Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Methadone for Pain in Paediatric Palliative Care

Series 51

RAPID Pharmacovigilance in Paediatric Chronic Pain
The Case Report Form (CRF) is to be completed in compliance with
University of Technology Sydney Standard Operating Procedures (SOP)

T_0 – Baseline: Demographic Data

Date of Assessment	DD/MM/YYYY

Gender	◯ Male	◯ Female	◯ Non-Binary	◯ Other; Please specify

Age (0 to <18yrs)	
	Years
	Months
	Weeks (only if < 3 months of age)
	Days (only if < 1 month of age)

Tick ✓	**Ethnicity (as identified on health record)**
	European
	NZ Maori
	Pacific Peoples
	Asian
	Middle Eastern
	Latin American/Hispanic
	Australian
	Aboriginal (Australian)
	Torres Strait Islander
	African
	Canadian first nations/Inuit
	American Classifications
	White American
	Black American
	Asian American
	American Indian/Alaskan Native
	Native Hawaiian/Pacific Islander
	American mixed ethnicity
	Other group not listed above; Please specify;_____

Tick ✓	**Primary life limiting illness** *(please choose only one)*
	Advanced Cancer **–** please specify.
	Osteosarcoma
	Neuroblastoma
	Ewings Sarcoma
	Other solid tumour: Please specify; _____
	CNS tumour
	Haematological malignancy.
	Neurological disease – please specify.
	Neuromuscular disorders
	Static encephalopathy – GMFCS I-V
	Progressive encephalopathy or Neurodegenerative disease
	Other neurological disorder – please specify
	Cardiac Condition
	Respiratory Condition
	Hepatic Condition
	Renal condition
	Congenital Condition
	Metabolic Condition
	Gastrointestinal Condition
	Other – (e.g. extreme prematurity) please specify; _____

Tick ✓	**Place of Care**
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify: _____

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

Was QTc interval from ECG recorded prior to commencement of Methadone?

(please tick 'yes' or 'no')

Yes	**No**	**QTc interval**
		If yes, please record interval here; _____

T_0 – Baseline: Pain Assessment - *Please score severity of pain at time of today's assessment using **either** FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -4/5 years

Revised FLACC Scale SCORING			
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

OR

Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years
– *see appendix for instructions on use*

*Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.***

◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

Visual Analogue Scale– <u>use this for children aged 10-18 years</u>											
What was the *<u>pain intensity at the time of assessment?</u>*** *(Circle number in box that best describes their pain)* 0 = no pain at all 5 = moderate pain 10 = worst possible pain											
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain					Moderate pain					Worst possible pain	

OR

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.
From clinicians' perspective, what was patient's pain at time of today's assessment?
○ Mild ○ Moderate ○ Severe ○ Ungradable

Tick ✓	**Is Methadone being commenced as?** *(Please choose only one)*
	First line opioid agent
	Rotating opioid agent
	Adjuvant analgesic agent to existing opioids
	Full conversion to Methadone

Tick ✓	**Primary reason for commencing methadone** *(Please tick only one)*
	Poor neuropathic pain control
	Poor non neuropathic pain control
	Pharmacokinetic properties – long duration of action
	Pharmacokinetic properties – poor renal function
	Adverse reaction to current opioid(s)
	Tolerance to current opioid(s)
	Very high doses of other opioid(s)
	Other – please specify:

Dosing of methadone commenced	
Dose of methadone commenced *(mg/kg/**<u>day</u>**)*	
Time and date of first dose *(please use 24hr time)*	D:M:Y:H:M
Frequency of dose *(e.g. 4th hourly, 6th hourly, 12 hourly*	

Tick ✓	Route of administration
	Oral
	IV
	Sub cutaneous
	Other – please specify:

Is a PRN dose of Methadone being prescribed as well? *(please tick yes or no)*		
Yes	**No**	
		If yes, please record PRN dosing details in table below.

