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)

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# $T_0$ — Baseline — at time of medication prescription

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

#### **DEMOGRAPHICS**

<b>Gende</b> r O 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 >/= Lansky Scale (recipients age < 16yrs)				
Karnofsky Scale (patient's age >/= 16yrs)					
Abl	Able to carry on normal activity; no		Able to carry on normal activity; no		
	special care is needed		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		
Una	ble to work, able to live at home				
	res for most personal needs, a		Mild to moderate restriction		
vary	ing amount of assistance needed				
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		
equi	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 <sub>0</sub> RESPI	RATORY ASSESSMENT					
What res	piratory support is patio	ent curren	tly receiving			
O no supp	oort OPRN as need	ded	○ continuo	us		
Please co	mplete Current Oxygen	Therapy	table (complete	e all aplicable s	ections)	
Current (	Oxygen Therapy	Tick ✓	O2 requirement (L/min)	O <sub>2</sub> saturation	FiO2	
Room air/ı						
O <sub>2</sub> via nas						
O <sub>2</sub> via face	e mask reather mask					
	n flow nasal prongs					
Non invasi	ve ventilation					
	PAP, CPAP) eal Tube (ETT) Ventilation					
Liladalacii	edi Tube (ETT) Veridiacion		1	<u> </u>		
Respirato	ory rate (breaths/min)					
DETERMI	NING RESPIRATORY D	ISTRESS S	SEVERITY			
Behaviou	r (Non verbal children)					
O Normal	O Some irritability	O Increasi	ng irritability an	d/or lethargy		
Ability to	talk with breathlessnes	ss (Verbal	children)			
O Able to	talk O Unal	ole to talk				
Accessor	y Muscle Use					
O Mild	○ Moderate ○ Severe					
Tracheal	tug/Nasal flaring					
O Mild	○ Moderate ○ Severe					
Respirato	ory Distress Severity Sco	ore (see A	ppendix)			
O Mild	○ Moderate	○ Severe				
SYMPTON	4 SEVERITY SCORE -	MSAS				
Tick ✓	How much does the br child? (Use parent/carer			-	your	
	0 = not at all					
	1 = a little bit					
	2 = somewhat					
	3 = quite a bit					
	4 = very much					

# **Baseline – T<sub>0</sub> – 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 com	menced 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:

<b>Prescribed dose of REGULAR opioid for breathlessness</b> (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 commend	ced (mg)		Please reco	rd mg/kg/dos	e as well	
			OR			
Dose commenc	ed (mcg)		Please recor	rd mcg/kg/dos	se as well	
Frequency of c	Frequency of dose prescribed (Please circle frequency, or indicate other)					
Q1h	Q2h		Q4h	Q6h	Q8h	Q12h
Q24h	Q72h		Continuous IV/24hrs	PCA	Other; ple	ase 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 - ple	ease complete tables below   No – proceed to concurrent medications section
Tick ✓	Name of <i>Pro re nata</i> (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:

<b>Prescribed dose of PRN opioid for breathlessness</b> (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 comme	nced (mg)		Please	record mg/kg/	dose as well	
			0	R		
Dose commer	nced (mcg)		Please	record mcg/kg/	dose as well	
Frequency of dose prescribed (Please circle frequency, or indicate other)						
Q15mins	Q30mins Q1h		Q1h	Q2h	Q3h	Q4h
Q6h	Q8h	Q8h Q12 PCA Other; please specify:			ecify:	
Maximum number of doses allowed in 24 hours period:						

## **CONCURRENT MEDICATIONS**

is patient aiready on an opioid for pain?				
Yes O	No O If yes please specify name, dose, route, and frequency:			
Is patien	t already on a benzodiazepine?			
Yes O N	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			

#### indicate that each has been assessed by ticking the square box next to each) □ Dizziness $\bigcirc$ 1 $\bigcirc$ 2 ○ 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 $\bigcirc 1 \bigcirc 2$ ○ 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 $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 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 $\bigcirc$ 2 $\bigcirc$ 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 $\bigcirc 1 \bigcirc 2$ ○ 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 $\bigcirc$ 1 ○ 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

To - Baseline Symptoms Assessment (Please grade all symptoms/harms;

