THE STATE HOSPITALS BOARD FOR SCOTLAND

INCIDENT REPORTING AND REVIEW POLICY

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The most up to date version of all State Hospital policies, procedures and guidance can be found on the Hospital's Intranet policies page.

REVIEW SUMMARY SHEET

No changes required to policy (evidence base checked)	☐

Changes required to policy (evidence base checked)	☒

Summary of changes within policy:

2024 Review:

- Updated Team Based Quality Review (TBQR) Flowchart.
- Additional Information relating to the reporting of RIDDORs.
- Updates made to the hospital groups in line with current reporting structure.

CONTENTS

1 INTRODUCTION

The State Hospital (TSH) is committed to ensuring the health, safety and wellbeing of its staff, patients, volunteers and visitors by being proactive in it approach to prevent, reduce and control the number of adverse events and near misses. This includes the reporting of incidents which happen off-site whilst staff and patients are on hospital business.

The State Hospital promotes a fair and open culture and encourages the reporting of incidents and near misses from all employees, visitors and volunteers. The organisation's continuing commitment to a 'fair blame' culture will positively encourage the reporting of errors, incidents, accidents and near misses.

1.1 Definitions

The following list explains the terminology used in this policy for ease of reading:

What is an adverse event?

An adverse event is any event which causes unexpected or unintended harm, loss or damage. Adverse events can include errors, accidents, emergency situations, incidences of violence or aggression and equipment malfunctions. Local incidents may have implications for other healthcare services, and it is essential that all adverse events are reported.

Harm is defined as an outcome with a negative effect. Harm to a person or groups of people may result from an unexpected worsening of a medical condition, the inherent risk of an investigation or treatment, violence and aggression, a system failure, provider performance issues, service disruption, financial losses or adverse publicity.

What is a Critical Incident?

A critical incident is an adverse event which has a major impact on patient care, carer involvement, service provision and / or the State Hospital's reputation.

What is a Near Miss?

A 'near miss' is an error or mishap that has the potential to cause an adverse event but fails to do so due to chance or because it is intercepted. This can also be referred to as a potential adverse event.

Datix

Datix is a risk management software programme which is used at departmental level to electronically record all adverse events within the hospital. Any member of staff can use Datix to record an adverse event via the link on the hospital's intranet.

People

People are identified as:

- Service users / patients.
- Members of staff.
- Carers.
- Family members.
- Visitors / professional visitors.
- Volunteers.
- Contractors.

Groups of people include any functional grouping of individuals such as an organisation. In this way, adverse events that result in, for example, reputational or financial harm are included within the scope of this policy.

RIDDOR – Reporting of Injuries, Diseases and Dangerous Occurrences Regulations, 2013

RIDDOR regulation states that the organisation must report to the Health and Safety Executive (HSE) any major injury, dangerous occurrence or occupational disease. Records must be kept of any absence lasting over three days following an injury at work and absences lasting over seven days, following an injury / accident at work, must be reported to the HSE.

2 PURPOSE

The reporting of incidents and near misses ensures that all events, no matter how minor, are dealt with appropriately, effectively and within a supportive framework. It is the philosophy of the State Hospital that reporting needs to be responsive in order to facilitate effective risk management. By identifying and assessing problems, potential and ongoing, this will therefore minimise risks to patients, staff, volunteers and visitors.

This policy has been produced in accordance with NHS QIS Clinical Governance and Risk Management Standards, as part of the Risk Management Strategy. This forms the organisation-wide procedure for reporting incidents and near misses to be adopted by all areas within the State Hospital. This policy encompasses the legislative framework and duties to report under the requirements of other statutory bodies in Scotland. In addition, the policy incorporates the recommendations made by NHS Healthcare Improvement Scotland (HIS) following their updated national framework in December 2019: *Learning from adverse events through reporting and review.*

Failure to implement this policy will not only leave a significant gap in the organisation's Risk Management arrangements but may result in an additional cost burden through increased premiums to the Clinical Negligence and Other Risk Indemnities Insurance Scheme (CNORIS).

To ensure all potential risks are identified and controlled, staff should also report near misses. A key advantage of near miss identification is that preventative measures can be taken to minimise the likelihood and impact of any similar events occurring in the future, which may result in actual harm.

3 SCOPE

This incident reporting policy applies to all staff, patients, volunteers, visitors, contractors and all others who visit the State Hospital. This includes all adverse events, critical incidents and near misses as defined above.

The State Hospital strived to embed a positive safety culture and creating an environment that is open, just and informed, in which reporting and learning from error is the norm and promotes and supports the elements of safety culture in the table below.

Culture	Impact
Open culture	Staff feel comfortable discussing adverse events and raising safety issues with both colleagues and senior managers.
Just culture	Staff, patients, service users, their families and carers are treated fairly, with empathy and consideration when they have been involved in an adverse event or have raised a safety issue. Duty of candour procedures are followed, and organisations are open about adverse events, apologising to the affected person.
Reporting culture	Staff have confidence in the local adverse event reporting system and use it to notify managers of adverse events that are occurring, including near misses. Barriers to adverse event reporting have been identified and removed: • Staff are not blamed and punished when they report adverse events. • Staff receive constructive timely communication and feedback after submitting an adverse event report. • The reporting process is easy. • Staff will be directly involved in reviews.
Learning culture	The organisation: • Is committed to learning safety lessons. • Communicates learning outcomes to colleagues. • Remembers them over time. • Shares key learning points more widely.
Informed culture	The organisation has learned from past experience and has the ability to identify and mitigate future adverse events because it: • Learns from events that have already happened (for example, adverse event reviews). • Shares key learning points. • Undertakes trend analysis and develops appropriate action plans. • Uses learning from adverse events to promote a positive safety culture.

4 MANAGING AN ADVERSE EVENT

The circumstances surrounding each adverse event will vary in terms of:

- Levels of harm.
- Numbers of people involved.
- Risk exposure.
- Financial loss.
- Media interest.

