Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Opioids for Paediatric Breathlessness
Series 34

IMPACCT Trials Coordination Centre (ITCC)
UTS IMPACCT Rapid Paediatric Program
The case report form (CRF) is to be completed in compliance with
ITCC Standard Operating Procedures (SOP)

T_0 – Baseline – at time of medication prescription

Date and Time of baseline assessment			
Date	dd/mm/yyyy	**Time (24hr clock)**	00:00

DEMOGRAPHICS

Gender ○ Male ○ Female ○ Other

Tick ✓	Ethnicity
	Aboriginal
	Torres Strait Islander
	African
	Asian
	European
	Latin American
	Maori
	Mayan people
	Middle Eastern
	Pacific Peoples
	Other; please specify:

Age (0 to <18yrs)	
Years	
Months	
Weeks (only if < 1 month of age)	
Days (only if < 1 week old)	

Weight (kg)	

Tick ✓	Place of Care
	Acute hospital ward
	Emergency department
	Palliative Care Unit / Hospice
	Patient's Home
	Community
	Intensive Care Unit (ICU)
	Other; please specify:

Tick ✓	Primary life limiting illness (please tick only one)
	Congenital condition
	Gastrointestinal condition
	Hepatic condition
	Advanced cancer
	Neurological disease
	Cardiac condition
	Respiratory condition
	End stage renal failure
	Other (e.g. extreme prematurity); please specify:

Tick ✓	Other comorbidities - if any (please tick all that apply)
	Congenital condition
	Gastrointestinal condition
	Hepatic condition
	Advanced cancer
	Neurological disease
	Cardiac condition
	Respiratory condition
	End stage renal failure
	Other (e.g. extreme prematurity); please specify:

Tick ✓	Palliative Care Phase/Period
	1. Stable Phase: The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.
	2. Unstable Phase: The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment.
	3. Deteriorating Phase: The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.
	4. End of Life Care Phase: Death is likely in a matter of days and no acute intervention is planned or required.

Karnofsky/Lansky Performance Status Scale *(please circle appropriate status)*			
The Karnofsky Scale is designed for recipients aged 16 years and older, and the Lansky Scale is designed for patients less than 16 years old. Use the table below to determine the score (10-100) that best represents the patient's activity status.			
Karnofsky Scale (patient's age >/= 16yrs)		**Lansky Scale (recipients age < 16yrs)**	
Able to carry on normal activity; no special care is needed		**Able to carry on normal activity; no special care is needed**	
100	Normal, no complaints, no evidence of disease	100	Fully active
90	Able to carry on normal activity	90	Minor restriction in physically strenuous play
80	Normal activity with effort	80	Restricted in strenuous play, tires more easily, otherwise active
Unable to work, able to live at home cares for most personal needs, a varying amount of assistance needed		**Mild to moderate restriction**	
70	Cares for self, unable to carry on normal activity or to do active work	70	Both greater restrictions of and less time spent in active play
60	Requires occasional assistance but is able to care for most needs	60	Ambulatory up to 50% of the time, limited active play with assistance/supervision
50	Requires considerable assistance and frequent medical care	50	Considerable assistance required for any active play, fully able to engage in quiet play
Unable to care for self, requires equivalent of institutional or hospital care, disease may be progressing rapidly		**Moderate to severe restriction**	
40	Disabled, requires special care and assistance	40	Able to initiate quiet activities
30	Severely disabled, hospitalisation indicated, although death not imminent	30	Needs considerable assistance for quiet activity
20	Very sick, hospitalisation necessary	20	Limited to very passive activity initiated by others (e.g. TV)
10	Moribund, fatal process progressing rapidly	10	Completely disabled, not even passive play

Karnofsky/Lansky Scale Score	

T_0 RESPIRATORY ASSESSMENT
What respiratory support is patient currently receiving
○ no support ○ PRN as needed ○ continuous

Please complete Current Oxygen Therapy table *(complete all aplicable sections)*				
Current Oxygen Therapy	**Tick ✓**	**O2 requirement (L/min)**	**O_2 saturation**	**FiO2**
Room air/no oxygen				
O_2 via nasal prongs				
O_2 via face mask				
O_2 via rebreather mask				
O_2 via high flow nasal prongs				
Non invasive ventilation (BiPAP, VPAP, CPAP)				
Endotracheal Tube (ETT) Ventilation				

