ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

Addition of Research Alert on Patient Administration System (PAS)

Policy Statement

The rapid identification of patients who are (or have been) participants in an interventional clinical trial can inform the appropriate management and support of the patient. This may include recognition of adverse events related to the trial or ensuring treatment does not negatively impact on the ongoing participation in the trial. For this reason, the Research alert has been part of the significant alerts recorded in the Patient Administration System (PAS) since the creation of the list of significant alerts in 2015.

Recently, the Australian Commission on Safety and Quality in Health Care has supported the development of 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. St Vincent's Hospital Melbourne (SVHM) has been selected to pilot the Framework. In the future, clinical trials will be assessed against the actions in the Framework as part of the organization-wide accreditation process.

Related Documents

- The National Clinical Trials Governance Framework and User Guide for Health Service Organizations Conducting Clinical Trials, Australian Department of Health (2022)

Objectives

This policy aims to: -

- Strengthen the responsibilities for documentation and oversight of the Research alert.
- Ensure staff at transitions of care can rapidly identify that a patient is (or has been) part of a clinical trial and respond appropriately.
- Automate the process for participant surveys.

Scope

- This policy only applies to any Interventional Clinical Trials conducted at SVHM.
- Each Department and their research staff will be responsible for adding the Clinical Trial Alert for each participant on the SVHM PAS when they are recruited to a study AND removing the alert when the participant completes the study including any follow-up period.
- Please note that when the Clinical Trial Alert is removed at study completion, there will still be a past alert visible in the PAS system.

Definitions

The *World Health Organization (WHO*) definition of a clinical trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

Clinical trial interventions include but are not restricted to:

- experimental drugs

- 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
- educational interventions

Clinical trials might also compare existing interventions, test new ways to use or combine existing interventions or observe how people respond to other factors that might affect their health (such as dietary changes).

Acronyms

NSQHS (The National Safety and Quality Health Service)
PAS (Patient Administration System)

Procedure

Each Department and their research staff will be responsible for adding the Clinical Trial Alert for each participant on the SVHM PAS when they are recruited to a study AND removing the alert when the participant completes the study including any follow-up period. Please note that when the Clinical Trial Alert is removed at study completion, there will still be a past alert visible in the PAS system.

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).

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