- The need to involve other stakeholders.

Therefore, the response to each adverse event should be proportionate to its scale, scope, complexity and the opportunity for learning.

4.1 Six Stages of Adverse Event Management

1) Risk assessment and prevention.
2) Identification and immediate actions following an adverse event, including consideration of Duty of Candour.
3) Initial reporting and notification.
4) Assessment and categorisation, including consideration for Duty of Candour.
5) Review and analysis.
6) Improvement planning and monitoring.

5 RESPONSIBILITIES

5.1 Accountability

The Chief Executive of the State Hospitals Board is ultimately accountable to the Board for the effective management of risks within the hospital. This responsibility has been delegated to the Director of Security, Estates and Resilience. The Scheme of Delegation is included as part of the hospital's Standing Documentation and sets out how, in practice, this is delegated to others. This is to ensure that organisational arrangements are in place, to promote awareness and to provide guidance as and when required.

All risks are managed through the State Hospital's governance and management arrangements to ensure, as far as reasonably practicable, that the organisation:

- Provides and maintains for employees, patients, carers and volunteers and environment that is safe without risks to health and wellbeing.
- In the event of an incident, which causes injury or ill-health to our employees, patients, carers and volunteers or others to whom we owe a duty of care, they provide a suitable person to investigate the circumstances of the incident.
- Appoints a nominated Health & Safety / Risk Advisor on whom the duty falls to report and notify accidents, death or dangerous occurrences as required by the HSE.

5.2 Reporting Structure

Incident reporting and statistical analyses of adverse events are reported by the Risk and Resilience Department to: Service Leadership, Teams; Corporate Management Team; Security, Risk and Resilience and Health and Safety Group; Clinical Governance Committee and Staff Governance Committee. Reports are also prepared for Clinical Teams monthly as well as patient or topic-specific on an ad-hoc basis. An annual Risk and Resilience Report is also provided to the Audit Committee.

5.3 Responsibilities for All Staff (including those working out with the State Hospital on a contractual agreement)

Staff at all levels have the responsibility to:

- Report all incidents and near misses to their line manager as soon as is reasonably practicable and record on Datix in a timely manner.
- Participate in Risk Management education and training.
- Comply with organisation policies and procedures.

- Work in partnership in the identification and minimisation of risk by proactively participating in the investigation of adverse incidents / near misses.
- Assist in the initiation, development and implementation of solutions to minimise the recurrence of incidents / near misses.

5.4 Responsibilities for Line Managers (All Levels)

Line managers at all levels will:

- Ensure that all adverse incidents / near misses occurring in their area of control are reported on Datix, together with any other issues of concern.
- Review the circumstances to determine causes and, if necessary, carry out a review of existing procedures, training requirements, contingency plans and / or risk assessments.
- Alert the Risk and Resilience Department as soon as they become aware of an injury / illness resulting from a staff member carrying out their duties.
- Make recommendations where practicable and introduce measures to prevent a recurrence, in consultation with relevant staff (including external experts if appropriate) and the Risk and Resilience Department.
- Ensure corrective action is taken where appropriate, that findings are cascaded, and lessons learned are shared both internally and externally, as appropriate.

6 INCIDENT REPORTING

The State Hospital will capture information that covers adverse incidents and near misses on the electronic risk management system: Datix.

The key objective of reporting incidents and near misses is facilitate organisational learning and improvement. This is achieved by carefully reviewing what happened before, during and after the adverse event. Reviews should include what aspects of the event were managed well, as well as considering where changes to existing practice might be beneficial to avoid or reduce the impact of similar future events.

The purpose of an incident review is not to apportion blame and disciplinary action will not normally be taken as a result of incident reporting. However, exceptions must apply, for example, in the event of:

- Criminal activities, for example assault and theft.
- Acts of Gross Misconduct such as treating patients whilst under the influence of alcohol or illicit drugs.
- Malicious activities which may include malicious, reckless or criminal reporting of untrue allegations.
- Repeated unreported errors or repeated reported errors.
- Intentionally unsafe and repeated errors or not complying with hospital policies and procedures.
- Deliberate failure to report a critical incident.

In some cases, where a management investigation is necessary, it may also be desirable to review the incident for additional organisational learning. Disciplinary action will be conducted under the NHSScotland Workforce Conduct Policy and the Corporate Management Team will decide whether the incident review can run concurrently. Depending on the circumstances it may be necessary to delay the incident review process until after disciplinary action is concluded. Statements taken during either process may be shared with any commissioned review team.

N.B. Completion of a Datix entry does not constitute any admission of liability. It is merely used to gather all the facts, not opinions, relating to an incident so they can be analysed, lessons can be learned and, where appropriate, action taken to reduce the likelihood of a recurrence.

6.1 Additional Reporting Duties

In certain circumstances, there are additional local and statutory reporting duties. These are detailed in Appendix 2 and include:

- Injuries / Illness Reportable to the Health and Safety Executive (RIDDORs).
- Resilience / Emergency Planning Incidents.
- Incident Reporting and Investigation Centre (IRIC).
- The Medicines and Healthcare Products Regulatory Agency (MHRA).
- Reporting of Deaths (Suicides to HIS).
- Reporting Incidents of Fraud, Theft or Corruption.
- Reporting of Infectious Diseases.
- Mental Welfare Commission.
- Information Commissioners Office (ICO):

    - Personal Data Breaches - any incident involving a breach of personal data that are likely to have a high risk to the rights and freedoms of an individual must be promptly reported to the ICO. Contact the Data Protection Officer as soon as possible for guidance. Where an incident involves a breach of personal data that is likely to have a high risk to the rights and freedoms of an individual, TSH should inform the individual about the incident. Contact the Data Protection Officer as soon as possible for guidance.

