Participant ID	

Initials of person entering data	

Staff email	

CONFIDENTIAL CASE REPORT FORM

Ketamine Infusion for Paediatric Chronic Non-Cancer Pain

Series 41

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)**
	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 ✓	**Place of Care**
	Medical Ward
	Surgical ward
	High Dependency/Step Down Unit
	Intensive Care Unit (ICU)
	Rehabilitation Facility
	Community Facility. Please specify here:
	Other place of care; Please specify here:

Tick ✓	**Comorbidities** *(Please tick all that apply)*
	No comorbidities
	Anxiety Disorder
	Attention Deficit with or without Hyperactivity Disorder
	Autistic Spectrum Disorder
	Chronic Fatigue Syndrome
	Depression
	Ehlers Danlos Syndrome
	Functional Neurological Disorder
	Inflammatory Bowel Disease
	Intellectual/Developmental Disability
	Learning Difficulties
	Obesity
	Postural Orthostatic Tachycardia Syndrome (POTS)
	Other; Please specify

Tick ✓	**Is the child receiving end-of-life care? †**
	No
	Yes

† As defined by WHO Guidelines on the management of chronic pain in children (who.int)
End-of-life care is a type of palliative care for people in the final weeks or months of life. End-of-life care enables people to live as well as possible before death and to die with dignity.

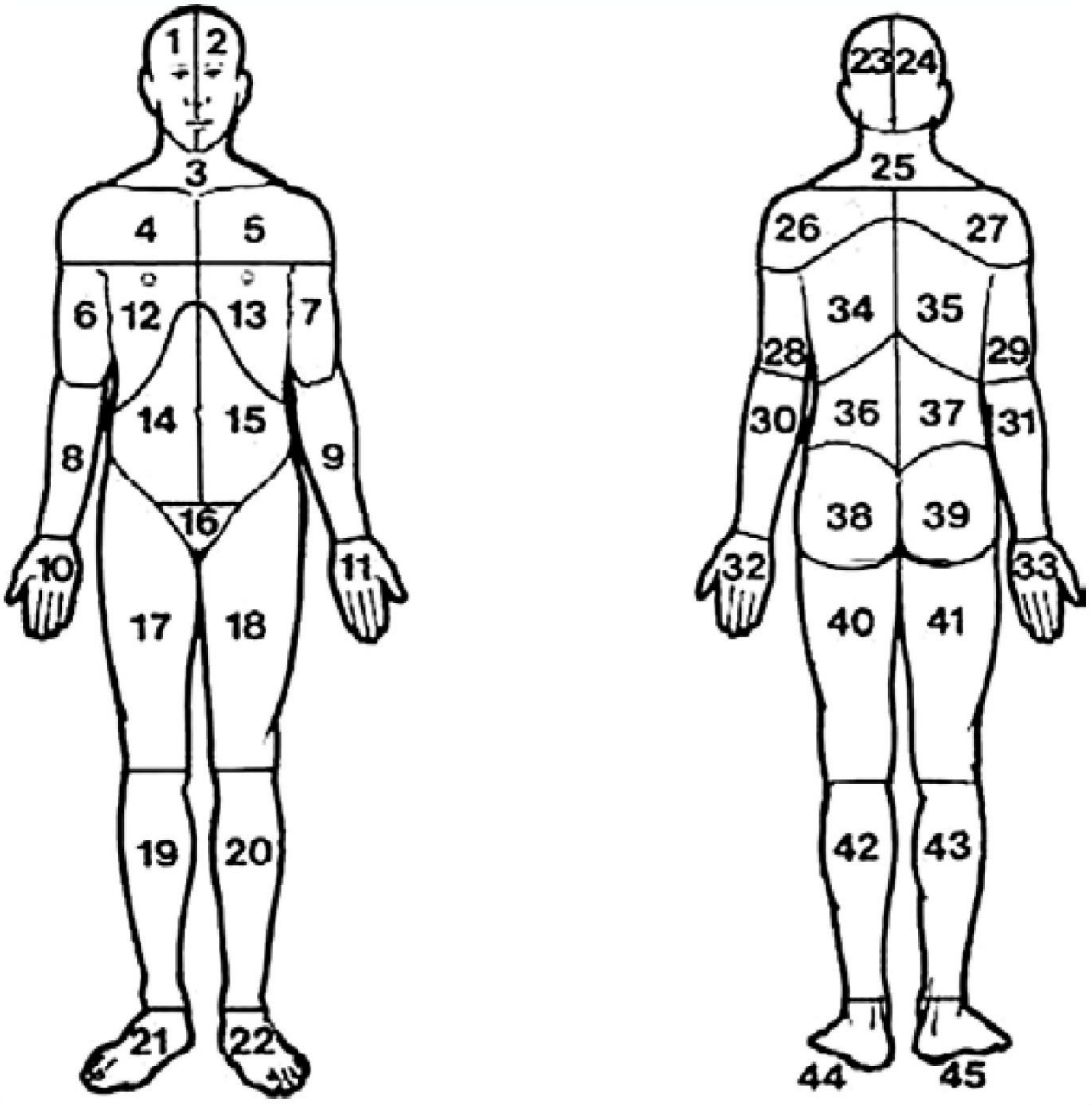
Tick ✓	**Does child have a life-limiting condition? ***
	No
	Yes; Please specify