☐ Pruritus	
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded	d
NCI Criteria	
Mild or localized; topical intervention indicated	lation accordations
2. Widespread and intermittent; skin changes from scratching (e.g., edema, papu lichenification, oozing/crusts); oral intervention indicated; limiting instrumental AD	
3. Widespread and constant; limiting self-care ADL or sleep; systemic corticostero	
therapy indicated	
☐ Muscle rigidity	
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded	<u>d</u>
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	b
NCI Criteria	
1. Mild 2. Moderate, limiting age-appropriate instrumental ADL	
3. Severe, limiting age appropriate self-care ADL	
☐ Hallucinations	
$\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 3 $\bigcirc$ 4 $\bigcirc$ 5 $\bigcirc$ ungradable $\bigcirc$ no symptom	O not recorded
NCI Criteria	
1.Mild hallucinations (e.g., perceptual distortions)	
Moderate hallucinations     Severe hallucinations; hospitalization not indicated	
4. Life-threatening consequences, threats of harm to self or others; hospitalization	n indicated
5. Death	
Respiratory Depression	<u> </u>
01 02 03 04 05 0 ungradable 0 no symptom	○ not recorded
NCI Criteria	contian not indicated
1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; interval. Moderate; minimal; local or non-invasive intervention indicated; limiting age-age-age-age-age-age-age-age-age-age-	
3. Severe or medically significant but not immediately life-threatening; hospitalisa	
existing hospitalisation indicated; disabling; limiting self-care ADL	. 5
4. Life-threatening consequences; urgent intervention indicated	
5. Death	
Other harms (if they have been experienced a g. teleran	so to opioid)
Other harms (if they have been experienced e.g., toleran	ce 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<sub>1</sub> – 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 ass	sessment					
Date:	dd/mm/yyy	Time (24hr clock):			00:00	
Number of minutes	since opioid c	d commenced:			mins	
If T <sub>1</sub> assessment is I	not within the	timefra	mes above, plo	ease p	orovide	the reaso
T <sub>1</sub> RESPIRATORY AS What respiratory su		nt curre	ntly receiving			
	PRN as need		○ continuo	us		
Please complete Cur	rrent Oxygen	Therapy	table (complet	e all a	pplicable	e sections)
Current Oxygen The	rapy	Tick ✓	O2 requirement (L/min)		O <sub>2</sub> ration	FiO2
Room air/no oxygen						
O <sub>2</sub> via nasal prongs						
O <sub>2</sub> via face mask						
O <sub>2</sub> via rebreather mask						
O <sub>2</sub> via high flow nasal prongs						
Non invasive ventilatio (BiPAP, VPAP, CPAP)	n					
Endotracheal Tube (ET	T) Ventilation					
Respiratory rate (bre	eaths/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 ther	e been any benefit?
	ete resolution 🗆 Partial resolution 🗀 No change 🗆 Worse
Is the RI	EGULAR and/or PRN dose of opioid for breathlessness different to that ed at $T_0$ ?
○ Yes - Æ	please explain variation below:
whether t	ptom/Harm Assessment (Please grade all harms/toxicities regardless of they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)
whether t	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)
whether the has been	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)
whether the has been  Dizzine  1  NCI Criteria	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2  3  ungradable on symptom on trecorded
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1 0 2  NCI Criteria 1.Mild unste 2.Moderate 3.Severe un	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1 0 2  NCI Criteria 1.Mild unste 2.Moderate 3.Severe un	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess  2
whether to has been  Dizzine  1	they are attributable to the medication of interest or not; indicate that each harm assessed by ticking the square box next to each)  ess 2

☐ Somnolence
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Mild but more than usual drowsiness or sleepiness</li> <li>2. Moderate sedation; limiting instrumental ADL</li> <li>3. Obtundation or stupor</li> <li>4. Life-threatening consequences; urgent intervention indicated</li> <li>5. Death</li> </ul>
□ Confusion
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Mild disorientation</li> <li>2. Moderate disorientation; limiting instrumental ADL</li> <li>3. Severe disorientation; limiting self-care ADL</li> <li>4. Life-threatening consequences threats of harm to self or others; hospitalization indicated</li> </ul>
5. Death
☐ Constipation
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Mild; asymptomatic or mild symptoms</li> <li>2. Moderate; minimal; local or non-invasive intervention indicated</li> <li>3. Severe or medically significant but not immediately life threatening</li> <li>4. Life threatening consequences; urgent intervention indicated</li> <li>5. Death</li> </ul>
☐ <b>Pruritus</b> ○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Mild or localized; topical intervention indicated</li> <li>2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL</li> <li>3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated</li> </ul>
☐ 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
□ Manadaman
<ul><li>☐ Myoclonus</li><li>☐ 1</li><li>☐ 2</li><li>☐ 3</li><li>☐ ungradable</li><li>☐ no symptom</li><li>☐ not recorded</li></ul>
NCI Criteria  1. Mild  2. Moderate, limiting age-appropriate instrumental ADL  3. Severe, limiting age-appropriate self-care ADL