- ASP / Child Protection.
- Ionising Radiation adverse events to the Warranted Inspector for IR(ME)R18.
- Serious crimes (homicides, serious assault, and serious sexual assault) by an individual who is receiving care from mental health or learning disability services to the Mental Welfare Commission for Scotland.

6.2 Reporting an Adverse Event or Near Miss

All adverse events must be reported using Datix. Staff most closely involved in the incident should complete an incident entry as soon as possible. The line manager may help with this if necessary. If it is not possible for the person(s) involved to complete this, it should be completed by the line manager with help from witnesses where required. In any case, the entry should be completed before the personnel involved go off shift and, at the most, **within 24 hours of the event**.

Self-reporting of incidents is not permitted where a person has been injured. In such cases, a witness or the injured person's line manager should complete the Datix entry.

It is important that all persons involved in the incident, whether directly or as a witness, are recorded in the Datix entry along with details of their involvement.

The entry should be completed and investigated as comprehensively as possible. When linking individuals to an incident report, formal names should be used, i.e.: those defined by payroll, RiO and not what the person is known by.

Witness reports and statements (Appendix 1) may be required for incidents which require further investigation and information. These should be appended to the Datix or submitted to the Risk and Resilience Department for inclusion within the Datix report. Witnesses should date and sign their statements and should retain a copy of their original statement. It is important that statements are formulated at an early stage to ensure accuracy.

Important: Information written on any entry must be factual, not opinions. Staff are reminded that any entries may be used in a court of law as evidence. Therefore, wilful misrepresentation of the facts may be construed as perverting the course of justice or perjury and incur court penalties. However, this does not supersede clinicians own professional judgement.

7 INCIDENT REVIEW

Incident reviews aim to establish the contributing factors of an incident, with a view to reducing the likelihood and / or impact of similar future events. It is important the level of review is proportionate to the severity of the incident.

There are two levels of review:

1) Local (standard) Review – Category 3 Review – local review will be undertaken for all incidents reported on Datix, this will be completed by the line manager or person responsible for the area where the incident occurred (e.g. a senior charge nurse for a ward incident) or by a nominated expert relevant to the issue in question (e.g. the Caldicott Guardian, Health & Safety Advisor etc).
2) Enhanced Review – following local review and grading of an incident further review may be necessary to establish the root cause of the incident and ensure organisational learning. Enhanced Review may take the form of either a Category 1 Review (previously known as a CIR) or a Category 2 Review (previously known as a Serious Untoward Incident).

Grading and local investigation of incidents requires to be undertaken within 7 days of the incident being reported via Datix.

The need for an enhanced review will be determined by the Corporate Management Team.

In addition to Local and Enhanced Reviews there is also the opportunity to undertake a Complex Case Review Morbidity and Mortality review through the Learning into Practice System. This would take place where an incident does not meet the criteria for an Enhanced Review however the Clinical Team / Management Team have agreed that an event, or series of events, would benefit from a review to provide professional learning.

7.1 Grading the Severity of an Adverse Event or Near Miss

Incidents will be assigned a risk grade based on the likelihood of an adverse event occurring and the impact should the risk be realised. This is in line with the Risk Matrix shown below (also available at Appendix 5):

Consequences / Impact

Likelihood	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

For example, if the consequence / impact of the incident happening is ‘moderate’ and the likelihood of it being repeated is ‘possible’ the risk will be assessed as being a Medium Risk.

All incidents will be assigned a risk grade as part of the line manager / supervisor’s review of the incident or near miss. This will also be recorded on Datix, along with details of the action taken and lessons learned.

Additional support and detailed guidance on the grading of incidents is available from the Risk and Resilience Department or from the hospital intranet. Members of the Risk and Resilience Department give final approval to all incidents submitted via Datix and are able to review the final grading and take appropriate action should the original grade be inappropriate.

The risk grading will be used to determine if further action or investigation is required to ensure that the risk is minimised appropriately across the organisation.

7.2 Enhanced Review – Category 1 (Category 1)

Category 1 (locally known as Major / Extreme impact) – Events that may have contributed to or resulted in permanent harm, for example death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHSScotland risk assessment matrix, or category G, H or I from NCC MERP index).

Terms of Reference for Category 1 reviews will be written by the commissioning Executive Director and agreed by the Corporate Management Team. Following agreement, the Risk and Resilience Department should be instructed to commission two reviewers (at least one of whom should have completed appropriate investigation training), and one of whom shall be appointed as lead reviewer. Consideration should also be given to the involvement of external experts where appropriate to ensure appropriate expertise and that a level of independence is maintained in the review.

Since January 2020, NHS boards in Scotland are required to report to HIS, the national dataset notification system in relation to Category 1 Significant Adverse Event Reviews. This notification should take place following agreement of Terms of Reference.

The lead reviewer should be in a position to commit at least six half-day sessions to the review process to increase the likelihood of the review being completed within the recommended timeframe. The Risk Manager will assist the Lead Reviewer with all aspects of the investigation in line with the terms of reference.

A member of the Risk and Resilience Department will facilitate the review including arranging interviews, minute taking and obtaining any relevant paperwork required.

The reviewers will draft their final report and present this to the Lead Director to ensure the report has sufficient detail to answer the Terms of Reference set. Following this agreement, the report will be redacted by a trained member of the Risk and Resilience Department, to protect individuals' privacy and confidentiality. The Clinical Team and / or appropriate persons will be presented with the report to check for factual accuracy.

The reviewers will then submit the final report with conclusions and recommendations to be agreed by the Corporate Management Team. The Corporate Management Team will allocate a Lead Director for each agreed action point and a timescale for completion. The report will then be presented in redacted format to the next available Corporate Management Team meeting.

The Risk and Resilience Department will monitor the progress of any completed or outstanding actions reporting to the Corporate Management Team and the Clinical Governance Committee. A monthly monitoring system will remind responsible officers of the outstanding actions and will escalate unresolved issues to the Chief Executives' office as required. An overview of Category 1 reviews will be included in the Clinical Governance Annual Report.

