

## SERIOUS INCIDENTS REQUIRING INVESTIGATION (SIRI) POLICY AND PROCEDURE

**This policy should be read in conjunction with the Untoward Event Reporting Policy, Duty of Candour Policy, Complaints, Concerns and Compliments Policy and the Claims Handling Policy and Procedure**

Version:	8
Ratified by:	Senior Management Team
Date ratified:	February 2017
Title of originator/author:	Acting Head of Clinical Risk
Title of responsible committee	Clinical Governance Group
Date issued:	<b>February 2017</b>
Review date:	<b>February 2020</b>
Relevant Staff Group/s:	All staff

**This document is available in other formats and other languages upon request.  
Should you require this please contact the Equality and Diversity Lead  
on 01278 432000**

## DOCUMENT CONTROL

<b>Reference</b> MC/Nov/12/SIRIP	<b>Version</b> 8	<b>Status</b> Final	<b>Author</b> Acting Head of Clinical Risk
<b>Amendments:</b> Rewritten to provide the integrated Trust with an effective procedure for reporting and investigating Serious Incidents Requiring Investigation (SIRI) and unexpected deaths (UED) to include RCA guidance and templates from the NPSA. Changes also reflect the new guidance released by NHS England on the Serious Incident Framework			
<b>Document objectives:</b> To provide all staff with clear instructions for the efficient management of Serious Incidents Requiring Investigation (SIRI).			
<b>Intended recipients:</b> All staff should be familiar with this document. This applies in particular to all managers, clinical/professional staff and staff in roles which support operations, all grade, role or status, permanent, temporary, full-time, part-time staff including locums, bank staff, volunteers, trainees and students.			
<b>Committee/Group Consulted:</b> Serious Incidents Requiring Investigations Group, Regulation Governance Group			
<b>Monitoring arrangements and indicators:</b> SIRI and Trust Board monthly. Reporting Trends Analysis Clinical Governance Group on a quarterly basis and distributing to Senior Managers for Local /Team discussion			
<b>Training/resource implications:</b> General awareness (any Teams needing support regarding the reporting of Serious Incident Requiring Investigation (SIRI)s should contact the Corporate Services Manager)			
<b>Approving body and date</b>	Clinical Governance Group		Date: January 2017
<b>Formal Impact Assessment</b>	Impact Part 1		Date: January 2017
<b>Clinical Audit Standards</b>	NO		Date: N/A
<b>Ratification Body and date</b>	Senior Management Team		Date: February 2017
<b>Date of issue</b>	<b>February 2017</b>		
<b>Review date</b>	<b>February 2020</b>		
<b>Contact for review</b>	Head of Clinical Risk		
<b>Lead Director</b>	Director of Nursing and Patient Safety		

## CONTRIBUTION LIST Key individuals involved in reviewing the document

Designation or Group	Designation or Group
SIRI Investigation Lead	Clinical Governance Group
Acting Deputy Director of Nursing	Heads of Division
Head of Corporate Business	Chief Executive
Head of Safeguarding	SIRI and Mortality Review Group
Risk Management Information Officer	Non-Executive Director

## CHECKLIST FOR STAFF FOLLOWING A SERIOUS INCIDENT REQUIRING INVESTIGATION (SIRI)

### What to do if a SIRI Occurs

#### CHECKLIST

- Call emergency services as appropriate (999)
- Ensure all patients and staff are safe
- Once all patients and staff are safe and any necessary medical intervention has taken place, staff should **preserve the scene** of the incident. Staff should not move or remove anything until requested to do so by police or senior manager (procedure available in Security Policy)
- Inform colleagues
- Inform Team/Ward Manager (in office hours) or On-call Manager (out of hours)
- Inform Risk Team (during office hours)
- Inform family (where appropriate) and offer support as required
- Inform GP (if patient related event)
- Update patient healthcare record (including electronic patient records)
- Complete untoward event report (DATIX)
- Support for patients and staff as required, using Trust guidance.
- Managers to review event
- 72 hour report

**This is not intended to be an exhaustive list. Different events require different approaches. The above is intended as a guide for staff.**

<b>CONTENTS</b>		
<b>Section</b>	<b>Summary of Section</b>	<b>Page</b>
Doc	Document Control	2
Diagram	Checklist for staff following a serious incident	3
Cont	Contents	4
1	Introduction	5
2	Purpose & Scope	6
3	Duties and Responsibilities	6
4	Definition of a Serious Incident Requiring Investigation (SIRI)	8
5	Immediate Action Following a Serious Incident	<b>10</b>
	Initial Actions	10
	72 Hour report	11
	Witness Statements for the Coroner	12
	Duty of Candour	12
	Staff Support	12
6	Investigating Serious Incidents (SI)	13
	Level of Investigation and timescales	13
	Timescales for completion of investigations	13
	Investigators	13
	The Serious Incident Review Multidisciplinary Review	14
	Communication between Provider Organisations and Other Regulators	14
	Identifying Learning and Recognising Good Practice	15
7	Trust Sign-Off	16
	Submission to SCCG	16
	SIRI Group	16
8	Reporting to external agencies	17
9	Training Requirements	17
10	Equality Impact Assessment	18
11	Counter Fraud	18
12	Monitoring Compliance and Effectiveness	18
13	Care Quality Commission Registration Standards	19
14	References, Acknowledgements & Associated documents	19
15	Appendices	21
Appendix A	RACI process	22
Appendix B	SIRI Process Flowchart	23
Appendix C	Levels of investigation	26

