

SECTION 3: DURING SURGERY**SUBJECT #**

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SITE #

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START OF SURGERYDATE: |_|_|_|/|_|_|_|_|_|/|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(DD/MMM/YYYY)TIME: |_|_|_| : |_|_|_|
(HR : MINS)

| SURGICAL PROCEDURE PERFORMED (single most appropriate) | Tick one | |
|--|---|--------------------------------|
| Resection of colon, rectum or small bowel | <input type="checkbox"/> | |
| Resection of liver, pancreas or gall bladder | <input type="checkbox"/> | |
| Resection of stomach (non-obesity surgery) | <input type="checkbox"/> | |
| Resection of oesophagus (non-obesity) | <input type="checkbox"/> | |
| Obesity surgery | <input type="checkbox"/> | |
| Vascular procedure | <input type="checkbox"/> | |
| Other intra-peritoneal surgery | <input type="checkbox"/> | |
| SURGICAL TECHNIQUE | YES | NO |
| Open surgical technique used during surgery | <input type="checkbox"/> | <input type="checkbox"/> |
| ANAESTHETIC TECHNIQUE | | |
| General Anaesthesia | <input type="checkbox"/> | <input type="checkbox"/> |
| Epidural anaesthesia | <input type="checkbox"/> | <input type="checkbox"/> |
| Spinal anaesthesia | <input type="checkbox"/> | <input type="checkbox"/> |
| Did the patient have an endotracheal tube inserted? | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, was the patient extubated before leaving the operating room? | <input type="checkbox"/> | <input type="checkbox"/> |
| MECHANICAL VENTILATION DURING SURGERY | | |
| Did the patient receive a recruitment manoeuvre during surgery? | <input type="checkbox"/> | <input type="checkbox"/> |
| Did the patient receive mechanical ventilation during surgery? | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, please answer the following: | | |
| Maximum positive end-expiratory pressure (PEEP) | _ _ _ cmH ₂ O | |
| Maximum set tidal volume (Vt) | _ _ _ _ ml | |
| Maximum respiratory rate | _ _ _ min ⁻¹ | |
| Maximum FiO ₂ (excluding pre-oxygenation during induction of anaesthesia) | _ _ _ % | |
| INTRAVENOUS FLUIDS DURING SURGERY | | |
| Total volume of intravenous fluid administered excluding blood products | _ _ _ _ _ mL | |
| Total volume of blood products administered | _ _ _ _ _ mL | |
| Date and time of the end of surgery | _ _ _ / _ _ _ _ _ / _ _ _ _ _ _ _ _ _ _ _ _ _ _ (DD/MMM/YYYY) | _ _ _ : _ _ _ (HR: MINS) |

SECTION 4: TRIAL INTERVENTION PERIOD

| | | | |
|------------------|-----------------|---------------|---------------------------|
| SUBJECT # | _ _ _ - _ _ _ _ | SITE # | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

| CPAP AFTER SURGERY | | YES | NO |
|--|---|---------------------------|--------------------------|
| Did the patient receive Continuous Positive Airway Pressure (CPAP) started within twelve hours after the end of surgery? | | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, please answer the following questions. If NO, please skip to next section. | | | |
| Date and time patient started CPAP | _ _ _ / _ _ _ _ / _ _ _ _ _ (DD/MMM/YYYY) | _ _ : _ _ (HR:MINS) | |
| Total duration of CPAP within twelve hours of the end of surgery | | _ _ _ (MINS) | |
| Maximum airway pressure received during this period | | _ _ _ cmH ₂ O | |
| Primary method of CPAP delivery (single most appropriate) | | | |
| Face mask | | <input type="checkbox"/> | |
| Helmet device | | <input type="checkbox"/> | |
| Nasal mask | | <input type="checkbox"/> | |
| | | YES | NO |
| Were extra research staff present to help deliver CPAP? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Did the staff administering CPAP use equipment to monitor airway pressures? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Did the staff administering CPAP use equipment to monitor the FiO ₂ ? | | <input type="checkbox"/> | <input type="checkbox"/> |
| Did the patient have a nasogastric tube <i>in situ</i> during CPAP? | | <input type="checkbox"/> | <input type="checkbox"/> |