Should there be a delay for whatever reason in completing the Category 1 review beyond the 90-day target deadline detailed in Appendix 4 the Review Team should notify the Corporate Management Team explaining the reasons for the delay and outlining the timetable for completion of the review. The Commissioning Director may request an interim report at that point.

Appendix 4 details the timescale for completion of all incidents.

Although not an exhaustive list, the following incidents will result in a Category 1 Review:

- Death of a patient which is sudden or unexpected, or where suicide is the most likely cause.
- Homicide allegedly committed by a patient.
- Actual escape or absconding.
- Hostage taking or major disturbance involving a potential riot.
- Near fatal or serious near misses in acts of deliberate self-harm.
- Violence to others leading to permanent injury or disability, including those that may be reported to the police.
- Planned (near miss) escape, hostage taking etc.
- Discovery of possible serious exploitation of a patient or patients.

7.3 Enhanced Review – Category 2 (Category 2)

Category 2 (locally known as Minor / Moderate incidents) – Events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as minor or moderate impact on NHSScotland risk assessment matrix, or category E or F from NCC MERP index).

There will be occasions when a Category 1 review is not required however local investigation is not sufficient to ensure learning across the organisation and minimise the risk of the incident recurring. In these circumstances, an abridged version of the Category 1 Review process may be appropriate, and the Corporate Management Team will commission a Category 2 Review. This will be undertaken by the departmental manager or a member of the Risk and Resilience Department. The process of investigation will be shortened by:

- Reducing the number of interviews with staff and others involved in the incident to focus only on key personnel.
- Focussing on existing sources of evidence, such as reports and emails.
- Focussing on the incident timeline, short-term antecedents and immediate action taken.
- Producing a shorter report, focussing on the key facts and salient points relevant to that incident.

On presenting the facts of the incident, the Corporate Management Team will establish if:

- A Category 1 review is required.
- A management investigation is required.
- Learning has been identified which should be actioned / shared across the organisation.
- No further action is required.

N.B. On occasion, interviews may be recorded where a note taker is unavailable for Category 1 or 2 reviews. This information will be stored in accordance with Information Governance requirements.

7.4 Local (Standard) Review

Category 3 (locally known as near miss / no harm) – **Events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person iii) an error reached the person but did not result in harm (near misses)** (likely to be graded as category A, B, C or D from NCC MERP index). These results can occur either by timely intervention or due to good fortune.

High and Very High Risk

Identification of an incident / near miss which presents a High (Orange) Risk will require a local investigation to be carried out by the ward / department line manager within 7 days, liaising with the Risk and Resilience Department. Details of the investigation and action taken should be recorded on Datix. All local Investigation Reports should utilise appropriate methodology and produce an action plan aimed at eliminating or reducing the risk and preventing a recurrence.

Where statistical reports indicate a concern over a number of similar incidents then further investigation may be required. The Line Manager will be responsible for actioning this and should obtain specialist advice from the Risk and Resilience Department.

Enhanced Review may also be undertaken on request from the Clinical Team, Lead Nurse or RMO subject to approval of the Corporate Management Team, or if directly requested by the Corporate Management Team.

Medium Risk

Identification of an incident / near miss which presents a Medium (Yellow) Risk will require a local investigation to be carried out by the ward / department line manager within 7 days. Details of the investigation and action taken should be recorded on Datix.

Where statistical reports indicate a concern over a number of similar incidents then further investigation may be required. The Line Manager will be responsible to action this and may obtain specialist advice from the Risk and Resilience Department.

Low Risk

Where an incident has been scored as Green (Low) Risk, the completed incident entry should be sufficient to address most issues within this category. The investigation and action sections must be completed prior to submitting DIF2 to the Risk and Resilience Department. The Line Manager will be responsible for ensuring appropriate feedback to those involved in the incident.

Where statistical reports indicate a concern over a number of similar incidents then further investigation may be required. The Line Manager will be responsible to action this and may obtain specialist advice from the Risk and Resilience Department.

7.5 Learning into Practice System – Team Based Quality Review

TSH recognises the importance of all staff engaging in systematic approaches to learning and improvement with the aim of continuously enhancing the quality and safety of patient care and promoting staff wellbeing. All clinical staff are required to participate in processes of appraisal and continuing professional development (CPD) as outlined by professional regulators. The sustained delivery of excellent patient care requires a responsible, open, honest culture of practice where staff are valued and learning opportunities are paramount. The TSH Learning into Practice (LiP) system is a set of linked processes with the shared goal of engaging multidisciplinary staff in continuous learning and improvement based upon their clinical practice. It complements the range of other learning and CPD opportunities available to TSH staff, including the monthly TSH Seminar Series (formerly Journal Club).

The process is described in Appendix 8.

The aims of the LiP system are to:

- Contribute to the culture of quality, safety, learning and improvement within TSH.
- Maximise learning from practice for all staff.
- Support staff wellbeing.

- Identify and share good practice as well as areas for improvement.
- Provide a forum to support clinical teams in their management of complex cases.
- Support staff to meet their training and CPD requirements.

“Morbidity & Mortality” (M&M) style review

Most LiP meetings take the form of an M&M style review. An M&M review is a systematic approach traditionally used in surgical and medical departments that provides members of a clinical team with the opportunity for peer review of adverse events, complications or mortality to reflect, learn and improve patient care. Importantly, M&M reviews also provide the opportunity to focus on learning from normal everyday clinical work and good practice. In the context of TSH, the M&M style review provides clinical teams the opportunity for learning and improvement from everyday work via a process of peer review and discussion. At an M&M style LiP meeting, clinical teams present up to three clinical scenarios which they have identified as providing useful learning for the wider staff group.

