

RiskMan

How To Enter A Clinical Trial
Incident



**Barwon
Health**

- A new incident form will open on login

Incident (V2) Entry

Submit this form to record the incident (v2).
You will be able to modify this page once it is submitted.

Who Is Reporting?

Reporter name	Default (Default)  	Role	
Email	<input type="text"/>		
Staff ID	<input type="text"/>		
Relationship to person affected			

- Your 'Reporter name' and 'Role' will auto-fill from your user profile
- Yellow fields are mandatory
- Hover over fields for further explanations

Who Was Affected?

The Event relates to a...	Patient/Client/Resident 
Client ID/MRN	<input type="text"/> 
First name	<input type="text"/>
Gender	
Date of birth	<input type="text"/> 
Indigenous Status	
NDIS known?	<input type="radio"/> Yes <input type="radio"/> No
Street	<input type="text"/>
Suburb/City	<input type="text"/>
Postcode	<input type="text"/>

Insert UR if available and click 'Retrieve Details' button – this will auto-fill Patient data from iPM.  Or type in manually.

When Did It Occur?

Incident date	25 Oct 2022		Time estimated?	<input type="radio"/> Yes	<input type="radio"/> No
Incident time			VAHI Transmission version date	6 Aug 2021	
Notification date	25 Oct 2022				

- Date fields are auto-filled from date you are entering the incident. If the event occurred previous to this date, manually override.

Where Did It Occur?

Site	University Hospital Geelong	▼
Location	ALCC Day Ward	▼
Service being provided	Clinical Trials	▼
Specific location		▲ ▼ ☰
Department/Programme	Emergency & Medicine	▼

- Site: select from drop down list
- 'Location': values are dependent on 'Site' chosen. Only 'Locations' linked to that 'Site' will appear.
- Service Provided: Always select Clinical Trials
- Specific Location: these details are to record where the incident happened
- Dept/Programme is the Directorate for the Location chosen.
- **These details are important as the selections notify key staff of the incident.**

What Happened?

Brief summary

Details

What happened next?

Immediate actions taken

Next of kin notified? Yes No

- Summary and Details are to be de-identified. DO NOT include names; instead use Positions or Titles such as 'Patient', 'Manager', 'Wife'.
- If names need recording, you can do this in 'Witness' section further down the form.
- Be sure to Identify the Clinical Trial by Trial **Title** and **BH Project Number** (if available) in the Summary area.

What was the impact/outcome of this event?

Level of harm sustained

Required level of care

Actions required

Incident severity rating

- The Incident Severity rating (ISR) is calculated based on the values entered under the three categories above (Level of harm sustained; Required level of care; Actions required). Click on the right corner arrows for detailed definitions.

Help Us Improve...

What actions or omissions do you think may have contributed to this incident?

What would you suggest to prevent this happening again?

Were there any witnesses?

Yes No

- Parts of this section are optional
- If there are witnesses or names to record, click 'Yes'.
- This will enable a sub form to appear where you can record witness details
- Click on the 'Add Witness' button to open the Witness Involved sub-form

Were there any witnesses? Yes No

Witnesses

Add Witness

Witness Involved

Type

Role

Persons' name 

Contact number

Click on the 'person' to find and add Barwon Health staff

Type of Event(s)

Type of event(s) ▲ ▢ ▣ ▤ ▥ ▦ ▧ ▨ ▩

Was an emergency response called? Yes No

Pandemic related? Yes No

- Type of Event is where the incident is classified into pre-determined categories set up by Victorian Agency for Health Information (VAHI)
- The values entered in here are very important as they are used in department reports and to notify key staff of events
- Click inside the box to open the ‘tiles’
- Select **Patient Care**> Select all tiles relevant to the incident then >**SAVE** via clicking the top right hand **green tick**.
- These ‘tiles’ will change depending on the incident type, ie. Patient/Client/Resident; Worker; Non-person

Patient Care
Support Services
Show All ▼

A Access / Assessment / Care Planning	B Behaviour	B lood Products	C ommunication
C onsent	D eteriorating Patient	D ocumentation	E quipment (P)
F all	H andover/Transfer	I nfection	I nvestigation(s)
M aternal/Neonatal Complications	M edication & IV fluids	N utrition	O rganisation & Management (P)

- If an emergency response was called tick 'Yes'. This will ask for further details.

Was an emergency response called?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Type of emergency response	Code Grey (unarmed threat) ▼
Emergency response status	Actual ▼

If the incident involves medication –select the 'Medication and IV fluids' tile.