Respiratory rate (breaths/min)	

DETERMINING RESPIRATORY DISTRESS SEVERITY
Behaviour (Non verbal children) ○ Normal ○ Some irritability ○ Increasing irritability and/or lethargy
Ability to talk with breathlessness (Verbal children) ○ Able to talk ○ Unable to talk
Accessory Muscle Use ○ Mild ○ Moderate ○ Severe
Tracheal tug/Nasal flaring ○ Mild ○ Moderate ○ Severe
Respiratory Distress Severity Score (see Appendix) ○ Mild ○ Moderate ○ Severe

SYMPTOM SEVERITY SCORE – MSAS

Tick ✓	**How much does the breathlessness bother or distress you/your child?** *(Use parent/carer score if patient cannot score):*
	0 = not at all
	1 = a little bit
	2 = somewhat
	3 = quite a bit
	4 = very much

Baseline – T_0 – Medication Commencement

Date and Time of first dose of opioid administered for breathlessness			
Date	dd/mm/yyyy	**Time (24hr clock)**	00:00

Indicate which opioid(s) are being commenced for breathlessness. (*If you are prescribing a regular opioid as well as PRN doses for breathlessness, please record in the separate tables provided:*

Has a <u>REGULAR</u> opioid been commenced for breathlessness?
◯ Yes - please complete table below ◯ No – proceed to PRN Opioid section

REGULAR OPIOID COMMENCEMENT

Tick ✓	Name of regular opioid for breathlessness
	Morphine
	Oxycodone
	Fentanyl
	Hydromorphone
	Other; please specify:

Tick ✓	Rout of administration/formulation
	Oral immediate release solution
	Oral immediate release tablet
	Oral extended-release tablet
	Intermittent subcutaneous
	Continuous subcutaneous infusion
	Intermittent intravenous
	Continuous intravenous infusion
	Transdermal
	Transmucosal
	PCA
	Other; please specify:

Prescribed dose of REGULAR opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **OR** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*			
Dose commenced (mg)		Please record mg/kg/dose as well	
OR			
Dose commenced (mcg)		Please record mcg/kg/dose as well	

Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q1h	Q2h	Q4h	Q6h	Q8h	Q12h
Q24h	Q72h	Continuous IV/24hrs	PCA	Other; please specify:	

Total dose of REGULAR opioid given in the last 24 hours for breathlessness (mg/mcg):	mg/mcg
How long has the patient been on this REGULAR dose (hours)**:**	hh

PRN OPIOIDS

Is patient being commenced on a <u>PRN</u>/as needed opioid for breathlessness?	
◯ Yes - please complete tables below ◯ No – proceed to concurrent medications section	
Tick ✓	**Name of *Pro re nata* (as needed/prn) opioid commenced for breathlessness**
	Morphine
	Oxycodone
	Fentanyl
	Hydromorphone
	Other(s); please specify:
Tick ✓	**Route of administration/formulation**
	Oral immediate release solution
	Oral immediate release tablet
	Subcutaneous
	Intravenous
	Transmucosal
	Intranasal
	PCA
	Other; please specify:

Prescribed dose of PRN opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **OR** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*			
Dose commenced (mg)		Please record mg/kg/dose as well	
OR			
Dose commenced (mcg)		Please record mcg/kg/dose as well	

Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q15mins	Q30mins	Q1h	Q2h	Q3h	Q4h
Q6h	Q8h	Q12	PCA	Other; please specify:	

Maximum number of doses allowed in 24 hours period:	

CONCURRENT MEDICATIONS

Is patient already on an opioid for pain? Yes ○ No ○ **If yes please specify name, dose, route, and frequency:**
Is patient already on a benzodiazepine? Yes ○ No ○ **If yes please specify name, dose, route, and frequency:**

Tick ✓	**Other Concurrent Medications (classes of drugs) (tick all that apply)**
	Anti-emetics
	Laxatives/aperients
	Tricyclic antidepressants
	NMDA antagonists – Ketamine, Dextromethorphan
	Alpha 2 agonists - Clonidine
	Paracetamol/NSAIDS
	Baclofen
	Anti-reflux medications
	Anti-epileptics
	Antipsychotics
	Steroids
	Other – please specify:
	Other – please specify:
	No other concurrent medications