Complex Case Review (CCR)

A CCR is an opportunity for a clinical team to host a detailed consideration of a case they have found particularly challenging to manage in TSH. There may have been an event, or series of events, that would benefit from review to provide professional learning. The presenting team can focus the discussion as they wish. CCRs are of most value when there is multidisciplinary involvement in the presentation and the discussion has a clear focus with the aim of tangible actions or outcomes that support the presenting team. The CCR process gives ownership to clinical teams and offers an opportunity to reflect on patient care, review practice against evidence or clinical guidance, carry out analysis of relevant data including any exploration of trends and share experiences of providing care. The option to hold a CCR at a LiP meeting can also be considered via TSH’s Incident Reporting and Review policy (RRO1) in response to a specific adverse event or incident. There may be occasions when TSH senior management request that a clinical team consider presenting a specific case or event that has been identified via incident reporting mechanisms (Datix) or another source. This is also an important mechanism for organisational learning and review. Patients with three or more violent incidents in any rolling six-month period will automatically be referred into the LiP system for consideration of further review by the LiP panel and clinical team.

7.6 Review Outcomes

a) **Appropriate care** - The adverse event review concluded that the care and / or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

b) **Indirect system of care issues** - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice points), however, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the patient notes, but these were unlikely to have affected the final outcome.

c) **Minor system of care issues** - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care / service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning points have been identified and improvement plans developed.

d) **Major system of care issues** - The adverse event review identified that a different plan and / or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.

7.7 RIDDOR

If an incident is suspected to meet the RIDDOR criteria described in Appendix 3 the following action should be taken as soon as reasonably possible:

- Datix report completed ensuring that all injuries sustained are noted on the Datix form and that the RIDDOR drop down is completed.
- Notification to the Risk and Resilience Team by email at tsh.riskmanagementteam@nhs.scot.
- Statements requested from injured person(s) and any witnesses.
- Fit note / hospital letter requested from staff when available.
- CCTV Reviewed where available by investigating manager.
- Thorough Datix (Category 3) investigation completed by investigating manager.
- Take any relevant action i.e. update Control Book risk assessments, contact estates for repairs, update operating procedures etc.

The above must be completed in the relevant timescales detailed in Appendix 3. The Risk and Resilience Team will collate the above information prior to reporting to the Health and Safety Executive. The Risk and Resilience Team can assist with any of the above points.

8 BEING OPEN

The Duty of Candour places a requirement on healthcare providers to be open with patients when things go wrong.

This policy is written taking cognisance of the publication ‘Learning from adverse events though reporting and review: A national framework for NHS Scotland and Being Open’.

The principles of being open include:

- Acknowledgement.
- Truthfulness, timeliness and clarity of communication.
- Apology.
- Recognising staff, patient, carer and volunteer expectations.
- Culture and professional support.
- Risk management and systems improvement.
- Multidisciplinary responsibility.
- Clinical governance.
- Confidentiality.
- Continuity of care.

It is recognised that engaging patients, carers and volunteers for the majority of our more serious incidents can be difficult. Patient’s RMOs should be asked whether they are well enough to be involved in the process (supported by the Patient Advocacy Service) and this should be documented within the report. Family and volunteer involvement should also be carefully considered.

The Duty of Candour Policy (RR06) should be reviewed where there is an issue over Duty of Candour.

9 PROVIDING FEEDBACK TO STAFF, PATIENTS, CARERS AND VOLUNTEERS INVOLVED IN AN INCIDENT

If staff disagree with the factual accuracy of the report, they should raise this immediately with the review's Lead Director.

Incident reporting and review supports learning and continuous improvement across the organisation. Following Corporate Management Team approval of Category 1 / 2 reports they will then be authorised for publication by the Caldicott Guardian and Chief Executive. This redaction is undertaken to ensure the protection of individual's privacy and confidentiality. It will also be used to ensure the organisation is not exposed to any additional risk with the release of information for example, security related. A copy of the redacted report will be published on the hospital intranet. This report will also be emailed to all staff interviewed. Discussion will take place with the Lead Director and RMO as to appropriate sharing with others for example, patients, carers, volunteers.

10 SHARING LEARNING WITH THE ORGANISATION

Redacted copies of reports will be made available on the hospital's intranet site within the Risk and Resilience section. Additionally, redacted reports are presented / highlighted where recommendations are made relevant to a particular governance committee.

Reports relating to incidents involving individual patients, carers and volunteers can be collated over specific timeframes to assist and inform Clinical Teams for care planning purposes.

Similarly, tailored reports can help inform service providers of learning outcomes from incidents which should assist in any review / redesign of their services e.g. pharmacy, security, infection control etc.

10.1 Redaction

Redaction is the process of censoring text on a document of a sensitive nature prior to publication. Category 1 and 2 reports may be redacted prior to publication on the State Hospital intranet to protect the confidentiality of those involved and the security of the hospital.

Information on what can be redacted is available in Appendix 6: Redaction Guidance and Appendix 7: Redaction Checklist, this is not an extensive list. The State Hospital provides training on the theory of what can be redacted as well as the technical aspect of the software, this training must be attended prior to redacting any Category 1 or Category 2 reports.

Once a document is redacted it must be sent to the Chief Executive and Caldicott Guardian for approval prior to publication.

11 EQUALITY AND DIVERSITY

The State Hospitals Board (the Board) is committed to valuing and supporting equality and diversity, ensuring patients, carers, volunteers and staff are treated with dignity and respect. Policy development incorporates consideration of the needs of all Protected Characteristic groups in relation to inclusivity, accessibility, equity of impact and attention to practice which may unintentionally cause prejudice and / or discrimination.

The Board recognises the need to ensure all stakeholders are supported to understand information about how services are delivered. Based on what is proportionate and reasonable, we can provide information / documents in alternative formats and are happy to discuss individual needs in this respect. If information is required in an alternative format, please contact the Risk and Resilience Team.