☐ Hallu	icinations	
$\bigcirc$ 1 $\bigcirc$	2 03 04 05 0 ungradable 0 no symptom 0 not reco	orded
NCI Criteri 1.Mild hall	<i>ia</i> ucinations (e.g., perceptual distortions)	
2. Moderat	te hallucinations	
	hallucinations; hospitalization not indicated eatening consequences, threats of harm to self or others; hospitalization indicated	
5. Death		
☐ Resp	iratory Depression	
$\bigcirc$ 1 $\bigcirc$	2 $\bigcirc$ 3 $\bigcirc$ 4 $\bigcirc$ 5 $\bigcirc$ ungradable $\bigcirc$ no symptom $\bigcirc$ not rec	orded
NCI Criteri	<i>ia</i> omatic or mild symptoms; clinical or diagnostic observations only; intervention not ir	dicated
2. Moderat	te; minimal; local or non-invasive intervention indicated; limiting age-appropriate ins	trumental ADL
	or medically significant but not immediately life-threatening; hospitalisation or prolor ospitalisation indicated; disabling; limiting self-care ADL	igation of
4. Life-thre 5. Death	eatening consequences; urgent intervention indicated	
□ Other	harms (if they have been experienced e.g., tolerance to opio	oid)
Please s	specify additional other harm:	
○ mild	○ moderate ○ severe ○ ungradable	
	ional other harms (if they have been experienced)	
Please s	specify additional other harm:	
○ mild	○ moderate ○ severe ○ ungradable	
		1
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	

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 <sub>1</sub> 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 <sub>2</sub> : Assessed/Not assessed reason
	Assessed today (continue to complete T <sub>2</sub> ) OR
	Died – record date of death below
	Not able to be contacted / located
	Too unwell
	Other

Date of Death* dd/mm/yyyy
---------------------------

<sup>\*</sup>End survey here

Date of T <sub>2</sub> Assessment	dd/mm/yyyy
Time of Assessment (24 hr clock)	00:00

If T <sub>2</sub> assessment is not within the timeframe above, please provide the reason:				
Number of hours	since opioid was first c	ommenced for		
breathlessness				
T <sub>2</sub> RESPIRATORY	ASSESSMENT			
What respiratory support is patient currently receiving				
O no support	O PRN as needed	O continuous		

Please complete Current Oxygen Therapy table					
Current Oxygen Therapy	Tick ✓	O2 requirement (L/min) (if applicable)	O <sub>2</sub> saturation (if available)	FiO2 (if available)	
Room air/no oxygen					
O <sub>2</sub> via nasal prongs					
O <sub>2</sub> via face mask					
O <sub>2</sub> via rebreather mask					
O <sub>2</sub> via high flow nasal prongs					
Non invasive ventilation (BiPAP, VPAP, CPAP)					
Endotracheal Tube (ETT) Ventilation					

# **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 fo	or breathlessness?	
○ Yes - please complete table below	○ No – proceed to PRN Opioid section	

Current prescr appropriate table Only write a nui	le - either do	ose in	mg and mg/kg/d	dose <u>OR</u> dose	e in mcg and n	ncg/kg/dose.
Dose commen	ced (mg)		Please reco	rd mg/kg/dos	se as well	
			OR			
Dose commend	ced (mcg)		Please recor	rd mcg/kg/do	se 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 breathle	essness?
○ Yes - please complete table below	○ No – proceed to next section

appropriate ta	ble - either do	ose in mg and mg	r/kg/dose <u>OR</u> d	ness (complete a dose in mcg and r to be recorded a	ncg/kg/dose.	
Dose comme	enced (mg)	Please	record mg/kg/	dose as well		
	OR					
Dose commer	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	Have there been any changes to opioids for breathlessness since T <sub>1</sub> ?				
(please	e tick ye	es 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<sub>2</sub> – 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
Loss of appetite without alteration in eating habits     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
<ul> <li>NCI Criteria</li> <li>1. Mild or localized; topical intervention indicated</li> <li>2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL</li> <li>3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated</li> </ul>
☐ Muscle rigidity
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded    NCI Criteria
1. Mild
Moderate, limiting age-appropriate instrumental ADL     Severe, limiting age appropriate self-care ADL
<ul><li>☐ Myoclonus</li><li>☐ 1</li><li>☐ 2</li><li>☐ 3</li><li>☐ ungradable</li><li>☐ no symptom</li><li>☐ not recorded</li></ul>
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