* As defined by WHO Guidelines on the management of chronic pain in children (who.int)
Life-limiting condition is an illness for which there is no cure, and an early death is expected, but with which a person may continue to live for several more years.

T_0 – Baseline: Pain Assessment

Tick ✓	**Indications for Ketamine Use** *(please choose only one)*
	Primary Pain Disorder
	Pain associated with Medical Condition
	Neuropathic Pain

Tick ✓	**Main Aetiology of Non-Cancer Pain** *(Please choose one)*
	Primary Pain Disorder
	Chronic daily headache
	Complex Regional Pain Syndrome
	Erythromelalgia
	Fibromyalgia / Generalised Musculoskeletal Pain Disorder
	Headache Disorder
	Irritable Bowel Syndrome
	Widespread Pain Disorder
	Other pain disorder; please specify; _____
	Associated with Medical Condition
	Ehlers Danlos Syndrome
	Inflammatory Bowel Disease
	Persistent Post-operative
	Post Traumatic Injury
	Rheumatological Disease
	Neurological Disease
	Sickle cell Disease
	Other pain disorder; please specify;_____
	Neuropathic Pain
	Neuropathic Pain – Peripheral; Please specify here;
	Neuropathic Pain – Central; Please specify here;

Site of Pain	
	
Main Site of Pain: *(circle the number from the body map in the box to the right that is the site of the main pain)*	**1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 245, 25, 26, 27, 28, 19, 30, 31, 33, 34, 35, 36, 37, 38, 29, 40, 41, 42, 43, 44, 45**
Other Site(s) of Pain; If any: *(circle the number/s from the body map in the box to the right of other pain sites)*	**1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 245, 25, 26, 27, 28, 19, 30, 31, 33, 34, 35, 36, 37, 38, 29, 40, 41, 42, 43, 44, 45**

Tick ✓	Duration of Pain
	< 3 months
	3 months to 12 months
	> 1 year

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 Intensity Score *(Use Appropriate Pain Tool – see Appendix)*

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 re-ported

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 re-ported

No pain Moderate pain Worst possible pain

T_0 – Baseline Assessment: Medication & Other Strategies

Tick ✓	**Previous Analgesic Medications Used** *(Tick all that apply)*
	Alpha 2 agonist i.e., Clonidine
	Anti-epileptics (other than gabapentinoid) i.e. Carbamazepine, Sodium valproate
	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

Tick ✓	**Previous Non-Medication Strategies Used** *(Tick all that apply)*
	Acceptance Commitment Therapy
	Biofeedback
	Cognitive Behavioural Therapy
	Distraction incl. online apps
	Goal setting
	Graded Exercise
	Guided Imagery
	Hypnosis
	Massage Therapy
	Other Manual Therapy; Please specify
	Mirror Therapy
	Relaxation incl. online apps
	Strengthening Exercises
	Stretching Exercises
	Transcutaneous Electrical Nerve Stimulation
	Other; Please specify
	Other; Please specify