## 1. INTRODUCTION AND POLICY STATEMENTS

- 1.1 Somerset Partnership NHS Foundation Trust recognises the need for the prompt and proper reporting of all incidents: clinical, non-clinical and 'near misses', as part of its Risk Management Strategy in order to improve service user and staff safety and its quality of care.
- 1.2. The Trust supports an active approach to managing incidents and places emphasis on lessons learnt rather than apportioning blame; there may however be occasions when the Trust's disciplinary procedures will need to be considered.
- 1.3. The Trust recognises its particular obligations towards serious incidents and the need to follow strict reporting and investigation guidelines based on national and local commissioning guidelines as well as best practice. In particular, it has in place such systematic measures to:
  - Safeguard people, property, the Trust's resources and its reputation
  - Understand why the event occurred
  - Ensure that steps are taken to reduce the chance of a similar incident happening again
  - Report to other appropriate bodies where necessary
  - Share the learning with other NHS organisations and providers of NHS-funded care
- 1.4. This document outlines the procedure that must be undertaken to firstly identify incidents that meet the Serious Incident Requiring Investigation (SIRI) criteria, and then their subsequent management.
- 1.5 This process is governed by The Serious Incident Framework, set out by NHS England, which requires the investigation of all serious incidents to be:
  - Open and transparent
  - Preventative
  - Objective
  - Timely and responsive
  - Systems based
  - Proportionate
  - Collaborative
- 1.6 The focus of all SIRI investigations must be to ensure that there is appropriate learning and recognition of good practice, where possible to reduce the risk of further occurrences.
- 1.7 All Serious Incidents must be reported to Somerset Clinical Commissioning Group (SCCG).

## 2. PURPOSE AND SCOPE

- 2.1 The Purpose of this policy is to:
- Provide a definition of a serious incident that requires investigation; Clarify roles and responsibilities;
  - Provide information on the legal and regulatory requirements and timescales;
  - Provide a resource for staff based on good practice, with resources to support effective investigations and learning.
- 2.2 This policy applies to all Trust staff, including bank, agency, volunteers, students and contractors engaged in work on behalf of the Trust.
- 2.3 The Trust has developed a 'checklist for staff following a SIRI' (see page 3 of this document).
- 2.4 A flow chart to show the process for SIRI investigations is available in Appendix A.
- 2.5 All documents relating to the SIRI Process are available on the Trust Intranet ([http://intranet.sompar.nhs.uk/a\\_-\\_z\\_directory/clinical\\_risk.aspx](http://intranet.sompar.nhs.uk/a_-_z_directory/clinical_risk.aspx)).

## 3. DUTIES AND RESPONSIBILITIES

- 3.1 The **Chief Executive** has ultimate responsibility for all aspects of risk management, including the management of incidents and SIRI. This involves ensuring services are adequately resourced to comply fully with this policy.
- 3.2. The **Executive Lead is the Director of Nursing and Patient Safety. The Director of Nursing and Patient Safety is strategically responsible for:**
- Ensuring compliance with this policy
  - Ensuring that all investigations are carried out effectively and appropriately
  - Providing evidence that lessons have been learnt.
- 3.3. The **Heads of Division and Clinical Directors** have a responsibility to:
- Be aware of, and comply with this policy
  - Provide support to all staff and patients involved in reporting of SIRI or potential SIRI (actual and near miss)
  - Ensure that investigators are allocated and all investigations are carried out effectively and appropriately
  - Ensure that action plans are appropriate and are implemented within their services
  - Provide evidence that lessons have been learnt
  - Monitor the quality and effectiveness of reporting and subsequent investigations by receiving and commenting on trend analysis and investigation reports.

- 3.4 The **SIRI Panel** is made up of the **Director of Nursing and Patient Safety, the Medical Director, The Deputy Director of Nursing and the Head of Mental Health Nursing**. The panel is responsible for:
- Confirming which incidents will be categorised and reported as a SIRI
  - Reviewing the 72 hour reports
  - Reviewing and signing-off SIRI reports and action plans before they go to SCCG.
- 3.5 The **Head of Clinical Risk** has delegated responsibility from the Director of Nursing and Patient Safety, and is responsible for ensuring:
- SIRIs are appropriately identified and reported to the SIRI Panel, Strategic Executive Information System (StEIS) and SCCG.
  - That all investigations are carried out effectively and appropriately
  - That action plans are appropriate and have been shared with the local teams.
  - That any trends or concerns relating to SIRIs are immediately raised with the SIRI panel and Heads of Division
  - SIRI updates and Reports are provided to the Clinical Governance Group and Trust Board on a monthly basis and as required.
- 3.6 The **SIRI Investigation Lead** is responsible for:
- Liaising with SCCG to ensure appropriate Terms of Reference are developed for each investigation
  - Providing advice and support for investigators, to ensure
    - They are meeting the required deadlines
    - they provide timely feedback with recommendations for learning and the recognition of good practice to the local teams
  - Work with local teams to ensure
    - duty of candour has been undertaken
    - 72 hour reports are provided within 72 hours of an incident
    - Local Action Plans are developed at the start of the process
  - Escalating to the HODs any investigations that are at risk of not meeting the required deadlines
  - Investigating a portfolio of SIRIs
  - Liaising with the Head of Corporate Business regarding Inquests where HM Coroner requires witness statements, SIRI reports and other documentation.
- 3.7 The **Risk Management Team** has a responsibility to:
- Be aware of, and comply with this policy
  - Identify potential SIRIs reported through various means i.e. Datix, HM Coroner, safeguarding alerts, and alert the Head of Clinical Risk.
  - Notify and provide detail of SIRI's to the Executive Team, SIRI Panel and Senior Managers.
  - Maintain the SIRI spreadsheet and folders
  - Alert the Head of Clinical Risk of any potential trends or concerns
  - Provide administrative support to the SIRI group
  - Provide data for SIRI reports.