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

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

		ended treatment based on the T <sub>2</sub> assessment? (Tick yes or no to 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 <sub>3</sub> : Assessed/Not assessed reason				
	Assessed today (continue to complete T <sub>3</sub> ) OR				
	Died – record date of death below				
	Not able to be contacted / located				
	Too unwell				
	Other				

Date of Death*	dd/mm/yyyy
----------------	------------

<sup>\*</sup>End survey here

Date of T <sub>3</sub> 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	
---	--

T <sub>3</sub> RESPIRATORY ASSESSMENT				
What respiratory support is patient currently receiving				
O no support	O PRN as needed	○ continuous		

Please complete Current Oxygen Therapy table				
Current Oxygen Therapy	Tick ✓	O2 requirement (L/min) (if applicable)	O <sub>2</sub> saturation (if available)	FiO2 (if available)
Room air/no oxygen				
O <sub>2</sub> via nasal prongs				
O <sub>2</sub> via face mask				
O <sub>2</sub> via rebreather mask				
O <sub>2</sub> 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			

appropriate tabi	le - either da	se in	GULAR opioid mg and mg/kg/c ne box. (e.a., 2m	dose <u>OR</u> dose	e in mcg and n	ncg/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 commend	ced (mcg)		Please recor	d mcg/kg/do	se as well	
Frequency of	dose presci	ribed	(Please circle fre	equency, or i	ndicate other)	
Q1h	Q2h		Q4h	Q6h	Q8h	Q12h
Q24h	Q24h Q72h Continuous IV/24hrs PCA Other; please speci			ase 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 <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 comme	enced (mg)		Please record mg/kg/dose as well				
			0	R			
Dose comme	nced (mcg)		Please record mcg/kg/dose as well				
Frequency of	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?
$\square$ Complete resolution $\square$ Partial resolution $\square$ No change $\square$ Worse

Have	Have there been any changes to opioids for breathlessness since T₂?					
(please	tick ye	es 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:				

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  $\bigcirc$  1  $\bigcirc$  2  $\bigcirc$  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  $\bigcirc$  1  $\bigcirc$  2 ○ 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  $\bigcirc$  2  $\bigcirc$  1 ○ Ungradable ○ No Symptom ○ not recorded  $\bigcirc$  4  $\bigcirc$  5 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  $\bigcirc$  1 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded  $\bigcirc$  4 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  $\bigcirc$  1  $\bigcirc$  2  $\bigcirc$  5 ○ Ungradable ○ No Symptom ○ not recorded  $\bigcirc$  4 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  $\bigcirc$  1 ○ 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

T<sub>3</sub> – Symptom/Harm Assessment (Please grade all harms/toxicities regardless of

☐ Pruritus						
$\bigcirc$ 1 $\bigcirc$ 2	○ 3 ○ ungrada	ble O no sympto	om O 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					
			; systemic corticosteroid or immunosuppressive			
therapy indicat		•				
□ Msala						
☐ Muscle						
$\bigcirc 1 \bigcirc 2$	○ 3 ○ ungrada	ible $\cup$ no sympto	m O not recorded			
NCI Criteria 1. Mild						
-	imiting age-appropriate in	nstrumental ADL				
	ting age appropriate self					
□ Mala.						
<b>☐</b> Myoclor						
$\bigcirc 1 \bigcirc 2$	○ 3 ○ ungrada	ible $\cup$ no sympto	m ○ not recorded			
NCI Criteria 1. Mild						
-	imiting age-appropriate in	nstrumental ADL				
	ting age appropriate self					
☐ Hallucin		-				
$\bigcirc 1 \bigcirc 2$	03 04 05	$\odot$ ungradable	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria	ations (e.g., perceptual c	listortions)				
2. Moderate ha		iistoi tioris)				
	ucinations; hospitalization	not indicated				
	ning consequences, three	ats of harm to self or	others; hospitalization indicated			
5. Death						
☐ Respira	tory Depression					
$\bigcirc$ 1 $\bigcirc$ 2	03 04 05	5 O ungradable	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria		o ungradabi	e o no symptom o not recorded			
1. Asymptoma			oservations only; intervention not indicated			
			licated; limiting age-appropriate instrumental ADL			
	nedically significant but n calisation indicated; disab		nreatening; hospitalisation or prolongation of			
	ning consequences; urge					
5. Death	mig consequences, ange	are meer verteren maree				
☐ Other ha	rms (if they have	been experience	ced e.g., tolerance to opioid)			
Please spe	cify additional oth	ner harm:				
-	-					
O mild	$\bigcirc$ moderate	○ severe	$\bigcirc$ ungradable			
□ Addition	al other harms (if	they have been	n experienced)			
Please spe	cify additional oth	ner harm:				
	,					
		_				
○ mild	<ul><li>moderate</li></ul>	○ severe	O 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