T_0 - Baseline Symptoms Assessment *(Please grade all symptoms/harms; indicate that each has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1. Mild or localized; topical intervention indicated 2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL 3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1. Mild 2. Moderate, limiting age-appropriate instrumental ADL 3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1. Mild 2. Moderate, limiting age-appropriate instrumental ADL 3. Severe, limiting age appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1.Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalization not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL 3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated 5. Death

☐ **Other harms (if they have been experienced e.g., tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathlessness) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

T_1 – Following first opioid dose for breathlessness

-within 30-min following intravenous (bolus or infusion) or transmucosal dose, OR,

-within 60-min following bolus subcutaneous dose, OR

-within 3-hours following oral dose or start of subcutaneous infusion

Date and time of assessment			
Date:	dd/mm/yyyy	**Time (24hr clock):**	00:00
Number of minutes since opioid commenced:			mins

If T_1 assessment is not within the timeframes above, please provide the reason:

T_1 RESPIRATORY ASSESSMENT		
What respiratory support is patient currently receiving		
○ no support	○ PRN as needed	○ continuous

Please complete Current Oxygen Therapy table *(complete all applicable sections)*				
Current Oxygen Therapy	**Tick ✓**	**O2 requirement (L/min)**	**O_2 saturation**	**FiO2**
Room air/no oxygen				
O_2 via nasal prongs				
O_2 via face mask				
O_2 via rebreather mask				
O_2 via high flow nasal prongs				
Non invasive ventilation (BiPAP, VPAP, CPAP)				
Endotracheal Tube (ETT) Ventilation				

Respiratory rate (breaths/min)	

SYMPTOM SEVERITY SCORE – MSAS

Tick ✓	**How much does the breathlessness bother or distress you/your child?** *(Use parent/carer score if patient cannot score):*
	0 = not at all
	1 = a little bit
	2 = somewhat
	3 = quite a bit
	4 = very much

Has there been any benefit?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

Is the REGULAR and/or PRN dose of opioid for breathlessness different to that prescribed at T_0?	
○ Yes - *please explain variation below:*	○ No

T_1 – Symptom/Harm Assessment *(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age-appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1.Mild hallucinations (e.g., perceptual distortions) 2. Moderate hallucinations 3. Severe hallucinations; hospitalization not indicated 4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated 5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria 1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated 2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL 3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL 4. Life-threatening consequences; urgent intervention indicated 5. Death

☐ **Other harms (if they have been experienced e.g., tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathlessness) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*			
Yes	**No**	**Don't know**	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

HARM ASSESSMENT FOLLOW-UP

What is the intended treatment based on the T_1 assessment? *(tick yes or no)*		
Yes	**No**	**Changes to opioid for breathlessness**
		No change to opioid/continue current dose
		Opioid for breathlessness ceased
		Opioid dose decreased
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, dose & frequency:
		Has a NON-OPIOID medication been started for breathlessness? Please specify medication, dose & frequency:
		Has a non-pharmacological strategy been started? Please specify new strategy:
		Has a medication been added to treat a specific harm? Please specify medication:

T_2 – 24 hours after start of opioid for breathlessness

Tick ✓	T_2: Assessed/Not assessed reason
	Assessed today (continue to complete T_2) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	dd/mm/yyyy

End survey here

Date of T_2 Assessment	dd/mm/yyyy
Time of Assessment (24 hr clock)	00:00

If T_2 assessment is not within the timeframe above, please provide the reason:

Number of hours since opioid was first commenced for breathlessness	

T_2 RESPIRATORY ASSESSMENT		
What respiratory support is patient currently receiving		
○ no support	○ PRN as needed	○ continuous

Please complete Current Oxygen Therapy table				
Current Oxygen Therapy	**Tick ✓**	**O2 requirement (L/min) (if applicable)**	**O_2 saturation (if available)**	**FiO2 (if available)**
Room air/no oxygen				
O_2 via nasal prongs				
O_2 via face mask				
O_2 via rebreather mask				
O_2 via high flow nasal prongs				
Non invasive ventilation (BiPAP, VPAP, CPAP)				
Endotracheal Tube (ETT) Ventilation				

Respiratory rate (breaths/min)	