- 3.8 **Service Leads /Departmental Managers** have a responsibility to:
- Be aware of, and comply with, this policy.
  - Investigate all reported SIRIs.
  - Be aware of all SIRIs reported in their team/department.
  - Raise any concerns regarding SIRI with the relevant Service Manager.
  - Ensure all 72 hour reports are completed within 72hours of incident occurring:
  - Review the relevant risk assessments following a SIRI.
  - Inform the Risk Team if the SIRI results in staff absence from work (even if this does not happen immediately after the incident) or any changes to staff duties.
  - Inform the Risk Management Team of any changes to action plans
  - Consider and, where appropriate, implement the Duty of Candour Policy when reporting SIRIs.
- 3.9 The **Serious Incident Requiring Investigation and Mortality Review Group** (SIRI and Mortality Review Group) is chaired by the Medical Director. The group will review investigation reports, and action plans and record lessons learnt which will be disseminated within the Trust. Changes may include the review of policies and procedures, further development of systems within the Trust or changes in practice.
- 3.10 The **Head of Corporate Business** will be the first point of contact for HM Coroner's Office and will provide advice and support to any staff required to provide a Coroner's Report or Witness Statement to assist with either a pending inquest or claims investigation and attendance at inquests.
- 3.11 The **Security Manager** will have direct access to all untoward events including violence and aggression, theft, damage to property/equipment and all other security incidents and which may result in prosecution (please refer to the Security Policy).
- 3.12 The **Patient Advice and Liaison Specialists** (PALS) may be contacted for advice to patients, carers and the general public.

#### 4. **DEFINITION OF A SERIOUS INCIDENT REQUIRING INVESTIGATION (SIRI)**

- 4.1 NHS England defines the following incidents as SIRIs:
- Unexpected or avoidable death of one or more people. This includes:
    - suicide/self-inflicted death
    - homicide by a person in receipt of mental health care within the recent past (6 months)
  - Unexpected or avoidable injury to one or more people that has resulted in serious harm;



- Unexpected or avoidable injury to one or more people which requires further treatment by a healthcare professional in order to prevent
  - the death of the patient or
  - serious harm
  
- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
  - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or
  - where abuse occurred during the provision of NHS-funded care
  - (This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry (SAE) or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident
  
- An incident (or series of incidents) which prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
  - failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
  - property damage
  - security breach/concern
  - incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population
  - inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act Deprivation of Liberty Safeguards (MCA DOLS)
  - systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/unit closure or suspension of services)
  - activation of Major Incident Plan (by provider, commissioner or relevant agency)
  - major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation
  
- A Never Event – (See below) all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.

## 4.2 **Never Events**

4.3 Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

4.4 The list of core Never Events which must be reported are updated by NHS England on an annual basis. For the latest list and further guidance, please refer to the NHS England website at <https://www.england.nhs.uk/patientsafety/never-events/>

4.5 Never Events must be reported to SCCG and investigated in line with the Serious Incident Framework and the process as outlined within this policy.

## 5. **IMMEDIATE ACTION FOLLOWING A SERIOUS INCIDENT**

### 5.1 **Initial Actions**

5.1.1 A SIRI may be reported by a Department, Service or Division, or from another source such as HM Coroner, Complaints Team, Safeguarding Team or Information Governance Team. The SIRI may also be identified by trend analysis or by recommendation by SCCG.

5.1.2 All Trust staff are expected to follow the Untoward Event Reporting policy, when an incident occurs.

5.1.3 As with all incidents, the main priority is to ensure the safety of those involved and those who may be affected as a result of the incident.

5.1.4 Any potential SIRI must be reported **immediately** (or as soon as is practicable) by telephone to a member of the Risk Team, the Service Manager or deputy, if not available direct to an Executive Director at Trust Headquarters and ensure the Responsible Clinician is informed. Out of hours the relevant On-call Manager must be informed, who will notify the On-call Director and ensure that the Risk Team are informed of the incident during working hours.

5.1.5 If there is the possibility that the police should be made aware of the incident, this must be discussed with the relevant operational Director or Medical Director, the Director of Nursing and Patient Safety or the Director of Governance and Corporate Development (see section 9).

5.1.6 A DATIX must also be completed for the incident. If, in extraordinary circumstances, a member of staff feels unable to complete a DATIX, then other avenues exist. For instance, they may wish to discuss an event with their staff side representative or in some cases feel the need to use such policies as Whistle-blowing, Grievance/Disputes or Anti-Bullying and Harassment.

- 5.1.7 The Head of Risk or SIRI Investigation Lead will report the SIRI to the SIRI Panel, and further formal notification will be provided to notify Executive Directors/Senior Managers of the SIRI. Where it is not yet clear if the incident fits the SIRI criteria, the SIRI Panel will await the 72 hour report to make a decision. SCCG may be consulted for advice on complex incidents.
- 5.1.8 If the SIRI involves a child, the Head of Risk or SIRI Investigation Lead will notify the Trust Safeguarding Lead who will in turn notify the Local Safeguarding Children's Board (LSCB).
- 5.1.9 For events which are likely to produce significant legal/media interest an Executive Director, Head of Risk or the on-call Manager/on-call Consultant should notify the Communications Manager and SCCG. Mobile phone numbers are available from the On-Call Manager's pack