| RESPIRATORY SUPPORT AFTER SURGERY | | YES | NO |
|---|--|--------------------------|--------------------------|
| Did the patient receive any of the following within four hours of the end of surgery? | | | |
| Invasive mechanical ventilation | | <input type="checkbox"/> | <input type="checkbox"/> |
| Non-invasive mechanical ventilation | | <input type="checkbox"/> | <input type="checkbox"/> |
| High flow nasal oxygen therapy | | <input type="checkbox"/> | <input type="checkbox"/> |

| LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY | Tick one |
|---|--------------------------|
| Critical care unit level 3 | <input type="checkbox"/> |
| Critical care unit level 2 | <input type="checkbox"/> |
| Post-anaesthesia care unit | <input type="checkbox"/> |
| Surgical ward | <input type="checkbox"/> |

SECTION 5: 30-DAY FOLLOW-UP



SUBJECT #

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SITE #

|_|_|_|_|_|_|_|_|_|_|_|_|_|

Date of follow-up

|_|_|/|_|_|_|_|/|_|_|_|_|_|_|_|_|
(DD-MMM-YYYY)

All of the outcomes in section 5 refer to the time period within 30 days of randomisation

| Primary outcome | YES | NO | If yes, date of event |
|----------------------------|--------------------------------|-------------------------------|---|
| Pneumonia | <input type="checkbox"/> | <input type="checkbox"/> | _ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY) |
| Endotracheal re-intubation | <input type="checkbox"/> | <input type="checkbox"/> | _ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY) |
| Death | <input type="checkbox"/> Alive | <input type="checkbox"/> Dead | Date of death: _ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY) |

| Respiratory complications | I | II | III | IV | V | NONE |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Pneumonia | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pleural effusion | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pneumothorax | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Bronchospasm | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Aspiration pneumonitis | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Acute Respiratory Distress Syndrome (ARDS) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Infective complications | I | II | III | IV | V | NONE |
| Surgical site infection (superficial) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Surgical site infection (deep) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Surgical site infection (organ space) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Urinary tract infection | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Infection, source uncertain | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Laboratory confirmed blood stream infection | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Please refer to the protocol appendix for specific definitions of complications. Please grade complications using the Clavien-Dindo scale as follows:

- I. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course.
- II. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I.
- III. Requires surgical, endoscopic or radiological intervention.
- IV. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission
- V. Death

SECTION 5: 30-DAY FOLLOW-UP


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|------------------|-----------------|---------------|---------------------------|
| SUBJECT # | _ _ _ - _ _ _ _ | SITE # | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

| Cardiac complications | I | II | III | IV | V | NONE |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Myocardial infarction | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Arrhythmia | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Cardiogenic pulmonary oedema | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Cardiac arrest with successful resuscitation | | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Other complications | I | II | III | IV | V | NONE |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Acute kidney injury | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Pulmonary embolism | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Stroke | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Acute psychosis or delirium | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Bowel infarction | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Anastomotic leak | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Perforation of viscus (e.g. bowel, gall bladder etc) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Postoperative haemorrhage | | | | | | |
| Gastro-intestinal bleed | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other postoperative haemorrhage | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Any other complication, <i>please give details here:</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| Additional treatments | YES | NO |
|---|--------------------------|--------------------------|
| Blood transfusion | <input type="checkbox"/> | <input type="checkbox"/> |
| Parenteral (intra-venous) nutrition | <input type="checkbox"/> | <input type="checkbox"/> |
| Endoscopy or interventional radiology procedure | <input type="checkbox"/> | <input type="checkbox"/> |
| Repeat surgery | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, please indicate the reason for repeat surgery | | |
| Infection | <input type="checkbox"/> | <input type="checkbox"/> |
| Bleeding | <input type="checkbox"/> | <input type="checkbox"/> |
| Anastomotic leak | <input type="checkbox"/> | <input type="checkbox"/> |
| Other | <input type="checkbox"/> | <input type="checkbox"/> |
| Invasive mechanical ventilation after leaving the operating room | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, what was the total duration of invasive mechanical ventilation? | _ _ _ hours | |
| Non-invasive mechanical ventilation after leaving the operating room | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, what was the total duration of non-invasive mechanical ventilation? | _ _ _ hours | |