Line Managers are responsible for ensuring that staff can undertake their role, adhering to policies and procedures. Specialist advice is available to managers to ensure that reasonable adjustments are in place to enable staff to understand and comply with policies and procedures. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

Patient pre-admission assessment processes and ongoing review of individual care and treatment plans support a tailored approach to meeting the needs of patients who experience barriers to communication (e.g. Dementia, Autism, Intellectual Disability, sensory impairment). Rapid access to interpretation / translation services enables an inclusive approach to engage patients for whom English is not their first language. Admission processes include assessment of physical disability with access to local services to support implementation of reasonable adjustments. Patients are encouraged to disclose their faith / religion / beliefs, highlighting any adapted practice required to support individual need in this respect. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy.

Carers / Named Persons are encouraged to highlight any barriers to communication, physical disability or anything else which would prevent them from being meaningfully involved in the patient's care (where the patient has consented) and / or other aspects of the work of the Hospital relevant to their role. The EQIA considers the Protected Characteristic groups and highlights any potential inequalities in relation to the content of this policy".

12 STAKEHOLDER ENGAGEMENT

Key Stakeholders	Consulted (Y / N)
Patients	Y
Staff	Y
Carers	N
Volunteers	N

13 COMMUNICATION, IMPLEMENTATION, MONITORING AND REVIEW OF POLICY

This policy will be communicated to all stakeholders within the State Hospital via the intranet and through the staff bulletin. The Person Centred Improvement Service will facilitate communication with Patients.

The Security and Resilience Group will be responsible for the implementation and monitoring of this policy.

Any deviation from policy should be notified directly to the policy Lead Author. The Lead Author will be responsible for notifying the Advisory Group of the occurrence.

This policy will be reviewed every three years or sooner if required.

APPENDIX 1: WITNESS STATEMENT FORM

Please complete form in BLOCK CAPITALS

Name ……..

Designation …….

Address ……..……..

…….

Ward / Dept. …… Extension ……..

Date of Incident ……. Datix Ref…..……

Exact Location of Incident…….

Details of Incident (Describe to the best of your knowledge what happened just before, during and after the incident in question)

Continue overleaf if necessary

Signed…… Date……

Send copy of witness statement to Risk and Resilience Department

APPENDIX 2: ADDITIONAL REPORTING FOLLOWING AN ADVERSE INCIDENT OR NEAR MISS

Reporting to the Health & Safety Executive (see Appendix 3)

If the incident is RIDDOR reportable, under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013) (RIDDOR), i.e. a major injury, dangerous occurrence, over seven day absence following an incident / accident at work or occupational disease, then the Risk and Resilience Department should be contacted as soon as is reasonably practicable after the incident has occurred, to allow them to report the incident to the Health and Safety Executive. The Health and Safety / Risk Advisor or other appropriate senior manager will investigate RIDDOR incidents in line with the category of risk.

Resilience / Emergency Planning Incidents

The Resilience Framework and supporting plans allow the hospital to respond to an interruption or emergency without adversely affecting the level of care provided to patients as well as maintaining a safe environment. These incidents should be recorded through Datix with reference to the Framework for guidance on steps to be taken if an incident occurs (i.e. site wide power failure).

Reporting Equipment Failure

For incidents involving medical devices / equipment (including nebulizers), the Estates Department must be informed immediately via Extension 2100, Estates hotline or as soon as possible if the incident occurs out with normal working hours. This is to make sure that the equipment is withdrawn from use. This incident must also be recorded in Datix. The Estates department will take relevant action and if appropriate pass the equipment to Medical Physics for further investigation.

NHSScotland staff have a responsibility to report adverse incidents involving health, social care, estates and facilities equipment as instructed in CEL 43 (2009) (pdf).

Information Technology Incidents

Any incidents or breaches of Information Technology Security will be investigated in accordance with the Information and Network Security Policy (IG08). Other IT incidents may be subject to investigation as directed by the IT Services Manager, for example offensive email (internally or outbound), downloading inappropriate material from the internet, failure to encrypt confidential information during transit, infection with a virus etc.

Reporting of Deaths under Medical Care / Medical Mishap

All deaths must be recorded through Datix. Patient deaths in the State Hospital will be subject to enhanced incident review. The Death of Patient / Palliative and End of Life Care (incl Sudden Death) Policy) (CP49) explains what action has to be taken in relation to reporting a Death of a Patient.

Reporting Incidents of Fraud, Theft or Corruption

Any cases of fraud, theft or corruption should be reported to the Director of Finance and eHealth who will investigate in line with the hospital's Theft, Fraud, & Other Financial Irregularities Policy & Response Plan (QP20).

Reporting of Notifiable Diseases

Under the Public Health (Notification of Infectious Diseases (Scotland) Regulations, 1988, medical practitioners are required to notify the Director of Public Health of the local Health Board of any patient they believe to be suffering from any of the notifiable infectious diseases.

APPENDIX 3: REPORTING OF INCIDENTS DISEASES AND DANGEROUS OCCURRENCES REGULATIONS, 2013. (RIDDOR)

RIDDOR is the law that requires employers, and other people in control of work premises, to report and keep records of:

- Work-related accidents which cause death.
- Work-related accidents which cause certain serious injuries (reportable injuries).
- Diagnosed cases of certain industrial diseases.
- Certain 'dangerous occurrences' (incidents with the potential to cause harm).

There are also special requirements for gas incidents.

The duty to report applies not only in the case of accidents to employees, but also to visitors, customers and members of the public killed or injured by work activities.

TYPES OF 'REPORTABLE' INJURY WHICH MUST BE REPORTED IMMEDIATELY TO THE HEALTH & SAFETY EXECUTIVE (HSE)

Deaths

All deaths to workers and non-workers must be reported if they arise from a work-related accident, including an act of physical violence to a worker. Such incidents must be notified immediately to the Health & Safety Executive and the Health & Safety Department.