## 5.2 72 Hour Report

- 5.2.1 A 72 hour report must be completed by the local team within three working days of the incident being identified, and submitted to the Risk Management Team. (The 72 hour report template is available on the Trust intranet: [http://intranet.sompar.nhs.uk/a\\_-\\_z\\_directory/clinical\\_risk.aspx](http://intranet.sompar.nhs.uk/a_-_z_directory/clinical_risk.aspx)). The aim of the initial review is to:
- identify and provide assurance that any necessary immediate action to ensure the safety of staff, patients and the public has taken place
  - assess the incident in more detail (and to confirm if the incident does still meet the criteria for a serious incident and does therefore require a full investigation), and propose the appropriate level of investigation
  - ensure any initial risks are identified and appropriate mitigation put in place
  - To identify any initial learning and good practice
  - ensure the 'Duty of Candour' obligations have been initiated (see section 5.4 below)
- 5.2.2 The 72 hour report will be reviewed by the Head of Clinical Risk/the SIRI Investigation Lead, and the SIRI Panel, in order to inform the level of investigation required. Once this has been finalised it will be sent by the Risk Management Team to SCCG and the Trust Safeguarding Service to ensure that all necessary safeguarding processes have been considered and implemented.
- 5.2.3 Once a SIRI has been formally identified, The Head of Clinical Risk or SIRI Investigation Lead will report it to SCCG. The Risk Management Information Officer/SIRI Investigation Lead will complete the Strategic Executive Information System (STEIS) report within two working days of a Grade 1 and Grade 2 SIRI occurring
- 5.2.4 On receipt of the 72 hour report, SCCG will, in consultation with the Trust, agree the Terms of Reference for the investigation. This will include the involvement of any other providers, agencies or persons to be involved in the investigation, identified through the use of the RACI model (see appendix A).

### **5.3 Witness Statements for the Coroner**

- 5.3.1 If the SIRC is an Unexpected Death, HM Coroner may ask for witness statements from the member of staff who last saw the patient and the clinician with overall responsibility for their care. The witness statement must be provided within a month of the death of the patient.
- 5.3.2 This process will be coordinated by The Head of Corporate Services, who will provide the correct format for the statements.

### **5.4 Duty of Candour (Communicating with patients, families and carers)**

- 5.4.1 The Being Open principle is now a statutory requirement, which places a Duty of Candour on providers to advise patients and /or their family of a serious incident, to apologise and offer them the opportunity to be advised of the outcome. Please refer to the Trust's Duty of Candour Policy for more information.
- 5.4.2 This ensures that health care providers operate in an open and transparent way when incidents occur.
- 5.4.3 The local team must contact the patient (if applicable) and/or their family/carer to discuss the incident that has occurred/or is suspected to have occurred and let them know an investigation will be undertaken. This must be done within 10 working days after the SIRC is reported. The patient/family/carer should be offered support, and invited to contribute to the investigation. They should also be offered feedback on the findings and action plan, following the investigation. The wishes of the patient/family/carer must be documented in the patient's record and communicated to the investigator.
- 5.4.4 If the patient/family/carer wishes to be involved in the investigation, and/or receive feedback they should be contacted at the earliest opportunity by the investigator to determine how this should take place.
- 5.4.5 Where contact with the patient / relatives may not be indicated, for example in safeguarding incidents or where a criminal investigation is in progress, the Duty of Candour may be withheld following discussion with the relevant agencies e.g. safeguarding team
- 5.4.6 When logging incidents on STEIS, the Duty of Candour field must confirm that the patient / family have been informed and the extent of planned involvement of the patient / family in the investigation.

### **5.5 Support for Staff following a Serious Incident**

- 5.5.1 Following a serious Incident, an immediate debrief should take place with staff involved, to identify any immediate actions.

5.5.2 A formal post incident support session should be arranged by the team/ward manager within 7 days. This should be offered to all relevant staff (including medical staff and psychological therapists). As part of this session resources such as counselling should be offered if appropriate; The Stress Management Policy should be discussed, and appropriate supervision arrangements should be confirmed for all staff involved.

## **6. INVESTIGATING SERIOUS INCIDENTS (SI)**

### **6.1 Levels of investigation and timescales**

6.1.1 The nature, severity and complexity of SIRIs vary on a case-by-case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident. The appropriate level of investigation should be informed by an initial review of the 72 hour report.

6.1.2 There are three levels of SIRI investigation, as shown in Appendix B.

6.1.3 Root Cause Analysis reports are completed for all SIRIs. These reports include an in depth analysis of contributing factors, an action plan to address these issues and lessons learned in order to prevent recurrence and to influence change to policy, practice and training (the Root Cause Analysis Report template, is available on the Trust Intranet ([http://intranet.sompar.nhs.uk/a\\_-\\_z\\_directory/clinical\\_risk.aspx](http://intranet.sompar.nhs.uk/a_-_z_directory/clinical_risk.aspx))).

### **6.2 Timescales for completion of investigations**

6.2.1 Timescale for the completion of investigations is determined by the NHS England Serious Incident framework as follows:

- for level 1 and level 2 investigations – 60 days;
- for cases that require an independent investigation (such as mental health homicides) (level 3 investigations) – 26 weeks from the date the investigation is commissioned.

6.2.2 Exceptions to the above timescales may be agreed with SCCG in exceptional circumstances (this does not include a provision for staff annual leave).

### **6.3 Investigators**

6.3.1 It is the responsibility of each Head of Division to maintain a pool of staff with the right skills to undertake SIRI investigations. The Head of Division is responsible for allocating investigators when requested for a new SIRI.