SYMPTOM SEVERITY SCORE – MSAS

Tick ✓	How much does the breathlessness bother or distress you/your child? (Use parent/carer score if patient cannot score):
	0 = not at all
	1 = a little bit
	2 = somewhat
	3 = quite a bit
	4 = very much

Is patient on a <u>REGULAR</u> opioid for breathlessness?
◯ Yes - please complete table below ◯ No – proceed to PRN Opioid section

Current prescribed dose of REGULAR opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **<u>OR</u>** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*					
Dose commenced (mg)		Please record mg/kg/dose as well			
OR					
Dose commenced (mcg)		Please record mcg/kg/dose as well			
Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q1h	Q2h	Q4h	Q6h	Q8h	Q12h
Q24h	Q72h	Continuous IV/24hrs	PCA	Other; please specify:	
Total dose of REGULAR opioid given in the last 24 hours for breathlessness (mg/mcg):					mg/mcg
How long has the patient been on this REGULAR dose (hours)**:**					hh

PRN OPIOIDS

Is patient on a PRN opioid for breathlessness?	
◯ Yes - please complete table below	◯ No – proceed to next section

Current prescribed dose of PRN opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **OR** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*					
Dose commenced (mg)		Please record mg/kg/dose as well			
OR					
Dose commenced (mcg)		Please record mcg/kg/dose as well			
Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q15mins	Q30mins	Q1h	Q2h	Q3h	Q4h
Q6h	Q8h	Q12	PCA	Other; please specify:	
Total dose of PRN opioid given in the last 24 hours for breathlessness (mg/mcg):					mg/mcg
How long has the patient been on this PRN dose (hours)**:**					hh

Has there been any benefit?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

Have there been any changes to opioids for breathlessness since T_1?

(please tick yes or no to all)

Yes	No	Changes to opioids for breathlessness
		No change to opioid/continue current dose
		Opioid for breathlessness ceased
		Opioid dose decreased
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, dose & frequency:
		Has a NON-OPIOID medication been started for breathlessness? Please specify medication, dose & frequency:
		Has a non-pharmacological strategy been started? Please specify new strategy:
		Has a medication been added to treat a specific harm? Please specify medication here:

T_2 – Symptom/Harm Assessment *(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Other harms (if they have been experienced e.g., tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathlessness) (Select one only) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

Yes	No	Don't know	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

HARM ASSESSMENT FOLLOW-UP

What is the intended treatment based on the T_2 assessment? *(Tick yes or no to indicate changes to opioid for breathlessness)*		
Yes	**No**	**Changes to opioid for breathlessness**
		No change to opioid/continue current dose
		Opioid for breathlessness ceased
		Opioid dose decreased
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, dose & frequency:
		Has a NON-OPIOID medication been started for breathlessness? Please specify medication, dose & frequency:
		Has a non-pharmacological strategy been started? Please specify new strategy:
		Has a medication been added to treat a specific harm? Please specify medication:

T_3 – 48 to 60 hours after opioid started for breathlessness

Tick ✓	T_3: Assessed/Not assessed reason
	Assessed today (continue to complete T_3) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death*	dd/mm/yyyy

End survey here

Date of T_3 Assessment	dd/mm/yyyy
Time of Assessment (24 hr clock)	00:00

If T_3 assessment is not within the timeframe above, please provide the reason:

Number of hours since opioid was first commenced for breathlessness	hh

T_3 RESPIRATORY ASSESSMENT
What respiratory support is patient currently receiving
○ no support ○ PRN as needed ○ continuous

Please complete Current Oxygen Therapy table				
Current Oxygen Therapy	**Tick ✓**	**O2 requirement (L/min) (if applicable)**	**O_2 saturation (if available)**	**FiO2 (if available)**
Room air/no oxygen				
O_2 via nasal prongs				
O_2 via face mask				
O_2 via rebreather mask				
O_2 via high flow nasal prongs				
Non invasive ventilation (BiPAP, VPAP, CPAP)				
Endotracheal Tube (ETT) Ventilation				

Respiratory rate (breaths/min)	

SYMPTOM SEVERITY SCORE – MSAS

Tick ✓	**How much does the breathlessness bother or distress you/your child?** *(Use parent/carer score if patient cannot score):*
	0 = not at all
	1 = a little bit
	2 = somewhat
	3 = quite a bit
	4 = very much