SECTION 5: 30-DAY FOLLOW-UP

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|------------------|-----------------|---------------|---------------------------|
| SUBJECT # | _ _ _ - _ _ _ _ | SITE # | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

| Patients admitted to a critical care unit | YES | NO |
|---|--------------------------|--------------------------|
| Was the participant admitted to a critical care unit? <i>NB. If 'no', move to the next section.</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| Was the critical care admission to treat a complication? | <input type="checkbox"/> | <input type="checkbox"/> |
| Was a planned critical care admission prolonged by a postoperative complication? | <input type="checkbox"/> | <input type="checkbox"/> |
| What was the total duration of the level 2 critical care stay within 30 days of randomisation? | _ _ days | |
| What was the total duration of the level 3 critical care stay within 30 days of randomisation? | _ _ days | |
| Details of the hospital stay | YES | NO |
| Duration of primary hospital admission (from randomisation) | _ _ days | |
| Re-admission to hospital within 30 days of randomisation | <input type="checkbox"/> | <input type="checkbox"/> |

| Investigator self-assessment of blinding | |
|---|--------------------------|
| I was suitably blinded | <input type="checkbox"/> |
| I may have known the study group allocation | <input type="checkbox"/> |
| I definitely knew the study group allocation | <input type="checkbox"/> |

The self-assessment of blinding should be completed by the investigator that collects the 30-day follow up data. This assessment only applies to data collection at this time point

SECTION 6: ONE-YEAR FOLLOW-UP**SUBJECT #**

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SITE #

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Date of follow-up|_|_|/|_|_|_|_|_|/|_|_|_|_|_|
(DD-MMM-YYYY)**Patient status on date of follow-up** Alive Dead: date of death: |_|_|/|_|_|_|_|_|/|_|_|_|_|_|
(DD-MMM-YYYY)

SUPPLEMENTARY FORM: WITHDRAWAL**SUBJECT #**

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|-------------------|
| _ _ _ - _ _ _ _ _ |
|-------------------|

SITE #

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| _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ |
|-------------------------------|

ONLY COMPLETE THIS FORM IF THE PARTICIPANT PREMATURELY STOPPED THEIR PARTICIPATION IN THE TRIAL OR IF THEY COULD NOT BE CONTACTED

| | | | |
|--|---|---------------------------|------------------------------|
| Date the patient prematurely discontinued study participation: | <table border="1"> <tr> <td> _ _ / _ _ _ _ / _ _ _ _ _ </td> </tr> <tr> <td align="center"><small>(DD-MMM-YYYY)</small></td> </tr> </table> | _ _ / _ _ _ _ / _ _ _ _ _ | <small>(DD-MMM-YYYY)</small> |
| _ _ / _ _ _ _ / _ _ _ _ _ | | | |
| <small>(DD-MMM-YYYY)</small> | | | |
| What was the primary reason for the discontinuation of the study? | <input type="checkbox"/> Inclusion/Exclusion criteria not fulfilled <input type="checkbox"/> Surgical procedure abandoned <input type="checkbox"/> Adverse event related <input type="checkbox"/> Patient initiated <input type="checkbox"/> Other, specify: _____ | | |
| In the case of patient withdrawal, please check: | <input type="checkbox"/> The participant agrees that any data collected up to the date of withdrawal can still be used. <input type="checkbox"/> The patient would like their data removed from the database. | | |

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP



| | | | |
|------------------|-----------------|---------------|---------------------------|
| SUBJECT # | _ _ _ - _ _ _ _ | SITE # | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

ONLY COMPLETE THIS FORM IF THE PATIENT EXPERIENCED AN ADVERSE EVENT DURING CPAP

In the case of multiple adverse events, please complete a separate form for each one.

