Research Clinical Trial Alerts

Overarching SVHA or SVHM policy: Research
Overview and purpose: The rapid identification of patients who are, or have been, participants in an interventional clinical trial can inform appropriate patient management, including prompt recognition of trial-related adverse events, and ensuring treatment does not negatively impact on ongoing trial participation. A Clinical Trial alert is entered into the Patient Administration System (PAS) immediately upon recruitment to an interventional research study to optimise clinical care, meet our mandatory obligations against the National Clinical Trials Governance Framework, and support the automation of the Clinical Trial Participant Survey.
Scope (where?): All SVHM sites and services.
Scope (who?): All SVHM clinical and administrative staff involved with interventional clinical trials.
Key related documents: • Clinical Handover • Patient Alerts

Procedure

A. Responsibilities

Each Department and their research staff are responsible for:

- Entering a Clinical Trial alert into PAS for each participant at the time of recruitment to a study, consistent with Appendix A: Adding a Clinical Trial alert into PAS.
- Ensuring the alert remains active throughout the participant's involvement in the trial, including any follow-up period.
- Removing the alert upon study completion, while ensuring that a past alert remains visible in the PAS system for historical reference.
- Complying with this policy, taking action to improve the quality of the Clinical Trial alerts that are entered, and ensuring the alerts are meaningful to staff outside the Research environment.
- Facilitating the automated participant survey process and ensuring that feedback is captured in RiskMan for analysis and quality improvement.
- Reviewing feedback in Riskman and escalating participant / consumer complaints, as necessary.

Research Governance Unit and their staff are responsible for:

- Overseeing compliance with this policy and taking action to improve gaps in performance.

B. Patient alert information and purpose

- Alerts are high risk issues that, once entered into PAS, support timely, informed decision making, and assist in the handover of information about those risks when there is an unplanned presentation to hospital and at transitions of care.
- The electronic systems where alerts are visible are character-limited and only display around 25 words; long alerts will be truncated and may cut off important information if too long.
- The basic principles of language to use in an alert are:
  a) be concise,
  b) identify the risk so busy staff understand at a glance, and
  c) if the action isn't obvious, give concise direction.
- Meaningful but concise language is most effective to inform decision-making and clinical trial alerts are to include key information only and in Sentence case (never all in capitals), i.e.:
  HREC ###, Contact details (name/number) and department (Dept. responsible for the trial), Study name Abbrev.

C. Adding a Clinical Trial alert

- Enter the Clinical Trial alert into PAS immediately upon enrollment into an interventional trial; refer to Appendix A: Adding a Clinical Trial alert into PAS.
- Use the information recommended in Appendix A, including the HREC number, contact details of the key staff contact for the study, the department responsible for the study, and the abbreviated title of the study in Sentence case (never in all capitals).
- Once entered, the Clinical Trial alert is considered an Active Current Alert in the alert database.
- The next Clinical Trial Participation Survey will be automatically be sent to the patient via the contact details (email / SMS) recorded in PAS.

D. Editing a Clinical Trial alert

- The alert will remain Active Current if there is no End Date, or if the End Date is set in the future.
- Edit the Clinical Trial alert if there is a change or update in:
  - the End Date,
  - the Contact details for the responsible staff member, or
  - other information in the existing alert.
- The alert can also be edited if the free text added did not comply with Appendix A.

E. Closing a Clinical Trial alert

- Alerts are closed when the End Date is today, or the End Date is in the past.
- Alerts are to be **closed** in the following situations:
  - completion of the clinical trial (including all the follow-up visits), or
  - withdrawal of participation for any reason, e.g.:
    - adverse events,
    - personal choice,
    - safety concerns,
    - study termination, or
    - death of the patient.
- Close an alert by following the instructions in Appendix B: Editing an EXISTING Clinical Trial alert in PAS, and amending the End Date to be the date that the patient completed or withdrew from the trial. At the same time, add a concise explanation for withdrawal at the beginning of the free text section in the PAS Alert.
- Closing a Clinical Trial alert will prompt the automatic sending of the final Clinical Trial Participant Surveys to that patient.
- Closing a Clinical Trial alert maintains the integrity of the patient's clinical record.

F. Deleting an incorrect Clinical Trial alert

Alerts are only deleted if added onto a patient profile in error. Otherwise, do not delete any alert.

G. Mandatory Clinical Trials Governance Obligations

The Australian Commission on Safety and Quality in Health Care (ACSQHC) has developed the National Clinical Trials Governance Framework (the Framework) to ensure that clinical trials are conducted in a safe environment and in a high-quality manner for optimal health outcomes. Clinical trials are assessed against the actions in the Framework as part of the hospital-wide accreditation process. The patient safety and quality system, as well as the continuous improvement process, are assessed as a key component of the Framework. Moving forward, failure to meet these requirements may result in the loss of hospital accreditation.

H. Monitoring and continuous improvement

A Clinical Trial Participant Survey is used to gather feedback from patients about their experience, including any perceived impact on their care. Insights gained from the survey will inform policy

refinements, ensuring that the alert system remains patient-centred and supports both clinical staff and research teams in delivering high-quality care. Feedback from the survey will be captured on RiskMan, enabling systematic tracking, analysis, and integration into quality improvement initiatives. The feedback will also contribute to SVHM's compliance with the Framework by demonstrating a commitment to patient safety, engagement, and quality improvement in clinical trials.

The Research Governance Unit and their staff will coordinate audits of compliance with this policy and request action from any department that demonstrates opportunities to improve performance.

Definitions and Acronyms

Interventional clinical trial:
Any research that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include, but are not limited to: experimental medications, cells and other biological products, vaccines, medical devices, surgical and other medical treatments and procedures, psychotherapeutic and behavioral therapies, health service changes, preventive care strategies, and educational interventions. Clinical trials may compare existing interventions, test new ways to use or combine existing interventions, or observe how people respond to other factors that may affect their health, e.g. dietary changes.

Active Current Alert
This alert either does not have an End Date, or the End Date is set in the future. The Clinical Trial alert hazard symbol is visible in the PAS patient banner, in MRO on the Cover Page, and on the Electronic Patient Journey Board (EPJB).

Closed Alert
This alert has an End Date that is in the past. The alert hazard symbol is no longer visible in MRO or the EPJB, but Closed alerts are visible on the Alerts page in PAS after going into the Information drop down and selecting Alerts. Reports run by Research Governance will include these alerts, which will be identified in the data as Closed.

Deleted Alert
Alerts are only to be deleted if they have been entered incorrectly, e.g. in the wrong patient's clinical record. Once an alert is deleted, it is not visible in the Alerts Screen (after going into the Information drop down and selecting Alerts).
Deleted alerts are visible after clicking the Deleted Alerts tab in the Alerts screen in PAS.

PAS	Patient Administration System
SVHA	St Vincent's Health Australia
SVHM	St Vincent's Hospital Melbourne

References

1. What is a clinical trial? (2015) *Australian Government National Health and Medical Research Council*. Taken from https://www.australianclinicaltrials.gov.au/what-clinical-trial (April 2022).
2. The National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trial (2022) Australian Commission on Safety and Quality in Health Care, taken from https://www.safetyandquality.gov.au/publications-and- resources/resource-library/national-clinical-trials-governance-framework-and-user-guide (April 2022).

Authorship Details

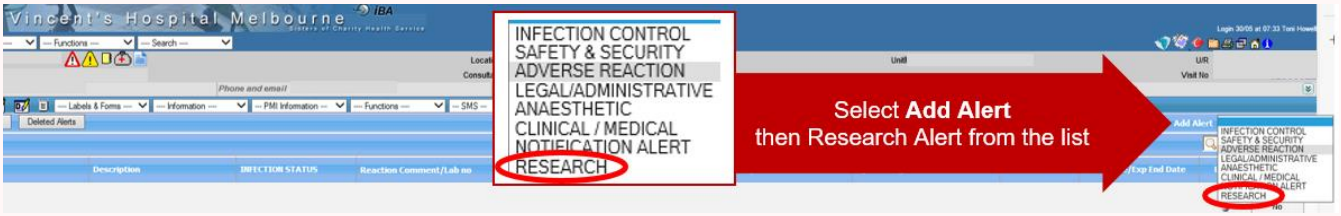
Primary guideline author: Sue Ngeow, Clinical Trials Liaison Officer
Head of Department responsible: Megan Robertson, Director of Research
Endorsed by: Megan Robertson, Director of Research
Next review date: April 2026

Appendix A: Adding a Clinical Trial alert into PAS

1.

2.

3.



4.

1. Select **Clinical Trial Alert** from the drop down.
2. Add **Date Activated**.
3. If appropriate, add a **Next Review Date** (e.g. estimated study completion date for participant).
4. If known, add **End Date** (confirmed trial end date for participant, including follow up period).
5. Skip the next few fields.
6. In Reaction Comment, enter **concise** text that identifies the risk **at a glance** for busy staff and an action to take, if urgent.
   e.g. HREC ##. Contact (*name, number*). Department responsible for the clinical trial. Study Name Abbrev.
7. Select **Add**

Do you have questions about adding or editing Patient Alerts?

Check the Patient Alerts policy via Sharepoint.