Is patient on a <u>REGULAR</u> opioid for breathlessness?
◯ Yes - please complete table below ◯ No – proceed to PRN Opioid section

Current prescribed dose of REGULAR opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **<u>OR</u>** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*					
Dose commenced (mg)		Please record mg/kg/dose as well			
OR					
Dose commenced (mcg)		Please record mcg/kg/dose as well			
Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q1h	Q2h	Q4h	Q6h	Q8h	Q12h
Q24h	Q72h	Continuous IV/24hrs	PCA	Other; please specify:	
Total dose of REGULAR opioid given in the last 24 hours for breathlessness (mg/mcg):					mg/mcg
How long has the patient been on this REGULAR dose (hours)**:**					hh

PRN OPIOIDS

Is patient on a PRN opioid for breathlessness?	
◯ Yes - please complete table below	◯ No – proceed to next section

Current prescribed dose of PRN opioid for breathlessness *(complete the appropriate table - either dose in mg and mg/kg/dose **OR** dose in mcg and mcg/kg/dose. Only write a numerical value in the box. (e.g., 2mg/kg/dose to be recorded as 2)*			
Dose commenced (mg)		Please record mg/kg/dose as well	
OR			
Dose commenced (mcg)		Please record mcg/kg/dose as well	

Frequency of dose prescribed *(Please circle frequency, or indicate other)*					
Q15mins	Q30mins	Q1h	Q2h	Q3h	Q4h
Q6h	Q8h	Q12	PCA	Other; please specify:	

Total dose of PRN opioid given in the last 24 hours for breathlessness (mg/mcg):	mg/mcg
How long has the patient been on this PRN dose (hours)**:**	hh

Has there been any benefit?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

Have there been any changes to opioids for breathlessness since T_2?

(please tick yes or no to all)

Yes	No	Changes to opioids for breathlessness
		No change to opioid/continue current dose
		Opioid for breathlessness ceased
		Opioid dose decreased
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, dose & frequency:
		Has a NON-OPIOID medication been started for breathlessness? Please specify medication, dose & frequency:
		Has a non-pharmacological strategy been started? Please specify new strategy:
		Has a medication been added to treat a specific harm? Please specify medication here:

T_3 – Symptom/Harm Assessment *(Please grade all harms/toxicities regardless of whether they are attributable to the medication of interest or not; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Other harms (if they have been experienced e.g., tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathless ness) (Select one only) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

Yes	No	Don't know	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

HARM ASSESSMENT FOLLOW-UP

What is the intended treatment based on the T_3 assessment? *(Tick yes or no to indicate changes to opioid for breathlessness)*		
Yes	**No**	**Changes to opioid for breathlessness**
		No change to opioid/continue current dose
		Opioid for breathlessness ceased
		Opioid dose decreased
		Opioid dose increased
		Current opioid ceased and new opioid started. Please specify new opioid, dose & frequency:
		Has a NON-OPIOID medication been started for breathlessness? Please specify medication, dose & frequency:
		Has a non-pharmacological strategy been started? Please specify new strategy:
		Has a medication been added to treat a specific harm? Please specify medication:

Medication Cessation *(Complete this page if the intervention/medication of interest is ceased at any point during the study period)*	
Date of Assessment (medication cessation)	dd/mm/yyyy

Tick ✓	**Medication was ceased (related to indication of interest)**
	Symptom resolved; please indicate date symptom resolved: date of resolution: dd/mm/yyyy
	Symptom continued unchanged
	Symptom/s worsened; please grade below:

SYMPTOM SEVERITY SCORE – MSAS

Tick ✓	**How much does the breathlessness bother or distress you/your child?** *(Use parent/carer score if patient cannot score):*
	0 = not at all
	1 = a little bit
	2 = somewhat
	3 = quite a bit
	4 = very much

Tick ✓	**Intervention/medication was ceased (related to other reasons)**
	Harm/toxicity
	Patient unable to take medication due to swallowing difficulty
	Patient refused to take medication
	Other; please specify:

Ad hoc A - Unscheduled Adverse Event/Harm Assessment

Date of Assessment	dd/mm/yyyy

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Other harms (if they have been experienced e.g., tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathless ness) (Select one only) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