| ADVERSE EVENT RELATED TO CPAP FORM – PAGE 1 | | NO | YES |
|--|---|--------------------------|--------------------------|
| Did the patient experience an adverse event related to Continuous Positive Airway Pressure (CPAP) that was delivered as part of the PRISM trial? | | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, please answer the following questions. | | | |
| Date and time of onset of adverse event | _ _ / _ _ _ _ / _ _ _ _ (DD/MMM/YYYY) | _ _ : _ _ (HR:MIN) | |
| Adverse Event | NO | YES | |
| Interface intolerance due to excessive air leak | <input type="checkbox"/> | <input type="checkbox"/> | |
| Pain | <input type="checkbox"/> | <input type="checkbox"/> | |
| Cutaneous pressure area | <input type="checkbox"/> | <input type="checkbox"/> | |
| Claustrophobia | <input type="checkbox"/> | <input type="checkbox"/> | |
| Oronasal dryness | <input type="checkbox"/> | <input type="checkbox"/> | |
| Hypercapnia | <input type="checkbox"/> | <input type="checkbox"/> | |
| Haemodynamic instability | <input type="checkbox"/> | <input type="checkbox"/> | |
| Vomiting | <input type="checkbox"/> | <input type="checkbox"/> | |
| Aspiration of gastric contents | <input type="checkbox"/> | <input type="checkbox"/> | |
| Other: | <input type="checkbox"/> | <input type="checkbox"/> | |
| Response to adverse event | Tick one | | |
| CPAP was <i>unchanged</i> | <input type="checkbox"/> | | |
| CPAP was <i>modified</i> | <input type="checkbox"/> | | |
| CPAP was <i>stopped</i> | <input type="checkbox"/> | | |
| Outcome of adverse event | NO | YES | |
| If YES to any option below, please notify the PRISM trial coordinating centre within 24 hours by email. | | | |
| Death | <input type="checkbox"/> | <input type="checkbox"/> | |
| Life-threatening complication | <input type="checkbox"/> | <input type="checkbox"/> | |
| Prolonged hospital stay | <input type="checkbox"/> | <input type="checkbox"/> | |
| Significant disability or incapacity | <input type="checkbox"/> | <input type="checkbox"/> | |

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP**SUBJECT #**

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SITE #

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ADVERSE EVENT RELATED TO CPAP FORM – PAGE 2

Please describe the adverse event, including any treatment or medication required.

Name and signature:

Date:

SUPPLEMENTARY FORM: PROTOCOL DEVIATION



SUBJECT #

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SITE #

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ONLY COMPLETE THIS FORM IF THERE IS A PROTOCOL DEVIATION

Participant in the intervention group did *NOT* receive CPAP

NB. This includes instances where CPAP is started more than twelve hours after the end of surgery. If CPAP was administered, but for only a brief duration, please record this in the next section below.

Please indicate the reason

| | |
|--|--------------------------|
| CPAP was not offered | <input type="checkbox"/> |
| Participant remained intubated after surgery | <input type="checkbox"/> |
| Inadequate staffing or process issues | <input type="checkbox"/> |
| Participant or clinician refusal | <input type="checkbox"/> |
| Participant was too unwell to receive CPAP | <input type="checkbox"/> |
| Equipment failure | <input type="checkbox"/> |
| Other (please state): | <input type="checkbox"/> |

CPAP administered for less than 4 hours duration

NB. This includes instances where CPAP was administered, but only for a brief duration

Please indicate the reason

| | |
|--|--------------------------|
| Participant or clinician refusal | <input type="checkbox"/> |
| Inadequate staffing or process issues | <input type="checkbox"/> |
| Participant too unwell to continue with CPAP | <input type="checkbox"/> |
| Equipment failure | <input type="checkbox"/> |
| Other (please state): | <input type="checkbox"/> |

CPAP administered with significant interruption

NB. Brief interruptions to adjust mask, or for oral/nursing care are considered part of the intervention and do not require a protocol deviation form to be completed

Please indicate the reason

| | |
|--|--------------------------|
| Participant or clinician refusal | <input type="checkbox"/> |
| Inadequate staffing or process issues | <input type="checkbox"/> |
| Participant too unwell to continue with CPAP | <input type="checkbox"/> |
| Equipment failure | <input type="checkbox"/> |
| Other (please state): | <input type="checkbox"/> |

SUPPLEMENTARY FORM: PROTOCOL DEVIATION

SUBJECT #

| |
|-------------------|
| _ _ _ _ - _ _ _ _ |
|-------------------|

SITE #

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| _ _ _ _ _ _ _ _ _ _ _ _ _ _ |
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CPAP started at a dose other than 5cmH₂O

Please indicate the reason

Communication error

Decision by clinical staff

Other (please state):

Participant in the usual care group DID receive CPAP

Please indicate the reason

Randomisation

Communication error

Decision by clinical staff

Other (please state):

Other protocol deviation

Other (please state):

PROTOCOL DEVIATION

Briefly describe the protocol deviation.

Name and signature:

Date: