randomisation to End of Study

(1) Date and time bleed first identified

Date | | | | | 2 | 0 | | |
D D M M Y Y Y Y

Time (24 hour clock) | | | | |
H H M M

(2) Please describe the nature & circumstances of the bleed

Circulatory shock NO | | YES | |

Pulmonary NO | | YES | |

Frank rectal NO | | YES | |

Intracranial haemorrhage NO | | YES | |

If YES, please answer parts (i) to (iv) below
If NO, proceed to Form 13b

	LEFT		RIGHT	
(i) Subdural	NO	YES	NO	YES
(ii) Subarachnoid	NO	YES	NO	YES

(iii) Additional scanning CT / MRI performed? NO | | YES | |

If YES, date and time of scan

Date | | | | | 2 | 0 | | |
D D M M Y Y Y Y

Time (24 hour clock) | | | | |
H H M M

Results of scan .....

.....

.....

(iv) Neurosurgical intervention required? NO | | YES | |

If YES, please describe.....

.....

.....

PROCEED TO FORM 13b

PlaNeT-2 - Form 13b

NHS Blood and Transplant

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11May2011

Trial Number ☐☐☐☐☐☐ Neonate Initials ☐☐☐

If multiple births; birth order ☐ of ☐

MAJOR / SEVERE BLEED (cont'd)

Complete form at time of major or severe bleed as defined in the protocol and use 1 form per bleed

Record episodes occuring from Randomisation to End of Study

(2) Please describe the nature & circumstances of the bleed (cont'd)

IVH NO ☐ YES ☐ If YES, please tick all that apply below (see guidance notes)

Haemorrhage

LEFT		RIGHT
☐	H0	☐
☐	H1	☐
☐	H2	☐
☐	H3	☐

Ventricular size
V1 is dilatation > 12 mm

LEFT		RIGHT
☐	V0	☐
☐	V1	☐

Parenchymal injury

LEFT		RIGHT
☐	P0	☐
☐	P1	☐
☐	P2	☐
☐	P3	☐

LEFT		RIGHT
☐	PC	☐
☐	PVL	☐

Other NO ☐ YES ☐

If other, specify:.....

.....

.....

PROCEED TO FORM 13c

NHS Blood and Transplant

PlaNeT-2 - Form 13c

Final Version 1.00
11May2011

Trial Number | | | | | | | Neonate Initials | | | |

If multiple births; birth order | | of | |

MAJOR / SEVERE BLEED (cont'd)

Complete form at time of major or severe bleed as defined in the protocol and use 1 form per bleed
Record episodes occuring from Randomisation to End of Study

(3) Most recent laboratory results (i.e. those closest prior to the bleed)

Platelets | | | | x 10^9/L

Platelet sample date | | | | | 2 | 0 | | | (D D M M Y Y Y Y)

Time (24 hour clock) | | | | | (H H M M)

Clotting screen performed? **YES** | | **NO** | |

If YES, date and time sample taken

Clotting sample date | | | | | 2 | 0 | | | (D D M M Y Y Y Y)

Time (24 hour clock) | | | | | (H H M M)

Results: PT | | secs or INR | | . | | ratio

APTT | | | | | secs or APTR | | . | | ratio

(4) Within the last 7 days prior to the major bleed has the neonate been receiving:

Ibuprofen NO | | YES | | Indometacin NO | | YES | |

(5) Within the last 3 days prior to the major bleed has the neonate been receiving:

Therapeutic heparin* NO | | YES | | Other thrombolytics NO | | YES | | If Yes, specify details below:

Thrombolytic details: .....

.....

Principal Investigator Name (Print) | | Principal Investigator Signature | | Date | | | | | 2 | 0 | | | (D D M M Y Y Y Y)

Completed Major Bleed Form (parts a, b and c) must be sent to the NHSBT CSU within 24 hours of identification of the event
Fax: 01223 588 136 Email: planet2@nhsbt.nhs.uk

Send Form 13 within 24 hours