6.3.2 For the investigation of Unexpected Deaths, there must be two investigators, one of whom must be a doctor.

6.3.3 Each investigator will be expected to undertake, on average, two investigations a year to maintain competence.

- 6.3.4 The investigator(s) are responsible for working with the local team during the investigation, and for feeding back any good practice or learning throughout the investigation.
- 6.3.5 The investigator(s) are responsible for contacting the patient and /or their family/carer to invite them to contribute to the investigation. If the patient/family/carer wish to be involved, then the investigator(s) must meet with them as part of the investigation process. The investigator(s) are also responsible for feeding back the SIRI findings and actions to the patient and /or their family/carer, where this has been agreed with the patient and/or their family/carer.
- 6.3.6 Investigations must be completed within the timeframe set by NHS England. If it appears that this may not be possible, this must be raised with the HOD and the SIRI Investigation Lead at the earliest opportunity. Some investigation times may be extended in exceptional circumstances.
- 6.3.7 The SIRI Investigation Lead will provide advice and support for investigators throughout the investigation process.

#### **The Serious Incident Review Multidisciplinary Review**

The Team/ward manager must arrange a multidisciplinary review of the incident approximately two weeks after it occurred. This review should involve medical staff and staff from services who have contributed to the patient's care within the previous 6 months. If possible the investigator(s) should also attend.

The review should identify good practice, practice issues, contributory factors, root causes and lessons learned. The Serious Incident Review (local services) document should be used to guide the meeting (available at: [http://intranet.sompar.nhs.uk/a\\_-\\_z\\_directory/clinical\\_risk.aspx](http://intranet.sompar.nhs.uk/a_-_z_directory/clinical_risk.aspx)).

Notes of the multi-disciplinary review must be taken, and the LAP should be refined and developed further at this stage.

This review should be used by the investigator(s) to form the basis of the subsequent Investigation.

#### **6.4 Communication between Provider Organisations and Other Regulators**

- 6.4.1 It is expected multiple providers will work together to undertake a single investigation, where this is possible and appropriate. SCCG will coordinate such investigations to ensure all parties are aware and to establish a lead contact for each organisation.
- 6.4.2 However, when separate investigations are necessary, the multiple providers should work together and consider cross boundary issues and fully explore

the root causes and contributory factors, with co-ordination by SCCG. It is the responsibility of the lead investigator to produce a single investigation report.

- 6.4.3 The Trust and Avon and Wiltshire Mental Health Partnership Trust have a joint protocol for managing SIRIs. Please refer to the risk team for more details
- 6.4.4 Occasionally incidents will require investigation via different regulatory processes, for example safeguarding reviews. In such circumstances, co-operation and collaboration between different agencies is essential to reduce duplication and confusion. Ideally, only one investigation should be undertaken. Wherever possible, SIRI investigations should continue alongside criminal proceedings, Serious Case Reviews and Domestic Homicide Reviews.

## 6.5 Identifying Learning and Recognising Good Practice

- 6.5.1 The local team should identify learning and good practice at the time of the incident and through the 72 hour report. The local action plan (LAP) should be started at this stage, with SMART actions and any necessary actions put in place.
- 6.5.2 LAPs are the responsibility of the team/ward manager to develop and implement. Learning and good practice must be identified and fed back to the local team at key stages following an incident
- 6.5.3 The investigators should update the initial LAP as they investigate, feeding back to the local team at appropriate intervals. However the local team/ward manager maintains overall responsibility for the LAP.
- 6.5.4 Once the investigation has been completed, the LAP should be updated, and submitted with the draft SIRI report.
- 6.5.5 The investigators must meet with the local team once the SIRI report has been approved and feedback their findings.
- 6.5.6 All organisational and cross divisional learning and good practice will be agreed at the SIRI and Mortality Review Group and will be included on the organisational action plan, and shared through the divisional clinical governance process.  
In these circumstances the LAP may be shared by a number of teams.
- 6.5.7 Themes and trends arising from SIRI investigations will be identified by the SIRI and Mortality Review Group, and managed by the relevant Divisional Governance process.

## **7. TRUST SIGN-OFF**

7.1 The draft report will take a standard format as agreed with SCCG. The report format is available from [http://intranet.sompar.nhs.uk/a\\_-\\_z\\_directory/clinical\\_risk.aspx](http://intranet.sompar.nhs.uk/a_-_z_directory/clinical_risk.aspx).

7.2 The draft SIRI Report and LAP will be submitted to the SIRI Panel. Preliminary approval takes place once the SIRI Panel is satisfied that the investigation has considered the Terms of Reference and that all key questions have been answered. Additionally the SIRI Panel will ensure recommendations and action plans are appropriate. Relevant specialists may also be invited to comment at this time. The SIRI Panel may request further investigation and an amendment to the SIRI Report, or an additional piece of risk management work outside the remit of the report.

7.3 Once agreed by the SIRI Panel, the final draft SIRI Report will be submitted to SCCG.

7.4 The final draft SIRI report and LAP will be presented to the SIRI and Mortality Review Group at the next available meeting.

7.5 The SIRI Panel and Chief Executive will, on a weekly basis receive progress report on all current SIRIs investigations.

### **7.6 Submission to SCCG**

7.6.1 SIRI reports and LAPs must be submitted to SCCG once a final draft has been agreed by the SIRI panel. This should be within 60 working days of the incident being reported to them, unless an independent investigation is required, in which case the deadline is six months from the date the investigation commenced.

7.6.2 SCCG will close the SIRI on STEIS once:

- they receive the SIRI report, including lessons learned and an action plan
- the submission date, recommendations and learning (including identification of how learning is going to be disseminated) are updated on STEIS by the Risk team.

### **7.7 SIRI and Mortality Review Group**

7.7.1 The final draft SIRI report and LAP will be presented to the SIRI and Mortality Review Group at the next available meeting. The Investigator(s) and the local team/ward manager are required to attend and present the report and LAP, to discuss the learning and good practice.