Specified injuries to workers

The list of 'specified injuries' in RIDDOR 2013 (regulation 4) includes:

- A fracture, other than to fingers, thumbs and toes.
- Amputation of an arm, hand, finger, thumb, leg, foot or toe.
- Permanent loss of sight or reduction of sight.
- Crush injuries leading to internal organ damage.
- Serious burns (covering more than 10% of the body, or damaging the eyes, respiratory system or other vital organs).
- Scalping (separation of skin from the head) which require hospital treatment; unconsciousness caused by head injury or asphyxia.
- Any other injury arising from working in an enclosed space, which leads to hypothermia, heat-induced illness or requires resuscitation or admittance to hospital for more than 24 hours.

Over-seven-day injuries to workers

This is where an employee, or self-employed person, is away from work or unable to perform their normal work duties for more than seven consecutive days (not counting the day of the accident).

Reportable dangerous occurrences

Dangerous occurrences are certain, specified 'near-miss' events (incidents with the potential to cause harm.) Not all such events require reporting. There are 27 categories of dangerous occurrences that are relevant to most workplaces. For example:

- The collapse, overturning or failure of load-bearing parts of lifts and lifting equipment; plant or equipment coming into contact with overhead power lines; explosions or fires causing work to be stopped for more than 24 hours.

The Risk and Resilience Department must be advised if a dangerous occurrence is apparent.

Reportable occupational diseases

Employers must send a report to the HSE of diagnoses of certain occupational diseases, where these are likely to have been caused or made worse by their work. These diseases include (regulations 8 & 9):

- Carpal tunnel syndrome.
- Severe cramp of the hand or forearm.
- Occupational dermatitis.
- Hand-arm vibration syndrome.
- Occupational asthma.
- Tendonitis or tenosynovitis of the hand or forearm.
- Any occupational cancer.
- Any disease attributed to an occupational exposure to a biological agent.

Reporting

A **F2508** accident form must be completed and submitted to the HSE as soon as practicable and in any event **within 10 days of the accident.**

The reports will be made by the Health & Safety Advisor or their nominated deputy, on receipt of the Datix entry.

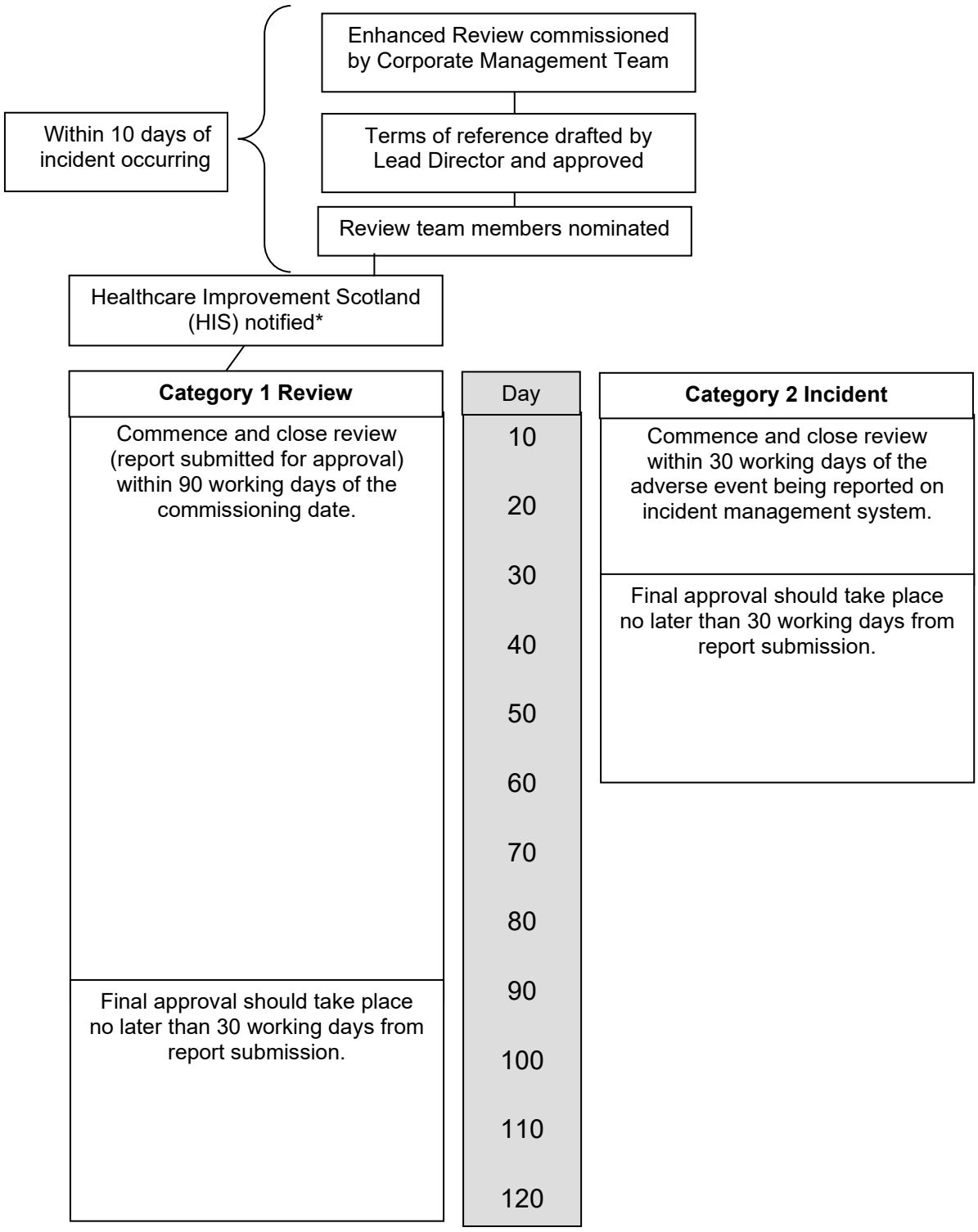
It is essential that the Datix entry is completed and as soon as possible, as late reporting is an offence. This form will be authorised by the Head of Risk and Resilience in the event of absence of the Health & Safety Advisor.