Tick ✓	**Concurrent Analgesic Medications** *(Tick all that apply)*
	Alpha 2 agonist i.e., Clonidine
	Anti-epileptics (other than gabapentinoid) i.e., Carbamazepine, Sodium valproate
	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

Tick ✓	**Functional Disability Index (see Appendix)**
	Not scored
	Scored

Functional Disability Index Score	

Tick ✓	**Paediatric Quality of Life Inventory (see Appendix)**
	Not scored
	Scored (if yes, record scores below)

Score	**PedQL**
	Physical function
	Emotional function
	Social function
	School function
	Overall

T_0 – Baseline Symptom/Harm Assessment *(Please grade all harms; indicate that each harm has been assessed by ticking the square box next to each)*

☐ **Dizziness**

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

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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 – 24 hours post commencing ketamine

(Please complete as close to 24 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/Died – record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

If not assessed at 24 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 interruptions to the Ketamine infusion?**
Yes	**No**	If yes, please give details of interruption here.

Tick ✓	**Have there been any changes to ketamine dose?**
	No (ketamine maintained at previous dose)
	Yes (ketamine dose changed)
Tick ✓	**If Yes; What change was made to medication?**
	Ketamine dose decreased: How long was patient on previous dose (hours) _____
	Ketamine dose increased: How long was patient on previous dose (hours) _____
	Ketamine dose ceased: (Complete Medication Cessation page 42) 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?
	No
	Yes; Please specify analgesic added here:

Tick ✓	Was there any change in pain from the medication of interest?
☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse	

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 Intensity Score (Use Appropriate Pain Tool – see Appendix)

What was the *pain intensity at time of assessment?*
(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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 42)
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_2 – 48 hours post commencing ketamine infusion *(Please complete as close to 48 hours as possible)*	
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 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 interruptions to the Ketamine infusion?**
Yes	**No**	If yes, please give details of interruption here.

Tick ✓	**Have there been any changes to Ketamine?**
	No (Ketamine maintained at previous dose)
	Yes (Ketamine dose changed)

Tick ✓	**If yes; What change was made to Ketamine?**
	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 42) 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?
	No
	Yes; Please specify analgesic added here:

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

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 Intensity Score (Use Appropriate Pain Tool – see Appendix)

What was the *pain intensity score at time of assessment?*
(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_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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration Impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 42)
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_3 – 72 hours post commencing ketamine infusion

(Please complete as close to 72 hours as possible)

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 72 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 interruptions to the Ketamine infusion?**
Yes	**No**	If yes, please give details of interruption here.

Tick ✓	**If Yes; What change was made to medication?**
	Ketamine dose decreased: How long was patient on previous dose (hrs.)? _____
	Ketamine dose increased: How long was patient on previous dose (hrs.)? _____
	Ketamine ceased: (complete Medication Cessation page 42) 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?**
	No
	Yes; Please specify analgesic added here:

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

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 Intensity Score *(Use Appropriate Pain Tool – see Appendix)*

What was the *pain intensity score at time of assessment?*

(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_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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration Impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 infusion ceased. (complete Medication Cessation page 42)
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_4 – 96 hours post commencing ketamine infusion or when ketamine infusion is discontinued

(Please complete as close to 96 hours as possible)

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

Date of Death*	DD/MM/YYYY

If not assessed at 96 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 interruptions to the Ketamine infusion?**
Yes	**No**	If yes, please give details of interruption here.