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 <sub>3</sub> 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)

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** Harm/toxicity Assessment (Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each) ☐ Dizziness $\bigcirc$ 2 ○ ungradable ○ no symptom ○ not recorded $\bigcirc$ 1 $\bigcirc$ 3 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 $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 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 $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 4 $\bigcirc$ 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 ○ 5 ○ Ungradable ○ No Symptom ○ not recorded $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 3 $\bigcirc$ 4 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 ○ Ungradable ○ No Symptom ○ not recorded $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 4 $\bigcirc$ 5 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
<ul> <li>NCI Criteria</li> <li>1. Mild; asymptomatic or mild symptoms</li> <li>2. Moderate; minimal; local or non-invasive intervention indicated</li> <li>3. Severe or medically significant but not immediately life threatening</li> <li>4. Life threatening consequences; urgent intervention indicated</li> <li>5. Death</li> </ul>
□ Pruritus
○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Mild or localized; topical intervention indicated</li> <li>2. Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental ADL</li> <li>3. Widespread and constant; limiting self-care ADL or sleep; systemic corticosteroid or immunosuppressive therapy indicated</li> </ul>
<ul><li>☐ Muscle rigidity</li><li>☐ 1</li><li>☐ 2</li><li>☐ 3</li><li>☐ ungradable</li><li>☐ no symptom</li><li>☐ not recorded</li></ul>
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
Moderate, limiting age-appropriate instrumental ADL     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)
Severe hallucinations     Severe hallucinations; hospitalization not indicated
Life-threatening consequences, threats of harm to self or others; hospitalization indicated     Death
J. Death
☐ Respiratory Depression
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom ○ not recorded
<ul> <li>NCI Criteria</li> <li>1. Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated</li> <li>2. Moderate; minimal; local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL</li> <li>3. Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of existing hospitalisation indicated; disabling; limiting self-care ADL</li> <li>4. Life-threatening consequences; urgent intervention indicated</li> <li>5. Death</li> </ul>

Other	harms (if they have	been experience	ced e.g., tolerance to opioid)	
Please	specify additional oth	er harm:		
○ mild	○ moderate	○ severe	O ungradable	
	ional other harms (if	-	n experienced)	
Please s	specify additional oth	er harm:		
$\bigcirc$ mild	○ moderate	○ severe	$\bigcirc$ ungradable	
	I			
Tick ✓			me? (excluding the target only) (Select one only)	
	Dizziness			
	Nausea			
	Vomiting			
	Somnolence			
	Confusion			
	Constipation			
	Pruritus			
	Myoclonus			
	Muscle rigidity			
	Hallucinations			
	Respiratory Depressio	n		
	Other harm			
	Additional other harm			
	Not applicable			
	•			