Recording requirements

- Investigate the incident.
- Retain records for the last three years from the date of the report.
- Reportable disease.
- On receipt of medical certificate from Doctor, that an employee had contracted reportable work-related disease, the Line Manager / Supervisor should refer the matter to the Health & Safety Advisers / and or Occupational Health, who can confirm if the disease is reportable and complete the report to the HSE.
- Wards and Departments should retain the records for at least three years from the date of the report at the place of work where the incident occurred or at the normal workplace of the responsible person for at least three years from the date of report. Copies of Datix information will be retained centrally on Datix.

For detailed guidance on RIDDOR Regulations see the HSE website.

APPENDIX 4: ENHANCED REVIEW PROCESS TIMELINE



Where timescales cannot be met, for whatever reason, regular updates will be provided to the individuals involved in the incident to keep them informed of progress.

*contact responsible for TSH→HIS notification would be the Head of Risk and Resilience

APPENDIX 5: NHS SCOTLAND RISK MATRIX AND DEFINITIONS

Table 1 – Impact / Consequence Definitions

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience / clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience / clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience / clinical outcome; short term effects – expect recovery <one week.	Unsatisfactory patient experience / clinical outcome; long term effects – expect recovery >one week.	Unsatisfactory patient experience / clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient / visitor / staff.	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and / or counselling.	Major injuries / long term incapacity or disability (loss of limb) requiring medical treatment and / or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim Complex justified complaint
Service / Business Interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service.	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility. Disruption to facility leading to significant “knock on” effect

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Staffing and Competence	Short term low staffing level temporarily reduces service quality (<one day). Short term low staffing level (>one day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. **Minor error** due to ineffective training / implementation of training.	Late delivery of key objective / service due to lack of staff. **Moderate error** due to ineffective training / implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective / service due to lack of staff. **Major error** due to ineffective training / implementation of training.	Non-delivery of key objective / service due to lack of staff. Loss of key staff. **Critical** error due to ineffective training / implementation of training.
Financial (including damage / loss / fraud)	Negligible organisational / personal financial loss. (£<1k). (**NB.** Please adjust for context)	Minor organisational / personal financial loss (£1-10k).	Significant organisational / personal financial loss (£10-100k).	Major organisational / personal financial loss (£100k-1m).	Severe organisational / personal financial loss (£>1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale / public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media / adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	National / international media / adverse publicity, more than three days. MSP / MP concern (Questions in Parliament). Court Enforcement. Public Inquiry / FAI.

Table 2 – Likelihood Definitions

Descriptor	Rare (1 x in 1000)	Unlikely (1 x in 100)	Possible (1 x in 20)	Likely (1 x a week)	Almost Certain (1 x every day)
Probability	Can't believe this event would happen – will only happen in exceptional circumstances.	Not expected to happen, but definite potential exists – unlikely to occur.	May occur occasionally, has happened before on occasions – reasonable chance of occurring.	Strong possibility that this could occur – likely to occur.	This is expected to occur frequently / in most circumstances – more likely to occur than not.

Table 3 – Risk Matrix - Impact / Consequences

Likelihood	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	**Medium**	**High**	**High**	**V High**	**V High**
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High

APPENDIX 6: REDACTION GUIDANCE

Subject Access Administrative Redaction Guidance (SA02). Redaction Information can only be redacted or withheld if:

1) **3rd Party Information**

   The information relates to another identifiable, living person. If the 3rd party has consented to disclosure, then the information should not be withheld. If it is reasonable in all cases to disclose the information without consent, then the information should not be withheld. Information identifying professionals carrying out their duties such as doctors, social workers, etc. should NOT normally be withheld.

2) **Duty of Confidence**

   The information was given with an expectation of professional confidence similar to a Counsellor and Client. If the information is widely available, then the duty of confidence does not apply. Information marked 'Confidential' does not automatically mean it should be withheld, it still requires to meet the confidentiality test.

3) **Crime and Taxation**

   The information relates to an ongoing criminal investigation, or an ongoing prosecution, or an ongoing taxation investigation. The information withheld must be likely to prejudice the investigation or prosecution.

4) **Management Information**

   The information relates to management information that would prejudice the conduct of business. E.g. If the hospital had notes regarding relocating a patient that if disclosed could cause unrest. This information may be withheld.

5) **Negotiations with the Requestor**

   The information relates to an ongoing negotiation with the data subject. E.g. If a patient was claiming compensation for an injury, then information relating to the Hospital's negotiating position may be withheld.

6) **Confidentiality in Communications**

   The information consists of information for which legal professional privilege could be claimed.

7) **The State Hospital is not the Data Controller**

   The information is the responsibility of another organisation. This does not include Social Work information.

For each redaction made, a record of the reason for redaction must be given.

APPENDIX 7: REDACTION CHECKLIST

Items to redact	Examples	Notes	Likely exemption
All patient Identifiers.	Names, CHI, Age, sex, gender, address, etc (he / she, male / female)	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
All dates relating to the adverse incident	01 / 01 / 2024	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
All patient medical history, direct quotes from medical records	-	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
All patient relationship terms	Husband, wife, carer, son, etc	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
All staff names (not author or investigator)	-	-	FOI S38(1)(b) – Personal Information
All unique staff roles (not author or investigator)	-	-	FOI S38(1)(b) – Personal Information
All staff identifies and personal details (start / end dates, sickness absence)	-	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
Hospital area identifiers (ward, clinic, therapy area)	University Hospital Wishaw, Arran 1, Skye Centre	-	FOI S38(1)(b) – Personal Information (jigsaw identification)
All information that may compromise site operations.	-	-	FOI S03(1)(b) or (c) – Prejudice to effective conduct of public affairs

APPENDIX 8: TEAM BASED QUALITY REVIEW (TBQR) FLOWCHART