7.7.2 The SIRI and Mortality Review Group will review and approve the action plan.



- 7.7.3 If any changes and/or additions are made to the final draft SIRI report by the SIRI and Mortality Review Group, an updated version of the SIRI report will be sent to SCCG.

## **8. REPORTING TO EXTERNAL AGENCIES**

- 8.1 The decision to report an incident/disclose information to the police should be made at a senior level, by the relevant operational Director or the Medical Director, in agreement with either the Director of Nursing and Patient Safety or the Director of Strategy and Corporate Affairs . The process of notification may be delegated to the Head of Corporate Business and in his/her absence the Head of Clinical Risk. Out of hours the decision to disclose information will be taken by the Executive Director On-Call.
- 8.2 The responsible Director will liaise with the Head of Clinical Risk, and where appropriate the Head of Safeguarding, to consider which of the following external agencies may need to be informed of the event, as appropriate (this is not an exhaustive list):
- Care Quality Commission (CQC) including Mental Health Act;
  - Police;
  - HM Coroner;
  - NHS Protect Counter Fraud Service;
  - Health and Safety Executive;
  - Home Office;
  - Information Commissioner
  - Local Safeguarding Children's Board (LSCB);
  - Medicines and Healthcare Products Regulatory Agency (MHRA);
  - National Confidential Inquiry of Suicide and Homicide of Mental Health Patients;
  - NHS Commissioning Board Special Health Authority;
  - NRLS;
  - NHS Litigation Authority (NHSLA);
  - Patient Advice and Liaison Officer;
  - Public Health Bodies;
  - Somerset Safeguarding Adults Board;
  - NHS Southwest, Strategic Health Authority (SHA);
  - Strategic Executive Information System (StEIS) (Appendix G);
  - Trust Legal Advisors;
  - Information Commissioners Office;
  - Specialist Commissioners for Low Secure Services.

## **9. TRAINING REQUIREMENTS**

- 9.1 Local Induction for all new staff must include awareness of:
- Risk Management Policy and Procedures;
  - Serious Incidents Requiring Investigation (SIRI) Policy and Procedures;
  - Untoward Event Report Policy and Procedures.
- 9.2 Root Cause Analysis Training will be provided by the SIRI Investigation Lead

or an external agency as required.

- 9.3 Preparation for attending inquests will be provided by the Head of Corporate Business.

## **10. EQUALITY IMPACT ASSESSMENT**

All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

## **11. COUNTER FRAUD**

The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

## **12. MONITORING COMPLIANCE AND EFFECTIVENESS**

- 12.1 The SIRI Panel and SIRI and Mortality Review group will ensure SIRI investigations are undertaken appropriately, and that LAPs and reports are written to the appropriate standard.
- 12.2 The SIRI and Mortality Review Group will review SIRI reports and approve LAPs. The group will also monitor trends in SIRIs and commission thematic reviews when indicated.
- 12.3 A monthly report of all Unexpected Deaths and SIRIs, including trends will be presented to the Trust Board and the Clinical Governance Group
- 12.4 The Divisional Governance Groups are responsible for monitoring the implementation of learning and sharing of best practice in their local areas, and feeding this back in their governance reports to the Clinical Governance Group.
- 12.5 This policy will be reviewed by the SIRI and Mortality Review Group on an annual basis and more frequently as required.

## 13. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

13.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)**, the fundamental standards which inform this procedural document, are set out in the following regulations:

Regulation 12:	Safe care and treatment
Regulation 13:	Safeguarding service users from abuse and improper treatment
Regulation 17:	Good governance
Regulation 20:	Duty of candour

13.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 11:	General
Regulation 16:	Notification of death of service user
Regulation 17:	Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
Regulation 18:	Notification of other incidents

13.3 Detailed guidance on meeting the requirements can be found at <http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf>

## 14. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

### 14.1 References

National Patient Safety Agency, 'Seven Steps to Patient Safety', 2004 – 2009. Available at <http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/>

Royal College of Surgeons (2014) Building a culture of candour: A review of the threshold for the duty of candour and of the incentives for care organisations to be candid. Available online <https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>

National Patient Safety Agency, 'Being Open: communicating patient safety incidents with patients, their families and carers', November 2009, available at: <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=83726>

Maria Dineen (2011) Six Steps to Root Cause Analysis (third edition) ISBN:978-0-9544328-2-9

NHS England (2014) Principles for managing quality in specialised commissioning (including RASCI template) available at: [https://nhs.uk/sharingpoint.com/TeamCentre/Operations/\\_layouts/15/WopiFrame.aspx?sourcedoc={1CAE2D20-BB4F-47A3-BFB6-3371A4D7AE6A}&file=Principles%20for%20managing%20quality%20in%20](https://nhs.uk/sharingpoint.com/TeamCentre/Operations/_layouts/15/WopiFrame.aspx?sourcedoc={1CAE2D20-BB4F-47A3-BFB6-3371A4D7AE6A}&file=Principles%20for%20managing%20quality%20in%20)

specialised%20commissioning%20including%20RASCI%20template.docx&action=default

NPSA, RCA toolkit, available at:

<https://report.nrls.nhs.uk/rcatoolkit/course/iindex.htm>

Work related deaths: A protocol for liaison (England and Wales). Available at: <http://www.hse.gov.uk/pubns/wrdp1.pdf>

Health and Social Care Information Centre guidance HSCIC Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (2015) Available at:

<https://www.igt.hscic.gov.uk>

/KnowledgeBaseNew/HSCIC%20SIRI%20Reporting%20and%20Checklist%20Guidance.pdf Counter Fraud and Security Management Service

Memorandum of Understanding: Investigating patient safety incidents involving unexpected death or serious untoward harm' published by the Department of Health in February 2006 – protocol for liaison and effective communications between the NHS, Association of Chief Police Officers and Health & Safety Executive.

