BUMPES Serious Adverse Event (SAE) Form

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

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

Please fax immediately to the BUMPES Co-ordinating office on [redacted]

Reporting information:

Date form completed: D D / M M / Y Y

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:** D D / M M / Y Y

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: D D / M M / Y Y h h : m m (24hr)

Date and time event resolved: *(If applicable)* D D / M M / Y Y h h : m m (24hr)

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?
			D D / M M / Y Y h h : m m 24hr	D D / M M / Y Y h h : m m 24hr	☐
			D D / M M / Y Y h h : m m 24hr	D D / M M / Y Y h h : m m 24hr	☐
			D D / M M / Y Y h h : m m 24hr	D D / M M / Y Y h h : m m 24hr	☐
			D D / M M / Y Y h h : m m 24hr	D D / M M / Y Y h h : m m 24hr	☐
			D D / M M / Y Y h h : m m 24hr	D D / M M / Y Y h h : m m 24hr	☐

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:** D D / M M / Y Y