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

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

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

Was there any change in pain from the medication of interest?			
□ Complete resolution	□ Partial resolution	□ No change	□ Worse

T_4 – 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 Intensity Score *(Use Appropriate Pain Tool – see Appendix)*

What was the *pain intensity score at time of assessment?*

(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_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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration Impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 infusion ceased.
Yes	**No**	Has a medication been added to treat a specific harm/toxicity? If yes, please specify medication to treat specific harm:

T_E – 3 months <u>after completing</u> ketamine infusion

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

Tick ✓	T_E: Assessed/Not assessed reason
	Assessed today (continue to complete T_E) OR
	Not assessed (reason)
	Lost to contact
	Participant withdrew/Died – record date of death below
	Other; please specify

Date of Death*	DD/MM/YYYY

Please provide reason why if today's assessment is not 3 months after completing infusion

Was there any continuing change in pain from ketamine?

☐ Complete resolution ☐ Partial resolution ☐ No change ☐ Worse

T_E – 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 Intensity Score (Use Appropriate Pain Tool – see Appendix)

What was the *<u>pain intensity score at 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 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
	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
Tick ✓	**Current Non-Medication Strategies** *(Tick all that apply)*
	Acceptance Commitment Therapy
	Biofeedback
	Cognitive Behavioural Therapy
	Distraction incl. online apps
	Goal setting
	Graded Exercise
	Guided Imagery
	Hypnosis
	Massage Therapy
	Other Manual Therapy; Please specify
	Mirror Therapy
	Relaxation incl. online apps
	Strengthening Exercises
	Stretching Exercises
	Transcutaneous Electrical Nerve Stimulation
	Other; Please specify
	Other; Please specify

T_E – Impact of Pain

Tick ✓	Functional Disability Index (see Appendix)
	Not scored
	Scored

Functional Disability Index Score	

Tick ✓	Pediatric Quality of Life Inventory (see Appendix)
	Not scored
	Scored

Tick ✓	PedQL Score
	Physical function
	Emotional function
	Social function
	School function
	Overall

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

☐ **Dizziness**

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

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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration Impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory Depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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 ✓	Has a medication been added to treat a specific harm/toxicity?
	No
	Yes, Please specify medication to treat specific harm here:

Tick ✓	What was the overall benefit from the ketamine infusion?
	Complete resolution of pain
	Partial resolution of pain
	Reduction in opioid requirement
	Not helpful
	Other; Please specify

Medication Cessation *(Complete this page if the ketamine infusion is ceased at any point during the study period)*	
Date and Time of Assessment (Medication Cessation)	DD:MM:YYYY

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

SYMPTOM SEVERITY SCORE

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

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

What treatment (if any) was initiated after cessation of ketamine? *(If none respond 'none')*

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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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?			

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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **Nausea**

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

NCI Criteria
7. Loss of appetite without alteration in eating habits
8. Oral intake decreased without significant weight loss.
9. 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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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?			

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)*

☐ **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

☐ **Syncope**

○ 3 ○ ungradable ○ no symptom ○ not recorded

NCI Criteria
1. -
2. -
3. Fainting; orthostatic collapse

☐ **Nausea**

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

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

☐ **Vomiting**

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

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

☐ **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

☐ **Somnolence**

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

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

☐ **Confusion**

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

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

☐ **Concentration impairment**

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

NCI Criteria
1. Mild inattention or decreased level of concentration
2. Moderate; short term memory loss; limiting instrumental ADL
3. Severe; long term memory loss; limiting self-care ADL.

☐ **Amnesia**

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

NCI Criteria
1.Mild; transient memory loss
2. Moderate impairment in attention or decreased level of concentration; limiting instrumental ADL
3. Severe impairment in attention or decreased level of concentration; limiting self-care ADL

☐ **Hallucinations**

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

NCI Criteria
1.Mild hallucinations (e.g., perceptual distortions)
2. Moderate hallucinations
3. Severe hallucinations; hospitalisation not indicated
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 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

☐ **Respiratory depression**

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

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

☐ **Injection site reaction (intravenous or subcutaneous)**

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

NCI Criteria
1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
2. Pain; lipodystrophy; edema; phlebitis
3. Ulceration or necrosis; severe tissue damage; operative intervention indicated
4. Life-threatening consequences; urgent intervention indicated
5. Death

☐ **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?			