Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Ketamine Infusion for Paediatric Cancer Related Mucositis
Series 42

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)

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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

Tick ✓	**Ethnicity (as identified on health record)**
	Aboriginal (Australian)
	African
	Asian
	European
	Latin American/Hispanic
	Middle Eastern
	NZ Maori
	Pacific Peoples
	Torres Strait Islander
	Aboriginal (other); Please specify
	Other ethnic group; Please specify

Tick ✓	Type of Cancer
	CNS Tumour
	Ewings Sarcoma
	Acute Lymphoblastic Leukaemia
	Acute Myeloid Leukaemia
	Lymphoma
	Neuroblastoma
	Osteosarcoma
	Soft Tissue Sarcoma
	Wilms Tumour
	Other cancer: Please specify

Laboratory Tests (only if available)	
Test	**Value**
Neutrophil Count	

Tick ✓	**Place of Care**
	Medical ward (not Oncology)
	Oncology Ward
	Bone Marrow Transplant Unit
	High Dependency/Step Down Unit
	Intensive Care Unit (ICU)
	Other; Please specify

Karnofsky/Lansky Performance Status (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

T_0 – Baseline: Mucositis Severity

☐ **Mucositis Symptom Severity**

○ **1** ○ **2** ○ **3** ○ **4** ○ **5**

NCI Criteria
1. Asymptomatic or mild symptoms; intervention not indicated
2. Moderate pain or ulcer that does not interfere with oral intake; modified diet not indicated
3. Severe pain; interfering with oral intake
4. Life-threatening consequences, urgent intervention indicated
5. Death

Tick ✓		**Mucositis Pain Sites (***tick yes or no to all)*		
Yes	**No**	*(If yes, please indicate if perforation is suspected)*		
		Oral		
		Abdominal - Is perforation suspected? –	○ Yes	○ No
		Rectal - Is perforation suspected? –	○ Yes	○ No
		Anal		

T_0 – Baseline: Mucositis Pain Assessment

Tick ✓	Frequency of Pain
	Always present (always the same intensity)
	Always present (intensity varies)
	Often present (pain free periods last less than 6 hours)
	Occasionally present (pain occurs once to several times per day, lasting up to an hour)
	Rarely present (pain occurs every few days or weeks)

PAIN ASSESSMENT SCALES:
Please use the most appropriate pain scale to assess your child's pain.

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

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.

Total Revised FLACC Score here for *<u>least pain</u>* in the last 24 hrs	
Total Revised FLACC Score here for *<u>worst pain</u>* in the last 24 hrs	

OR

Faces Pain Scale – Revised (FPS-R) <u>use for children aged 4-10 years</u> ***–*** *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 <u>least pain in 24hr</u> score below.***
◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**
*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 <u>worst pain in 24hr</u> score below.***
◯ **0** ◯ **2** ◯ **4** ◯ **6** ◯ **8** ◯ **10**

OR

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

What was the child's *<u>least pain intensity in the last 24hrs?</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 re-ported

No pain Moderate pain Worst possible pain

What was the child's *<u>worst pain intensity in the last 24hrs?</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 re-ported

No pain Moderate pain Worst possible pain

Tick ✓	**Concurrent Analgesic Medications** *(Tick all that apply)*
	Alpha 2 agonist i.e. Clonidine
	Anti-epileptics (other than gabapentinoid) i.e. Carbamazepine, Sodium valproate
	Benzodiazepines
	Anti-reflux medications
	Anti-psychotics i.e. Quetiapine
	Baclofen
	Bisphosphonate i.e. pamidronate, zoledronate
	Capsaicin
	Corticosteroids
	COX-II Inhibitor i.e. celecoxib
	Gabapentinoid i.e. Gabapentin, Pregabalin
	NSAIDS i.e. Ibuprofen, Naproxen, Diclofenac
	Opioid (minor) i.e. tramadol, codeine
	Opioid (major) i.e. tapentadol, morphine, oxycodone
	Paracetamol