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 assessed by ticking the square box next to each)	•		
☐ <b>Dizziness</b> ○ 1 ○ 2 ○ 3 ○ ungradable ○ no sympto	om O not recorded		
NCI Criteria 1.Mild unsteadiness or sensation of movement 2.Moderate unsteadiness or sensation of movement; limitin 3.Severe unsteadiness or sensation of movement; limiting s	g instrumental ADL		
Nausea ○ 1 ○ 2 ○ 3 ○ ungradable ○ no sympt	om ○ not recorded		
<ul> <li>NCI Criteria</li> <li>1. Loss of appetite without alteration in eating habits</li> <li>2. Oral intake decreased without significant weight loss.</li> <li>3. Inadequate caloric or fluid intake; tube feeding, TPN or have</li> </ul>	nospitalisation indicated.		
	le ○ No Symptom ○ not recorded		
<ul> <li>NCI Criteria</li> <li>1.Intervention not indicated</li> <li>2. Outpatient IV hydration; medical intervention indicated</li> <li>3. Tube feeding, TPN, or hospitalization indicated</li> <li>4. Life-threatening consequences</li> <li>5. Death</li> </ul>			
☐ Somnolence ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradab	le ○ No Symptom ○ not recorded		
<ul> <li>NCI Criteria</li> <li>1. Mild but more than usual drowsiness or sleepiness</li> <li>2. Moderate sedation; limiting instrumental ADL</li> <li>3. Obtundation or stupor</li> <li>4. Life-threatening consequences; urgent intervention indic</li> <li>5. Death</li> </ul>	ated		
<ul> <li>☐ Confusion</li> <li>○ 1</li> <li>○ 2</li> <li>○ 3</li> <li>○ 4</li> <li>○ 5</li> <li>○ Ungradab</li> </ul>	le $\bigcirc$ No Symptom $\bigcirc$ not recorded		
<ul> <li>NCI Criteria</li> <li>1. Mild disorientation</li> <li>2. Moderate disorientation; limiting instrumental ADL</li> <li>3. Severe disorientation; limiting self-care ADL</li> <li>4. Life-threatening consequences threats of harm to self or others; hospitalization indicated</li> <li>5. Death</li> </ul>			
$\Box$ <b>Constipation</b> $\bigcirc$ 1 $\bigcirc$ 2 $\bigcirc$ 3 $\bigcirc$ 4 $\bigcirc$ 5 $\bigcirc$ ungradable $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria  1. Mild; asymptomatic or mild symptoms 2. Moderate; minimal; local or non-invasive intervention inc 3. Severe or medically significant but not immediately life the description of the consequences; urgent intervention indicates to be described by the consequences of the co	dicated hreatening		

☐ Pruritus						
$\bigcirc$ 1 $\bigcirc$ 2	○ 3 ○ ungrada	able O no sympto	om O not recorded			
NCI Criteria						
	<ol> <li>Mild or localized; topical intervention indicated</li> <li>Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations,</li> </ol>					
			ng (e.g., edema, papulation, excoriations, miting instrumental ADL			
			systemic corticosteroid or immunosuppressive			
therapy indicat		. ,	· · · · · · · · · · · · · · · · · · ·			
□ M						
☐ Muscle r						
$\bigcirc 1 \bigcirc 2$	$\bigcirc$ 3 $\bigcirc$ ungrada	able $\odot$ no sympto	m ○ not recorded			
NCI Criteria 1. Mild						
-	miting age-appropriate i	nstrumental ADL				
	ing age appropriate self					
□ Massalass						
☐ Myoclon						
$\bigcirc 1 \bigcirc 2$	$\bigcirc$ 3 $\bigcirc$ ungrada	able $\odot$ no sympto	m ○ not recorded			
NCI Criteria 1. Mild						
-	miting age-appropriate i	nstrumental ADL				
	ing age-appropriate self					
	- <b>!</b> :					
☐ Hallucin		-				
$\bigcirc 1 \bigcirc 2$	$\bigcirc 3 \bigcirc 4 \bigcirc !$	5 O ungradable	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria  1 Mild hallucina	ations (e.g., perceptual o	distortions)				
2. Moderate ha		distortions)				
3. Severe hallu	cinations; hospitalization					
	ing consequences, thre	ats of harm to self or	others; hospitalization indicated			
5. Death						
☐ Respirat	tory Depression					
$\bigcirc$ 1 $\bigcirc$ 2	03 04 0	5 O ungradable	e ○ no symptom ○ not recorded			
NCI Criteria		5 Ungradabi	e o no symptom o not recorded			
1. Asymptomat			servations only; intervention not indicated			
			icated; 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 ha	rms (if they have	been experience	ced e.g. tolerance to opioid)			
Please spe	Please specify additional other harm:					
O mild	$\bigcirc$ moderate	○ severe	$\bigcirc$ ungradable			
☐ Additional other harms (if they have been experienced)						
Please specify additional other harm:						
○ mild	○ moderate	○ severe	O 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