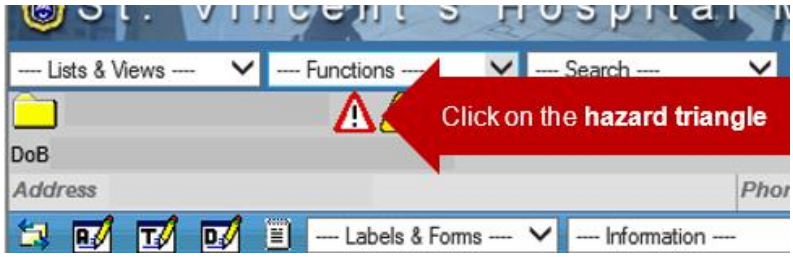
Questions about **Research – Clinical Trial – Alerts** can go directly to research.directorate@svha.org.au

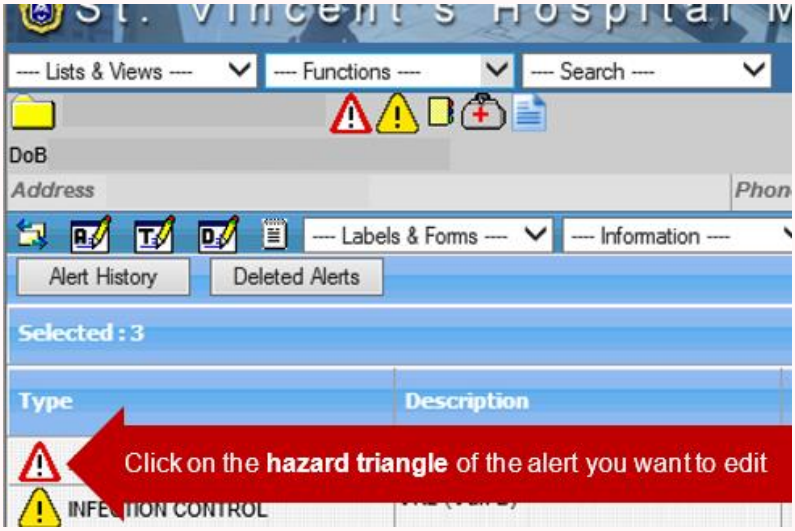
The Communicating for Safety Committee is responsible for governance of the alerts process and you can contact the committee via Quality and Patient Safety Unit, or contact Toni Howell in Pharmacy: toni.howell@svha.org.au

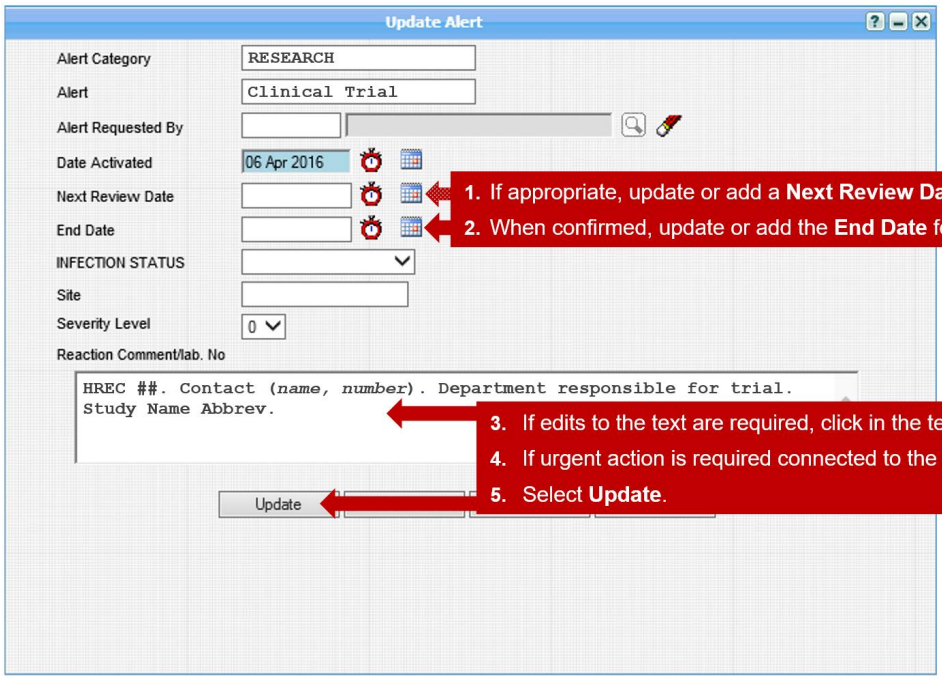
Appendix B: Editing an EXISTING Clinical Trial alert in PAS

If there is already a Research - Clinical Trial alert in PAS, the process is slightly different.

1. 

2. 

3. 

4. 

5. Alerts are **only** deleted if added onto a patient profile in error. Otherwise, do not delete any alert.