	Selective serotonin reuptake inhibitors (SSRI) i.e. fluoxetine, citalopram, sertraline
	Selective nor-adrenaline reuptake inhibitor (SNRI) i.e. venlafaxine
	Tricyclic anti-depressants i.e. Amitriptyline, Nortriptyline
	Other: Please specify
	Other: Please specify

Baseline 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)*

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom** (*only if present - can be related or unrelated to intervention*)

Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom** (*only if present - can be related or unrelated to intervention*)

Please specify additional other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

T_0 – Baseline: Ketamine Infusion Commencement

Weight of Child *(kg)*	

TIME infusion commenced (24-hour clock)	HH:MM

Tick ✓	**Route of administration**
	Subcutaneous
	Intravenous

Tick ✓		**Is bolus dosing allowed at your site?**
Yes	**No**	*If yes, please specify below*
		If no, please go to infusion dose commenced question.
Tick ✓		**Was an initial bolus dose given today prior to starting the infusion?**
Yes	**No**	*If yes, please specify dose below.*
		If no, please go to next question.

Please specify initial bolus dose here *(mcg/kg)*	
How many bolus doses are allowed <u>per hour</u>?	

Infusion Dose commenced *(mcg/kg/hour)*	
Anticipated Maximum Dose *(mcg/kg/hour)*	

T_1 – 48 hours post commencing ketamine infusion

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/Died – record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

If not assessed at 48 hours, please complete:	
Time since ketamine infusion commenced	
Reason for variance	

Current Ketamine Infusion Dose *(mcg/kg/hour)*	
Number of bolus doses given since baseline *(Record '0' if no bolus doses were given; or Record 'N/A' if not allowed at your site)*	

Tick ✓		**Were there any interruption(s) to the Ketamine infusion since baseline?**
Yes	**No**	
		If yes, please give details of interruption(s) here.

Tick ✓	**Has there been any change to the ketamine infusion since baseline?**
	No (ketamine maintained at previous infusion)
	Yes (ketamine infusion changed)
Tick ✓	**If Yes; What change was made to ketamine infusion?**
	Ketamine infusion decreased: How long was child on previous infusion (hours) _____
	Ketamine infusion increased: How long was child on previous infusion (hours) _____
	Ketamine infusion ceased: (Complete Medication Cessation page 22)

Tick ✓	Has a new analgesic medication been added since baseline?
	No
	Yes; Please specify analgesic added here:

T_1 – Mucositis Severity

☐ **Mucositis Symptom Severity**

○ **1** ○ **2** ○ **3** ○ **4** ○ **5**

NCI Criteria
1. Asymptomatic or mild symptoms; intervention not indicated
2. Moderate pain or ulcer that does not interfere with oral intake; modified diet not indicated
3. Severe pain; interfering with oral intake
4. Life-threatening consequences, urgent intervention indicated
5. Death

T_1 – Pain Assessment

Tick ✓	Frequency of Pain
	Always present (always the same intensity)
	Always present (intensity varies)
	Often present (pain free periods last less than 6 hours)
	Occasionally present (pain occurs once to several times per day, lasting up to an hour)
	Rarely present (pain occurs every few days or weeks)

PAIN ASSESSMENT SCALES:
Please use the most appropriate pain scale to assess your patient's ***pain in the last 6 hours.***

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.

Total Revised FLACC Score here for *least pain* in the last 6 hrs	
Total Revised FLACC Score here for *worst pain* in the last 6 hrs	

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 least pain in 6hr score below.***

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

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 worst pain in 6hr score below.***

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

OR

Pain Intensity – <u>use this for children aged 10-18 years</u>

What was the *<u>LEAST pain intensity in the last 6 hours?</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 re-ported

No pain Moderate pain Worst possible pain

What was the *<u>WORST pain intensity in the last 6 hours?</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 re-ported

No pain Moderate pain Worst possible pain

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)*

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **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
4. Loss of appetite without alteration in eating habits
5. Oral intake decreased without significant weight loss.
6. 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 hospitalisation indicated
4. Life-threatening consequences
5. Death

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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** (*only if present - can be related or unrelated to intervention*)

Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom** (*only if present - can be related or unrelated to intervention*)

Please specify additional other symptom here _____

○ mild ○ moderate ○ severe ○ 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? Please give details here if available.			
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? Please give details here if available.			