Yes	**No**	**Don't know**	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

Ad hoc B – Unscheduled Adverse Event/Harm Assessment

Date of Assessment	dd/mm/yyyy

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age-appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Other harms (if they have been experienced e.g. tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathless ness) (Select one only) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

Yes	No	Don't know	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

Ad hoc C – Unscheduled Adverse Event/Harm Assessment

Date of Assessment	dd/mm/yyyy

Harm/toxicity Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild unsteadiness or sensation of movement
2.Moderate unsteadiness or sensation of movement; limiting instrumental ADL
3.Severe unsteadiness or sensation of movement; limiting self-care ADL

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Loss of appetite without alteration in eating habits
2. Oral intake decreased without significant weight loss.
3. Inadequate caloric or fluid intake; tube feeding, TPN or hospitalisation indicated.

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1.Intervention not indicated
2. Outpatient IV hydration; medical intervention indicated
3. Tube feeding, TPN, or hospitalization indicated
4. Life-threatening consequences
5. Death

☐ **Somnolence**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild but more than usual drowsiness or sleepiness
2. Moderate sedation; limiting instrumental ADL
3. Obtundation or stupor
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded

NCI Criteria
1. Mild disorientation
2. Moderate disorientation; limiting instrumental ADL
3. Severe disorientation; limiting self-care ADL
4. Life-threatening consequences threats of harm to self or others; hospitalization indicated
5. Death

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild; asymptomatic or mild symptoms
2. Moderate; minimal; local or non-invasive intervention indicated
3. Severe or medically significant but not immediately life threatening
4. Life threatening consequences; urgent intervention indicated
5. Death

☐ **Pruritus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild or localized; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated

☐ **Muscle rigidity**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Mild
2. Moderate, limiting age-appropriate instrumental ADL
3. Severe, limiting age appropriate self-care ADL

☐ **Hallucinations**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalization not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalization indicated
5. Death

☐ **Respiratory Depression**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL
3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **Other harms (if they have been experienced e.g. tolerance to opioid)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

☐ **Additional other harms (if they have been experienced)**

Please specify additional other harm:			
○ mild	○ moderate	○ severe	○ ungradable

Tick ✓	**Which harm is the most troublesome?** *(excluding the target symptom breathless ness) (Select one only) (Select one only)*
	Dizziness
	Nausea
	Vomiting
	Somnolence
	Confusion
	Constipation
	Pruritus
	Myoclonus
	Muscle rigidity
	Hallucinations
	Respiratory Depression
	Other harm
	Additional other harm
	Not applicable

If a harm/toxicity scored 3 or more, please complete this set of questions from the Naranjo modified checklist. *(Tick 'yes', 'no', or 'don't know' for each question below) (If the symptom was present at baseline and grading remains unchanged the Naranjo questions are not required to be answered.)*

Yes	No	Don't know	
			1. Did the adverse reaction appear after the suspected drug was given?
			2. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was given?
			3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
			4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
			5. Was the adverse event confirmed by any objective evidence?

Appendix – Guide to determining Respiratory Distress Severity

< 2 years age and non-verbal child

MILD	MODERATE	SEVERE
Normal behaviour	Some/intermittent irritability	Increasing irritability and/or lethargy
Normal to mild tachypnoea	Increased RR	Marked increase or decreased RR
SPO2 > 92% in room air	SPO2 90 – 92%in room air	SPO2 < 90%
Minimal increased work of breathing	Mild increased work of breathing	Obvious accessory muscle use

> 2 years age

MILD	MODERATE	SEVERE
Able to talk	Able to talk	Too breathless to talk
Normal SPO2	SPO2 $\geq$ 92%	SPO2 < 92%
Normal to minimal increased work of breathing	Mild increased work of breathing	Obvious accessory muscle use

References:

A Respiratory Distress Observation Scale for Patients Unable To Self-Report Dyspnea: Margaret L. Campbell, Ph.D., R.N., F.A.A.N.,1–3 Thomas Templin, Ph.D.,2 and Julia Walch, R.N., M.S.N., F.N.P.3

Common Terminology Criteria for Adverse Events (CTCAE). Version 5.0. Published: November 27, 2017. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health, National Cancer Institute

Naranjo CA, Busto U, Sellers EM, et al. A Method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther (1981);30:239-45.