



A study of position during the late stages of labour in women with an epidural

BUMPES Serious Adverse Event (SAE) Form

Please complete pages 1 - 3 and one form for each Serious Adverse Event

Please fax immediately to the BUMPES Co-ordinating office on 0207 679 6761

Reporting information:

Date form completed:

/ /

Type of report:

Initial Follow-up

Name of hospital: _____

Name of person completing the form: _____

Clinical status:

Doctor Midwife Other

If Other, please specify: _____

Woman's Identification Details:

BUMPES study number: (found in section 2 of the data collection form)

Woman's initials:

Date of birth: / /

Treatment allocation: (Please tick only one) Upright OR Lying down

Participant affected: (Please tick only one) Woman OR Infant

Seriousness: (Please tick only one)

Results in death

Life threatening

Inpatient hospitalisation or prolongation of hospitalisation

Persistent or significant disability/incapacity

Medically significant or requires intervention to prevent one of the above outcomes

Event description:

Please describe the event as fully as possible:

Event details:

Date and time event started:

/ / :

Date and time event resolved: (If applicable)

/ / :

Indicate the severity of the event:

Mild Moderate Severe

Event causality:

Indicate whether the event is considered related to participation in the study:

Unrelated Possibly related Probably related Definitely related

Event outcome:

Recovered Recovering Continuing Patient died Unknown

Are there any clinical sequelae?

Yes No

If Yes, please describe:

Treatment required:

Did the event require treatment with medication?

Yes No

If Yes, please list any medication administered in the table on the next page;

Medication name (generic)	Dose	Route of administration	Date and time started	Date and time stopped	Ongoing?
			DD / MM / YY hh : mm 24hr	DD / MM / YY hh : mm 24hr	<input type="checkbox"/>
			DD / MM / YY hh : mm 24hr	DD / MM / YY hh : mm 24hr	<input type="checkbox"/>
			DD / MM / YY hh : mm 24hr	DD / MM / YY hh : mm 24hr	<input type="checkbox"/>
			DD / MM / YY hh : mm 24hr	DD / MM / YY hh : mm 24hr	<input type="checkbox"/>
			DD / MM / YY hh : mm 24hr	DD / MM / YY hh : mm 24hr	<input type="checkbox"/>

Did event require treatment with a procedure?

Yes No

If Yes, please list any procedures required in the box below:

Is there any other relevant information?

Yes No

If Yes, please detail in the box below:

Investigator's Review:

Investigator's name: _____

Investigator's signature: _____ Date: DD / MM / YY