Dosing of PRN methadone	
Dose of PRN methadone commenced *(mg/kg/**dose**)*	
Frequency of dose *allowed (e.g. 4th hourly, 6th hourly, 12 hourly*	
Maximum PRN doses allowed in a 24hr period	

CURRENT OTHER OPIOIDS
Record below all opioids used within the last 24 hours prior to the commencement of methadone. If an opioid is being used as a regular dose but also PRN, please record on two separate lines. *(e.g. Morphine sulphate 1mg regular q4h. Then on new line Morphine 0.5mg PRN q6h)*

Opioid Name	Immediate Release	Sustained Release	Dose in mg/kg/dose	Route	Regular	PRN
	☐	☐			☐	☐
	☐	☐			☐	☐
	☐	☐			☐	☐
	☐	☐			☐	☐
	☐	☐			☐	☐

Tick ✓	Concurrent Analgesic Agents	
	Name of Medication	**Dose (mg/day)**
	Alpha 2 agonist e.g., Clonidine	
	Anti-epileptic (other than gabapentinoid) e.g., Carbamazepine, Sodium valproate	
	Baclofen	
	Bisphosphonate e.g., Pamidronate, Zoledronate	
	Capsaicin	
	Corticosteroids e.g., Dexamethasone	
	COX-II Inhibitor i.e., Celecoxib	
	Gabapentinoid i.e., Gabapentin, Pregabalin	
	NSAIDS e.g., Ibuprofen, Naproxen, Diclofenac, Ketorolac	
	Paracetamol (Acetaminophen)	
	Tricyclic anti-depressants i.e., Amitriptyline, Nortriptyline	
	NMDA antagonists – Ketamine, Dextromethorphan	
	Benzodiazepines e.g., Midazolam, Lorazepam, Diazepam, Clonazepam	
	Other; Please specify	
	Other; Please specify	

Baseline Symptom/Harm/Toxicity Assessment *Please grade all symptoms/harms. Indicate that each harm has been assessed by ticking the square box next to each.*

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

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

☐ **Vomiting**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ No Symptom

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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other additional symptom grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

T_1 – 2 days post commencing Methadone

(Please complete as close to 48 hours as possible)

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	**T_1: Assessed/Not assessed reason**
	Assessed today (continue to complete T_1) OR
	Not assessed
	Participant Withdrew – Complete Medication Cessation
	Participant Died – Please record Date of Death, below
	Other; Please specify

Date of Death*	DD/MM/YYYY

If not assessed at 2 days, please complete:	
Time since Methadone (in hours) commenced	
Reason for variance	

Tick ✓	**Current place of Care**
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify: _____

Has QTc interval from ECG been remeasured since commencement of methadone? *(please tick yes or no)*

Yes	No	QTc interval
		If yes, please record interval here; _____

Current Methadone Dose *(mg/kg/**day**)*	
Total dose of Methadone given in last 24hrs *(mgs)*	

Has dose of any <u>Concurrent Opioid</u> changed since baseline? *(please tick yes or no)*		
Yes	**No**	
		If yes, please record change of Concurrent Opioid dose below.

Opioid Name	**Dose Change**			**New dose of concurrent opioid** *(mg/kg/**<u>dose</u>**)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	

Has the dose of <u>other</u> <u>Concurrent Analgesic</u> agent(s) changed since baseline? *(Please tick yes or no)*		
Yes	**No**	
		If yes, please record changes below.

Medication Name	**Dose Change**			**New dose of concurrent analgesic medication** *(mg/day)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	
4.	☐	☐	☐	

Have any <u>new concurrent analgesic</u> agents commenced since baseline. Y/N *(Please record details below)*	
1. Medication name:	**Dose** *(mg/day)*
2. Medication name:	**Dose** *(mg/day)*

T_1 – Pain Assessment - *Please score severity of pain at time of today's assessment using **either** FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -4/5 years

Revised FLACC Scale SCORING			
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

OR

Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years
– *see appendix for instructions on use*

*Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.***

◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

Visual Analogue Scale– <u>use this for children aged 10-18 years</u>

What was the *<u>pain intensity at the time of assessment?</u>*
(Circle number in box that best describes their pain)

0 = no pain at all 5 = moderate pain 10 = worst possible pain

0	1	2	3	4	5	6	7	8	9	10	Not reported

No pain Moderate pain Worst possible pain

OR

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.

From clinicians' perspective, what was patient's pain at time of today's assessment?