Tick ✓		**What is the intended treatment based on today's assessment?** *(Tick all that apply)*
		No change to Ketamine /continue current dose
		Ketamine dose decreased. Please record the new mcg/kg/hour dose here: _____
		Ketamine dose increased. Please record the new mcg/kg/hour dose here: _____
		Ketamine ceased; Please complete Medication Cessation (page 22)
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 commencing ketamine infusion

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/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 ketamine infusion commenced in hours	
Reason for variance	

Time since ketamine commenced (hours)	
Current Ketamine Dose (mcg/kg/hr)	
Number of bolus doses given since T_1	

Tick ✓	**Have there been any changes to Ketamine dose since T_1?**
	No (Ketamine maintained at previous dose)
	Yes (Ketamine dose changed)
Tick ✓	**If yes; What change was made to Ketamine dose since T_1?**
	Ketamine dose decreased: How long was patient on previous dose (hours) _____
	Ketamine dose increased: How long was patient on previous dose (hours) _____
	Ketamine ceased: (Complete Medication Cessation (page 22) How long was patient on Ketamine before it was ceased(hours) _____

Tick ✓	Has Maximum Dose been reached?
	Yes
	No
If Yes; Time to Maximum Dose (hours)	

Tick ✓	Has a new analgesic medication been added since T_1?
	No
	Yes: Please specify analgesic added here:

Was there any benefit from the medication of interest?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

T_2 – Mucositis Severity

☐ **Mucositis Symptom Severity**

○ **1** ○ **2** ○ **3** ○ **4** ○ **5**

NCI Criteria
1. Asymptomatic or mild symptoms; intervention not indicated
2. Moderate pain or ulcer that does not interfere with oral intake; modified diet not indicated
3. Severe pain; interfering with oral intake
4. Life-threatening consequences, urgent intervention indicated
5. Death

T_2 – Pain Assessment

Tick ✓	Frequency of Pain
	Always present (always the same intensity)
	Always present (intensity varies)
	Often present (pain free periods last less than 6 hours)
	Occasionally present (pain occurs once to several times per day, lasting up to an hour)
	Rarely present (pain occurs every few days or weeks)

PAIN ASSESSMENT SCALES:
Please use the most appropriate pain scale to assess your patient's
pain intensity in the last 24 hours

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.

Total Revised FLACC Score here for *least pain* in the last 24 hrs	
Total Revised FLACC Score here for *worst pain* in the last 24 hrs	

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 least pain in 24hr score below.***

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

*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 worst pain in 24hr score below.***

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

OR

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

What was the *<u>LEAST pain intensity in the last 24 hours?</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

What was the *<u>WORST pain intensity in the last 24hrs?</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

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)*

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom** (*only if present - can be related or unrelated to intervention*)
Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom** (*only if present - can be related or unrelated to intervention*)
Please specify additional other symptom here _____

○ mild ○ moderate ○ severe ○ 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 Ketamine/continue current dose
		Ketamine dose decreased. Please record the new mcg/kg/hour dose here: _____
		Ketamine increased. Please record the new mcg/kg/hour dose here: _____
		Ketamine ceased (complete Medication Cessation page 22)
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 commencing ketamine infusion

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/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 ketamine infusion commenced	
Reason for variance	

Time since ketamine commenced (hours)	
Current Ketamine Dose (mg/kg/hr)	
Number of bolus doses given since T_2	

Tick ✓	**Have there been any changes to ketamine infusion dose since T_2?**
	No (Ketamine maintained at previous dose)
	Yes (Ketamine dose changed)
Tick ✓	**If Yes; What change was made to ketamine dose?**
	Ketamine dose decreased: How long was patient on previous dose (hours) _____
	Ketamine dose increased: How long was patient on previous dose (hours)_____
	Ketamine ceased: Complete Medication Cessation page 22 How long was patient on Ketamine before it was ceased(hours) _____

Tick ✓	**Has Maximum Dose been reached?**
	Yes
	No

If Yes; Time to Maximum Dose (hours)	

Tick ✓	Has a new analgesic medication been added since T_2?
	No
	Yes; Please specify analgesic added here:

Was there any benefit from the Ketamine Infusion?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

T_3 – Mucositis Severity

☐ **Mucositis Symptom Severity**

○ **1** ○ **2** ○ **3** ○ **4** ○ **5**

NCI Criteria
1. Asymptomatic or mild symptoms; intervention not indicated
2. Moderate pain or ulcer that does not interfere with oral intake; modified diet not indicated
3. Severe pain; interfering with oral intake
4. Life-threatening consequences, urgent intervention indicated
5. Death

T_3 – Pain Assessment

Tick ✓	Frequency of Pain
	Always present (always the same intensity)
	Always present (intensity varies)
	Often present (pain free periods last less than 6 hours)
	Occasionally present (pain occurs once to several times per day, lasting up to an hour)
	Rarely present (pain occurs every few days or weeks)

PAIN ASSESSMENT SCALES:
Please use the most appropriate pain scale to assess your patient's
pain intensity in the last 24 hours

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.

Total Revised FLACC Score here for *least pain* in the last 24 hrs	
Total Revised FLACC Score here for *worst pain* in the last 24 hrs	

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 least pain in 24hr score below.***

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

*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 worst pain in 24hr score below.***

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

OR

Visual Analogue Pain Scale – use for children aged 10-18 years

What was the *LEAST pain intensity in the last 24 hours?*
(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 was the *WORST pain intensity in the last 24hrs?*
(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

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)*

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom** (*only if present - can be related or unrelated to intervention*)
Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom** (*only if present - can be related or unrelated to intervention*)
Please specify additional other symptom here _____

○ mild ○ moderate ○ severe ○ 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 Ketamine /continue current dose
		Ketamine dose decreased. Please record the new mcg/kg/hour dose here: _____
		Ketamine dose increased. Please record the new mcg/kg/hour dose here: _____
		Ketamine ceased. (Complete Medication Cessation page 22)
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 the ketamine infusion is ceased at any point during the study period **OR** when infusion continues beyond 10 days)*	
Date and Time of Assessment (Medication Cessation)	DD:MM:YYYY

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

SYMPTOM SEVERITY SCORE

What was the *WORST pain intensity in the last 24hrs?*
(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 re-ported

No pain Moderate pain Worst possible pain

Tick ✓	**Intervention/medication was ceased (related to other reasons)**
	Harm/toxicity
	Other; please specify:

What treatment did you subsequently initiate following the cessation of the Ketamine infusion?

Ad hoc A - Unscheduled Harm/Toxicity 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)*

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom**

Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom**

Please specify additional other symptom here _____

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

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom**

Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom**

Please specify additional other symptom here _____

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

☐ **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; hospitalisation not indicated
4. Life-threatening consequences, threats of harm to self or others; hospitalisation indicated
5. Death

☐ **Dizziness**

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

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

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **Urinary retention**

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

NCI Criteria
1. Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
2. Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
3. Elective invasive intervention indicated; substantial loss of affected kidney function or mass
4. Life- threatening consequences; organ failure; urgent operative intervention indicated
5. Death

☐ **Bladder spasm**

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

NCI Criteria
1. Intervention not indicated
2. Antispasmodics indicated
3. Hospitalisation indicated

☐ **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; hospitalisation indicated
5. Death

☐ **Pruritus**

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

NCI Criteria
1. Mild or localised; topical intervention indicated
2. Widespread and intermittent; skin changes from scratching (e.g., oedema, 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

☐ **Blurred Vision**

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

NCI Criteria
1. Intervention not indicated
2. Symptomatic; moderate decrease in visual acuity (best corrected visual acuity 20/40 and better or 3 lines or less decreased vision from known baseline); limiting instrumental ADL
3. Symptomatic with marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or more than 3 lines of decreased vision from known baseline, up to 20/200); limiting self-care ADL
4. Best corrected visual acuity of 20/200 or worse in the affected eye

☐ **Other symptom**

Please specify other symptom here _____

○ mild ○ moderate ○ severe ○ ungradable

☐ **Additional other symptom**

Please specify additional other symptom here _____

○ mild ○ moderate ○ severe ○ 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?			