National Patient Safety Agency (NPSA) National Reporting Learning System (NRLS)

National Framework for Reporting and Learning from Serious incident requiring Investigation 2010

NHS England (2015) Serious Incident Framework

NHS South West StEIS completion Guidance notes

NHSLA Risk Management Standards for Mental Health and Learning Disabilities January 2010

Patient Suicide; In what ways are professionals affected? Gina Bird. Somerset Partnership NHS and Social Care Trust. September 30th 2006

Somerset Clinical Commissioning Group (2015) Process for Reporting and Learning from Serious Incidents (SI)

#### 14.2 **Cross reference to other procedural documents**

Being Open and Duty of Candour Policy

Capability Policy

Claims Handling Policy and Procedure

Clinical Supervision Policy

Complaints, Concerns and Compliments Policy

Detained Patients Absent without Leave Policy (including Missing Persons Guidance)

Dignity at Work (Anti-Bullying and Harassment) Policy  
External Recommendation Policy  
Health and Safety Policy  
Incident Response Plan  
Induction Policy (Corporate and Local)  
Infections Prevention and Control Policy  
Information Governance Policy  
Lone Working Policy  
Medicines Policy  
Needlestick and Contamination Injury Policy (Blood-borne Viruses)  
Prevention and Management of Violence and Aggression (PMVA)  
Risk Management Policy  
Risk Management Strategy  
Safeguarding Adults at Risk Policy  
Security Policy  
Equality and Diversity Policy  
Staff Appraisal and Management Supervision Policy  
Untoward Event Reporting Policy  
Stress Management Policy  
Whistle-blowing Policy

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

## **15. APPENDICES**

Appendix A RACI Model  
Appendix B SIRI Procedure Flowchart  
Appendix C Levels of Investigation

### The RACI Model

The RACI model is a tool used for identifying roles and responsibilities and avoiding confusion over those roles and responsibilities. It can be useful to help determine which organisation should lead investigations into serious incidents, particularly when care is provided by multiple organisations.

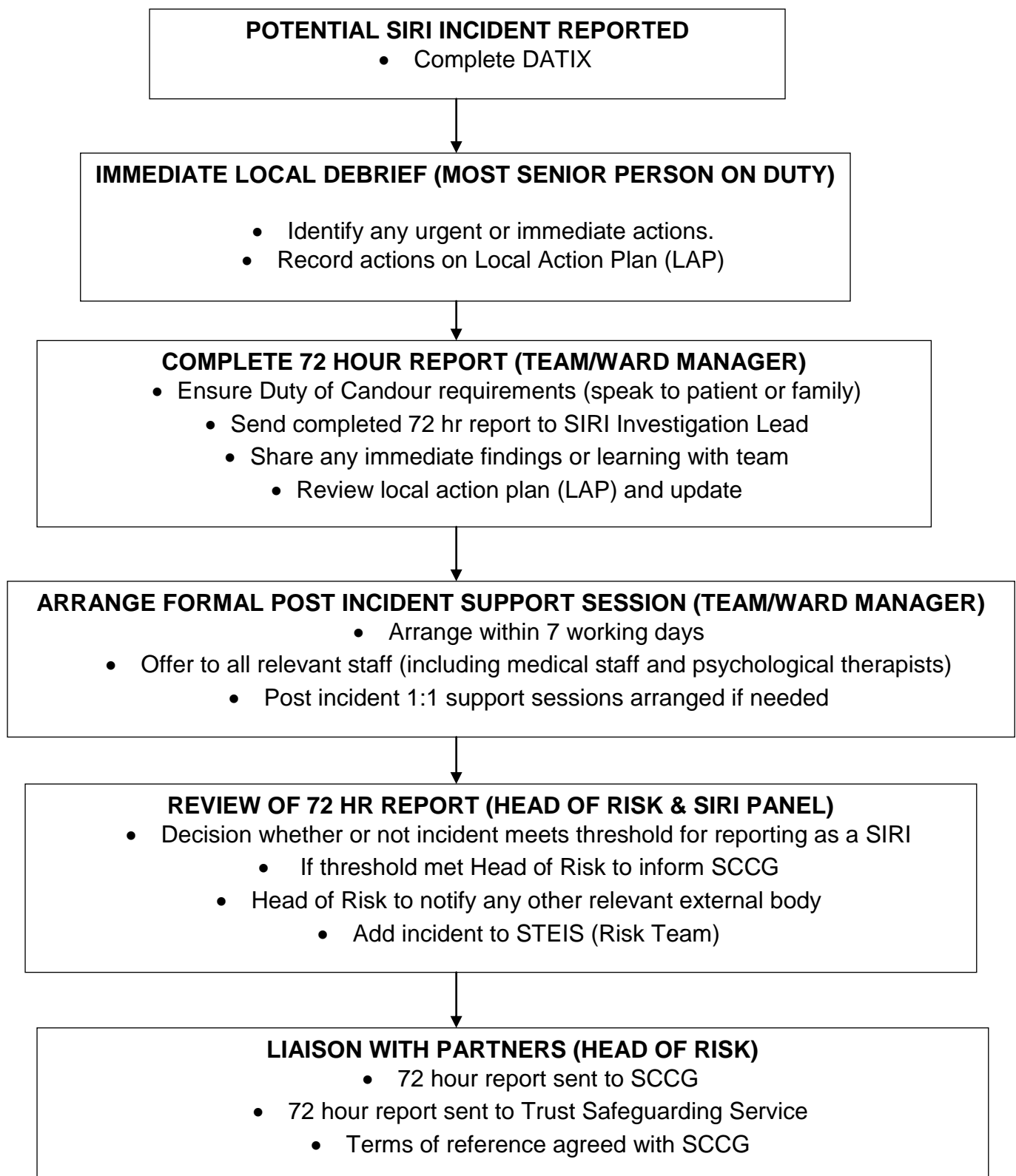
The acronym RACI stands for:

Responsible	The organisation/service that does the work to provide the care. They have responsibility for getting the work done or decisions made. As a rule this is one organisation/service;
Accountable	The organisation/service that is accountable for the correct and thorough completion of the care. This must be one organisation/service. This is the role that responsible is accountable to and approves their work.
Consulted	The organisations/services that provide specialist support for the patient. This may be several organisations/services, often subject matter experts.
Informed	The organisations/services kept informed of progress and with whom there is one-way communication. These are organisations/services that are affected by the patient's progress, so need to be kept up-to-date

Adapted from <https://www.projectsart.co.uk/raci-matrix.php>

## SIRI PROCEDURE FLOWCHART

## Immediate Actions Following a Serious Incident



## Investigating a Serious Incident

### INVESTIGATOR(S) IDENTIFIED BY HOD

#### INITIAL INVESTIGATION MEETING (LEAD SIRI INVESTIAGTOR/ INVESTIGATOR)

- Initial review of incident
- Discuss Terms of Reference
- Allocate responsibility within investigation team (if more than 1 investigator)

#### MULTI-DISCIPLINARY REVIEW MEETING (WARD/TEAM MANAGER) SIRI INVESTIGATOR, STAFF)

- Arrange a multi-disciplinary meeting within 14 working days of incident
- Attendance required by SIRI Investigator and staff Identify:
  - good practice
  - practice issues
  - contributory factors
  - root causes
  - lessons learned

#### INVESTIGATION UNDERTAKEN (SIRI INVESTIGATORS)

- Investigator review records
- Undertake discussion/interview
  - local team
  - patient/patient's family/carer
  - other relevant persons
- work with the local team to further develop the LAP as the investigation takes place

#### REVIEW PROGRESS WITH ACTION PLAN IN TEAM MEETINGS (TEAM/WARD MANAGER AND MDT)

- Provide a draft action plan for review by the SIRI Panel within 60 working days of incident



## Trust Sign-Off of SIRI Investigations

### SEND SIRI REPORT AND LAP TO SIRI INVESTIGATION LEAD (SIRI INVESTIGATOR)

- Within 60 days of incident

### REVIEW DRAFT SIRI REPORT AND LAP (SIRI PANEL AND RELEVANT HOD)

- Minimum of 4 members of SIRI panel quality check report and LAP
- (If care was provided by mental health team 2 panel members must be from mental health background)
- (If care was provided by physical health team 2 panel members must be from physical health background)
- Members of SIRI panel identify any further questions which need answering
- Members of SIRI panel provide feedback to SIRI Investigation Lead
- SIRI Investigation Lead collates feedback and liaises with Investigator
- Further amendment of SIRI report or LAP, if necessary

### FINAL DRAFT SIRI REPORT SENT TO SCCG (HEAD OF RISK)

### FINAL DRAFT SIRI REPORT AND LAP PRESENTED TO SIRI AND MORTALITY REVIEW GROUP (INVESTIGATOR AND TEAM/WARD MANAGER)

- SIRI group review
- SIRI group sign off final report and LAP

### FINAL SIRI REPORT AND LAP UPDATED SENT TO SCCG (HEAD OF RISK)

- Within 5 working days of SIRI and Mortality Group Meeting

### UPDATE STEIS (RISK TEAM)

- Within 5 working days of SIRI and Mortality Group Meeting

### FINAL SIRI REPORT AND LAP SHARED WITH TEAM/WARD MANAGER, STAFF, PATIENT/FAMILY/CARER, (SIRI INVESTIGATOR)

- Within 20 working days of SIRI and Mortality Group Meeting

## Levels of Investigation

## Appendix C

Level	Application	Product/ outcome	Owner	Timescale for completion
<p>Level 1</p> <p><b>Concise internal investigation</b></p>	<p>Suited to less complex incidents which can be managed by individuals or a small group at a local level</p>	<p>Concise / compact investigation report which includes the essentials of a credible investigation</p>	<p>Provider organisation (Trust Chief Executive / relevant deputy) in which the incident occurred, providing principles for objectivity are upheld</p>	<p>Internal investigations, whether concise or comprehensive must be completed within 60 working days of the incident being reported to the relevant commissioner</p>
<p>Level 2</p> <p><b>Comprehensive internal investigation</b></p> <p>(this includes those with an independent element or full independent investigations commissioned by the provider)</p>	<p>Suited to complex issues which should be managed by a multi-disciplinary team involving experts and / or specialist investigators where applicable</p>	<p>Comprehensive investigation report including all elements of credible investigation</p>	<p>Provider organisation (Trust Chief Executive / relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity</p>	<p>All internal investigation reports should be supported by a clear investigation action plan</p>
<p>Level 3</p> <p><b>Independent investigation</b></p>	<p>Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally due to the size of the organisation or the capacity / capability of the available individuals and / or number of organisations involved.</p> <p>This will be required for all mental health homicides.</p>	<p>Comprehensive investigation report including all elements of a credible investigation</p>	<p>The investigator and <b>all</b> members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated</p>	<p>6 months from the date the investigation is commissioned</p>