○ Mild ○ Moderate ○ Severe ○ Ungradable

T_1 - 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)*

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria
1.Loss of appetite without alteration in eating habits
2.Oral intake decreased without significant weight loss, dehydration, or malnutrition
3.Inadequate oral 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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?			

Tick ✓		**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here: _____
		Methadone dose increased. Please record the new mg/kg/day dose here: _____
		Methadone ceased (complete Medication Cessation page 33)
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_2 – 5 days post commencement of Methadone	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	T_2: Assessed/Not assessed reason
	Assessed today (continue to complete T_2) OR
	Not assessed
	Participant Withdrew – Complete Medical Cessation
	Patient Died – Record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

If not assessed at 5 days, please complete:	
Time since Methadone commenced (days)	
Reason for variance	

Tick ✓	**Current place of Care**
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify: _____

Has QTc interval from ECG been remeasured since T_1? *(please tick yes or no)*		
Yes	**No**	**QTc interval**
		If yes, please record interval here; _____

Current Methadone Dose *(mg/kg/**day**)*	
Total dose of Methadone given in last 24hrs *(mgs)*	

Has dose of any <u>Concurrent Opioid</u> changed since T_1? *(please tick yes or no)*		
Yes	**No**	
		If yes, please record change of Concurrent Opioid dose below.

Opioid Name	**Dose Change**			**New dose of concurrent opioid** *(mg/kg/**<u>dose</u>**)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	

Has the dose of <u>other Concurrent Analgesic</u> agent(s) changed since T_1? *(Please tick yes or no)*		
Yes	**No**	
		If yes, please record changes below.

Medication Name	**Dose Change**			**New dose of concurrent analgesic medication** *(mg/day)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	
4.	☐	☐	☐	

Has any <u>new concurrent analgesic</u> agent(s) commenced since T_1. Y/N *(Please record details below)*	
1. Medication name:	**Dose** *(mg/day)*
2. Medication name:	**Dose** *(mg/day)*

T_2 – Pain Assessment - *Please score severity of pain at time of today's assessment using **either** FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -4/5 years

Revised FLACC Scale SCORING			
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

OR

Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years
– *see appendix for instructions on use*

*Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.***

◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

Visual Analogue Scale– <u>use this for children aged 10-18 years</u>

What was the *<u>pain intensity at the time of assessment?</u>*
(Circle number in box that best describes their pain)

0 = no pain at all 5 = moderate pain 10 = worst possible pain

0	1	2	3	4	5	6	7	8	9	10	Not reported

No pain Moderate pain Worst possible pain

OR

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.

From clinicians' perspective, what was patient's pain at time of today's assessment?

○ Mild ○ Moderate ○ Severe ○ Ungradable

T_2 – 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)*

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria
1.Loss of appetite without alteration in eating habits
2.Oral intake decreased without significant weight loss, dehydration, or malnutrition
3.Inadequate oral 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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?			

Tick ✓		**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here: _____
		Methadone dose increased. Please record the new mg/kg/day dose here: _____
		Methadone ceased (complete Medication Cessation page 33)
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_3 – 10 days post commencement of Methadone

Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	**T_3: Assessed/Not assessed reason**
	Assessed today (continue to complete T_3) OR
	Not assessed
	Participant Withdrew – Complete Medical Cessation
	Patient Died – Record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

If not assessed at 10 days, please complete:	
Time since Methadone commenced (days)	
Reason for variance	

Tick ✓	**Current place of Care**
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify: _____

Has QTc interval from ECG been remeasured since T_2? *(please tick yes or no)*		
Yes	**No**	**QTc interval**
		If yes, please record interval here; _____

Current Methadone Dose *(mg/kg/**day**)*	
Total dose of Methadone given in last 24hrs (mgs)	

Has dose of any <u>Concurrent Opioid</u> changed since T_2? *(please tick yes or no)*		
Yes	**No**	
		If yes, please record change of Concurrent Opioid dose below.

Opioid Name	**Dose Change**			**New dose of concurrent opioid** *(mg/kg/**<u>dose</u>**)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	

Has the dose of <u>other concurrent analgesic</u> agent(s) changed since T_2? *(Please tick yes or no)*		
Yes	**No**	
		If yes, please record changes below.