- A sub-form relevant to your selection will appear within the form requesting further information
- Eg. Select 'Add Medication' button for a Medication incident

Medication	
Add Medication	
Medication chart type	<input type="radio"/> Electronic <input type="radio"/> Paper
New adverse drug reaction for this person?	<input type="radio"/> Yes <input type="radio"/> No

Hover over any values in this form for further information

This form has fields that have been modified and not saved. Click save to resolve this. Save

Medication

Medication Name (UU) * Medication not found 1

Generic name * No generic found

Brand name * Trial Drugs

Generic unit of use

Strength Units

Form capsule

Strength Type mg/each

AMT Strength Notes

Medication Class * Endocrine drugs

Medication Process involved * Storage/Handling/Disposal 2

Medication problem *

Did this involve a High Risk (PINCH) medication? *

TIPS:

- If the trial drug is not listed write 'medication not found'
- Brand Name: Trial Drug

1. Start typing the name of the medication.
A list of matching values will show

Medication Name (UU) * **ibupr**

Generic name * codeine phosphate hemihydrate 12.8 mg + ibuprofen 200 mg tablet
dressing with ibuprofen 10 cm x 10 cm foam dressing

Brand name * **ibuprofen 10 mg/2 mL injection, ampoule**

Generic unit of use ibuprofen 100 mg capsule
ibuprofen 100 mg chewable tablet

Strength Units ibuprofen 100 mg orally disintegrating tablet
ibuprofen 100 mg tablet: orally disintegrating

2. Complete the mandatory fields for the sub form to appear

Medication

Add Medication

Medication Name (UU) *	Generic name*	Brand name*	Medication Class*	Medication Process involved*	Medication problem*	Did this involve a High Risk (PINCH) medication?*
 ibuprofen 200 mg capsule	No generic found		Analgesics	Administration	Extra Dose	No ✖

Medication chart type Electronic Paper

New adverse drug reaction for this person? Yes No

Type of Event(s)

Type of event(s)

Was an emergency response called? Yes No

Pandemic related? Yes No

Internal notification

- Internal Notification is an optional field to record any additional teams or departments that need to know about the incident
- This will send key staff a notification to review the incident
- Click inside the box to open a menu of options 
- Be sure to select **'Research and Ethics'**
- **'Adverse Drug Reaction'** or **'Pharmacy'** may also be applicable for drug trials
- **'BMI'** may be applicable to trials involving radiation

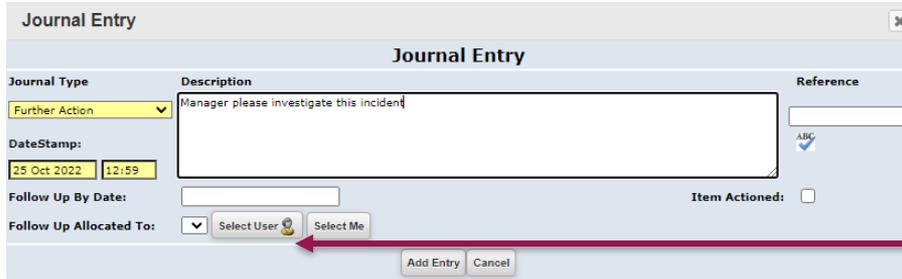
Internal Notifications

- Not Applicable
- Acute Pain Service
- Adverse Drug Reaction
- Anaesthetic M&M
- BMI
- BMI - Ultrasound
- Central Resource Unit
- Clinical Engineering
- Clinical Products Faults
- CSU
- Duplicate UR Number
- Dysphagia
- EMR
- Injury Management Team
- Interim Orders
- IT issue
- Junior Medical Staff
- Medication Keys Missing
- MH Records, TCM & Rapid Issue
- Needle Exchange Program
- Nursing Attendants

Journals and Actions

Add New Journal Entry

- You can use a Journal entry to advise someone of an incident or assign an action
- Click on the 'Add New Journal Entry' button



Click on the 'Select User' to find and add Barwon Health staff. This will send them an email notification to view the incident.

Documents

Add Document

- This section is to attach any documents such as photos or further reports to support your incident entry

<p>Create linked incident</p> <p>Clone details from this Incident (V2) to a new Incident (V2). These Incidents (V2) will be linked.</p> <p>Submit and Clone</p>	<p>Submit</p> <p>Submit this Incident (V2). RiskMan will check if you have completed all the mandatory fields.</p> <p>Submit</p>
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Need Assistance?
Call BH Research Quality
Manager on
(03) 4215 3040

- To save the incident, click 'Submit'
- 'Submit and Clone' should only be used if you are recording a Behaviour incident against a Patient and you need to enter another incident if the Behaviour was directed towards a Worker. If in doubt always select 'Submit'.
- Follow-up: Check in with your Manager, area Safety, Quality and Improvement Coordinator or log back into Riskman to find out about the Incident Review, corrections, actions and recommendations that may have resulted from your Riskman submission OR to document these updates yourself.