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)				
<ul><li>□ <b>Dizziness</b></li><li>○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom</li></ul>	om O not recorded			
NCI Criteria 1.Mild unsteadiness or sensation of movement 2.Moderate unsteadiness or sensation of movement; limitin 3.Severe unsteadiness or sensation of movement; limiting sensation of movement.	g instrumental ADL			
<ul><li>□ Nausea</li><li>○ 1 ○ 2 ○ 3 ○ ungradable ○ no sympt</li></ul>	om ○ not recorded			
<ul> <li>NCI Criteria</li> <li>1. Loss of appetite without alteration in eating habits</li> <li>2. Oral intake decreased without significant weight loss.</li> <li>3. Inadequate caloric or fluid intake; tube feeding, TPN or h</li> </ul>	nospitalisation indicated.			
<b>Vomiting</b> ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradab	le ○ No Symptom ○ not recorded			
<ul> <li>NCI Criteria</li> <li>1.Intervention not indicated</li> <li>2. Outpatient IV hydration; medical intervention indicated</li> <li>3. Tube feeding, TPN, or hospitalization indicated</li> <li>4. Life-threatening consequences</li> <li>5. Death</li> </ul>				
☐ Somnolence ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradab	le ○ 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				
☐ <b>Confusion</b> ☐ 1				
<ol> <li>NCI Criteria</li> <li>Mild disorientation</li> <li>Moderate disorientation; limiting instrumental ADL</li> <li>Severe disorientation; limiting self-care ADL</li> <li>Life-threatening consequences threats of harm to self or others; hospitalization indicated</li> <li>Death</li> </ol>				
☐ Constipation ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradabl	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
<ol> <li>NCI Criteria</li> <li>Mild; asymptomatic or mild symptoms</li> <li>Moderate; minimal; local or non-invasive intervention inc</li> <li>Severe or medically significant but not immediately life th</li> <li>Life threatening consequences; urgent intervention indicates</li> <li>Death</li> </ol>	licated nreatening			

☐ Pruritus						
$\bigcirc$ 1 $\bigcirc$ 2	○ 3 ○ ungrada	ble O no sympto	om O not recorded			
NCI Criteria						
	<ol> <li>Mild or localized; topical intervention indicated</li> <li>Widespread and intermittent; skin changes from scratching (e.g., edema, papulation, excoriations,</li> </ol>					
	oozing/crusts); oral inte					
			; systemic corticosteroid or immunosuppressive			
therapy indicat		•	,			
□ Mussla						
☐ Muscle						
$\bigcirc 1 \bigcirc 2$	$\bigcirc$ 3 $\bigcirc$ ungrada	ible $\odot$ no sympto	m ○ not recorded			
NCI Criteria 1. Mild						
-	imiting age-appropriate i	nstrumental ADL				
	ting age appropriate self					
□ Mala.						
<b>☐</b> Myoclor						
$\bigcirc 1 \bigcirc 2$	○ 3 ○ ungrada	ible $\cup$ no sympto	m ○ not recorded			
NCI Criteria 1. Mild						
-	imiting age-appropriate i	nstrumental ADL				
	ting age appropriate self					
☐ Hallucin		-				
$\bigcirc 1 \bigcirc 2$	03 04 05	$\odot$ ungradable	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria	ations (e.g., perceptual o	listortions)				
2. Moderate ha		iistoi tioris)				
	Severe hallucinations; hospitalization not indicated					
	ning consequences, three	ats of harm to self or	others; hospitalization indicated			
5. Death						
☐ Respira	tory Depression					
$\bigcirc$ 1 $\bigcirc$ 2	03 04 05	5 O ungradable	e $\bigcirc$ no symptom $\bigcirc$ not recorded			
NCI Criteria		o ungradabi	e o no symptom o not recorded			
1. Asymptoma			oservations only; intervention not indicated			
			licated; 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 ha	rms (if they have	been experience	ced e.g. tolerance to opioid)			
Please spe	Please specify additional other harm:					
•						
O mild	$\bigcirc$ moderate	○ severe	$\bigcirc$ ungradable			
☐ Additional other harms (if they have been experienced)						
Please specify additional other harm:						
		_				
○ mild	<ul><li>moderate</li></ul>	○ severe	O 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		

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	Mild increased work of	Obvious accessory muscle use
breathing	breathing	

#### > 2 years age

MILD	MODERATE	SEVERE
Able to talk	Able to talk	Too breathless to talk
Normal SPO2	SPO2 <u>&gt;</u> 92%	SPO2 < 92%
Normal to minimal increased	Mild increased work of	Obvious accessory muscle use
work of breathing	breathing	

#### **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

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