Medication Name	**Dose Change**			**New dose of concurrent analgesic medication** *(mg/day)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	
4.	☐	☐	☐	

Has any <u>new</u> concurrent analgesic agent(s) commenced since T_2. Y/N *(Please record details below)*	
1. Medication name:	**Dose** *(mg/day)*
2. Medication name:	**Dose** *(mg/day)*

T_3 – Pain Assessment - *Please score severity of pain at time of today's assessment using **either** FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -4/5 years

Revised FLACC Scale SCORING			
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

OR

Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years
– *see appendix for instructions on use*

*Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.***

◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

Visual Analogue Scale– <u>use this for children aged 10-18 years</u>											
What was the *<u>pain intensity at the time of assessment?</u>* *(Circle number in box that best describes their pain)* 0 = no pain at all 5 = moderate pain 10 = worst possible pain											
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain					Moderate pain					Worst possible pain	

OR

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.
From clinicians' perspective, what was patient's pain at time of today's assessment?
○ Mild ○ Moderate ○ Severe ○ Ungradable

T_3 – 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)*

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria
1.Loss of appetite without alteration in eating habits
2.Oral intake decreased without significant weight loss, dehydration, or malnutrition
3.Inadequate oral 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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?			

Tick ✓		**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here: _____
		Methadone dose increased. Please record the new mg/kg/day dose here: _____
		Methadone ceased (complete Medication Cessation page 33
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_4 – 30 days post commencement of Methadone	
Date of Assessment	DD/MM/YYYY
Time of Assessment (24hr clock)	HH:MM

Tick ✓	T_4: Assessed/Not assessed reason
	Assessed today (continue to complete T_4) OR
	Not assessed
	Participant Withdrew – Complete Medical Cessation
	Patient Died – Record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

If not assessed at 30 days, please complete:	
Time since Methadone commenced (days)	
Reason for variance	

Tick ✓	**Current place of Care**
	Acute hospital ward
	Emergency department
	Intensive Care Unit
	Palliative Care Unit / Hospice
	Long-term care/Skilled nursing facility
	Patient's Home
	Community
	Other; please specify: _____

Has QTc interval from ECG been remeasured since T_3? *(please tick yes or no)*		
Yes	**No**	**QTc interval**
		If yes, please record interval here; _____

Current Methadone Dose *(mg/kg/**day**)*	
Total dose of Methadone given in last 24hrs *(mgs)*	

Has dose of any <u>Concurrent Opioid</u> changed since T_3? *(please tick yes or no)*		
Yes	**No**	
		If yes, please record change of Concurrent Opioid dose below.

Opioid Name	**Dose Change**			**New dose of concurrent opioid** *(mg/kg/**<u>dose</u>**)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	

Has the dose of <u>other Concurrent Analgesic</u> agent(s) changed since T_3? *(Please tick yes or no)*		
Yes	**No**	
		If yes, please record changes below.

Medication Name	**Dose Change**			**New dose of concurrent analgesic medication** *(mg/day)*
	Dose Increased	**Dose Decreased**	**Medication Ceased**	
1.	☐	☐	☐	
2.	☐	☐	☐	
3.	☐	☐	☐	
4.	☐	☐	☐	

Has any <u>new</u> concurrent analgesic agent(s) commenced since T_3. Y/N *(Please record details below)*	
1. Medication name:	**Dose** *(mg/day)*
2. Medication name:	**Dose** *(mg/day)*

T_4 – Pain Assessment - *Please score severity of pain at time of today's assessment using **either** FLACC Scale, Faces Pain Scale, Visual Analogue Scale or clinician question.*

Pain Severity Score – (Revised FLACC Scale) Use for children aged 0 -4/5 years

Revised FLACC Scale SCORING			
Categories	**0**	**1**	**2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories **(F)** Face; **(L)** Legs; **(A)** Activity; **(C)** Cry; **(C)** Consolability is scored from 0-2, which results in a total score between zero and ten.

Record Total Revised FLACC Score here

OR

Faces Pain Scale – Revised (FPS-R) use for children aged 4-10 years
– *see appendix for instructions on use*

*Score the chosen face **0**, **2**, **4**, **6**, **8**, or **10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". **Record score below.***

◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

Visual Analogue Scale– <u>use this for children aged 10-18 years</u>											
What was the *<u>pain intensity at the time of assessment?</u>* *(Circle number in box that best describes their pain)* 0 = no pain at all 5 = moderate pain 10 = worst possible pain											
0	1	2	3	4	5	6	7	8	9	10	Not reported
No pain					Moderate pain					Worst possible pain	

OR

<u>If unable</u> to score pain using either the FLACC pain scale, the FPS-R scale or VAS scale please answer the following question.
From clinicians' perspective, what was patient's pain at time of today's assessment?
○ Mild ○ Moderate ○ Severe ○ Ungradable

T_4 – 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)*

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria
1.Loss of appetite without alteration in eating habits
2.Oral intake decreased without significant weight loss, dehydration, or malnutrition
3.Inadequate oral 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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?			

Tick ✓		**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
		No change to Methadone/continue current dose
		Methadone dose decreased. Please record the new mg/kg/day dose here: _____
		Methadone increased. Please record the new mg/kg/day dose here: _____
		Methadone ceased (complete Medication Cessation page 34
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

Medication Cessation *(Complete this page if Methadone is ceased at any point during the study period)*	
Date and Time of last dose of methadone	DD:MM:YYYY

Tick ✓	Methadone was ceased for following reason:
	Effective for pain and no longer required
	Effective for pain but intolerable adverse effects
	Ineffective with escalating pain; Please grade pain below
	Ineffective for pain and intolerable adverse effects
	Tolerance
	Other: Please specify

PAIN SEVERITY SCORE

What was the *WORST pain intensity in the last 24hrs?*
Use Pain Tool appropriate for age/cognition
(Circle number in box that best describes their pain)

0 = no pain at all 5 = moderate pain 10 = worst possible pain

0	1	2	3	4	5	6	7	8	9	10	Not reported

No pain Moderate pain Worst possible pain

What treatment (if any) was initiated after cessation of Methadone? *(If none respond 'none')*			
Medication	**Dose**	**Frequency**	**Route**

Ad hoc A - Unscheduled Harm/Toxicity Assessment

Date of Assessment	DD:MM: YYYY

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

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria
1.Loss of appetite without alteration in eating habits
2.Oral intake decreased without significant weight loss, dehydration or malnutrition
3.Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent
intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Constipation**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema
2. Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL
3. Obstipation with manual evacuation indicated; limiting self-care ADL
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

☐ **Other symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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 Harm/Toxicity Assessment

Date of Assessment	DD:MM:YYYY

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

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent
intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Anxiety**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3.Severe symptoms; limiting self-care ADL; hospitalization not indicated
4.Life-threatening; hospitalization indicated
5.Death

☐ **Restlessness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria-
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3.Severe symptoms; limiting self-care ADL

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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 symptom (if exists)**

Please specify other symptom:

Othersymptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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 Harm/Toxicity Assessment

Date of Assessment	DD:MM:YYYY

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

☐ **Drowsiness**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Nausea**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

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

☐ **Confusion**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild disorientation
2.Moderate disorientation; limiting instrumental ADL
3.Severe disorientation; limiting self-care ADL
4.Life-threatening consequences; urgent
intervention indicated
5.Death

☐ **Myoclonus**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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

☐ **Anxiety**

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

NCI Criteria
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3.Severe symptoms; limiting self-care ADL; hospitalization not indicated
4.Life-threatening; hospitalization indicated
5.Death

☐ **Restlessness**

○ 1 ○ 2 ○ 3 ○ ungradable ○ no symptom

NCI Criteria-
1.Mild symptoms; intervention not indicated
2.Moderate symptoms; limiting instrumental ADL
3.Severe symptoms; limiting self-care ADL

☐ **Respiratory Depression** (RR<8/min)

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ ungradable ○ no symptom

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 symptom (if exists)**

Please specify other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

☐ **Additional other symptom (if exists)**

Please specify additional other symptom:

Other symptom/toxicity grade here:

○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ Ungradable

If a harm/toxicity scored 3 or more AND was less than 3 at baseline; please complete this set of questions from the Naranjo modified checklist *(Tick 'yes', 'no', or 'don't know' for each question below)*

	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?			