<table>
<thead>
<tr>
<th>Policy Name:</th>
<th>INCIDENT REPORTING AND INVESTIGATION POLICY REPORTING AND INVESTIGATION OF INCIDENTS (NEAR MISS, ADVERSE EVENTS AND SERIOUS UNTOWARD INCIDENTS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Reference:</td>
<td>TW10/020</td>
</tr>
<tr>
<td>Version number :</td>
<td>9</td>
</tr>
<tr>
<td>Date this version approved:</td>
<td>APRIL 2011</td>
</tr>
<tr>
<td>Approving committee:</td>
<td>RISK &amp; ENVIRONMENTAL MANAGEMENT COMMITTEE</td>
</tr>
<tr>
<td>Author(s) (job title):</td>
<td>PATIENT SAFETY MANAGER &amp; HEALTH AND SAFETY MANAGER</td>
</tr>
<tr>
<td>Division/Directorate:</td>
<td>CORPORATE</td>
</tr>
<tr>
<td>Trust Wide Policy (Yes/No):</td>
<td>YES</td>
</tr>
<tr>
<td>Links to other Strategies, Policies, SOP's, etc.:</td>
<td>TW10/002 RISK MANAGEMENT STRATEGY, TW10/023 INVESTIGATION OF INCIDENTS, COMPLAINTS &amp; CLAIMS POLICY &amp; PROCEDURE, TW10/024 ANALYSIS OF, AND LEARNING FROM, INCIDENTS, COMPLAINTS &amp; CLAIMS POLICY, TW10/054 BEING OPEN POLICY</td>
</tr>
<tr>
<td>Date(s) previous version(s) approved: (if known)</td>
<td>Version: 8, Date: December 2008</td>
</tr>
<tr>
<td>DATE OF NEXT REVIEW:</td>
<td>MARCH 2013</td>
</tr>
<tr>
<td>Manager responsible for review:</td>
<td>Head of Quality &amp; Safety</td>
</tr>
</tbody>
</table>
## CONTENTS:

**Introduction** 2

1. **Policy Statement** 2

2. **Key Principles** 2

3. **Incident Type Definitions** 2

4. **Responsibilities** 4
   - 4.1 Statutory 4
   - 4.2 Mandatory 4
   - 4.3 Organisational 4

5. **Reporting procedure for Near Miss, Adverse Events and Serious Untoward Incidents** 8

6. **Investigation Procedure for Near Miss, Adverse Events and Serious Untoward Incidents** 9
   - 6.1 Investigation of Adverse Events and Near Misses 9
   - 6.2 Investigation of Serious Untoward Incidents 11

7. **External Agency Reporting Arrangements** 12
   - 7.1 Monitor 12
   - 7.2 Care Quality Commission 12
   - 7.3 Strategic Health Authority (SHA) Serious Untoward Incidents 12
   - 7.4 National Reporting and Learning System (NRLS) 12
   - 7.5 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) 13
   - 7.6 Medical Devices and Healthcare Products Regulatory Agency (MHRA)
     - 7.6.1 Medical Devices / Equipment 14
     - 7.6.2 Medication Incidents 14
     - 7.6.3 Blood Transfusion Incidents 14
   - 7.7 The Coroner 14

8. **Human Rights Act** 15

9. **Equality and Diversity** 15

10. **Monitoring and Review** 15

11. **Accessibility Statement** 16

APPENDIX 1 References, Further Information and Useful Websites 17

APPENDIX 2 Related Policies and Procedures 18

APPENDIX 3 Information Governance 19

APPENDIX 4 Glossary of Terms 20

APPENDIX 5 Equality Impact Assessment Form 20
INTRODUCTION:

Reporting an incident or a near miss is an integral part of personal, clinical and corporate governance. The aim of reporting incidents is to identify systems and processes which could be improved to promote safety and reduce all types of risk within the organisation, not to apportion blame to individuals and teams.

1. POLICY STATEMENT

Wrightington, Wigan and Leigh NHS Foundation Trust is committed to a programme of effective risk management. This policy supports the Trust’s Risk Management Strategy and Policy and explains the system to be used by staff for recording, reporting, escalating and investigating incidents both internally and to external agencies.

2. KEY PRINCIPLES

2.1 The aim of this policy for the recording, reporting, escalation and investigation of incidents is to enable the Trust to:

- Protect the safety and well being of patients, staff and visitors;
- Collect information about events involving patients, staff and visitors and the operation of the organisation;
- Ensure a systematic and fair approach to the recording, reporting, escalation and investigation of incidents;
- Learn lessons from reported incidents and identify areas for improvement to reduce the likelihood of such incidents recurring;
- Comply with legislation and external agency reporting requirements.

2.2 The principles of this policy apply equally to clinical and non-clinical incidents (see Section 3 below, ‘Incident Type Definitions’)

This policy does not concern the disciplining of Trust employees; however, staff do need to be aware and understand that there may be clearly defined situations where further action, including disciplinary action, will need to be taken, e.g. where there is evidence of a breach of law, or professional misconduct or malicious intent.

3. INCIDENT TYPE DEFINITIONS

An incident, leading to a near miss, adverse event or serious untoward incident, is an unplanned, uncontrolled or undesirable event which has led to, or could give rise to, injury / ill health, damage to plant, machinery or the environment and/or some other loss.

Various terms are commonly used to refer to different kinds of incidents. To provide consistency within the Trust, the following definitions have been adopted:

AT ALL TIMES STAFF MUST TREAT EVERY INDIVIDUAL WITH RESPECT AND UPHOLD THEIR RIGHT TO PRIVACY AND DIGNITY.
3.1 Clinical Incidents

A patient safety or clinical incident is any event or circumstance during NHS care that could have or did, lead to unintended or unexpected harm, loss or damage to patients.

*e.g. patient falls*

3.2 Non-Clinical Incidents

A staff or organisational incident is any event or circumstance connected with Trust work and business that could have, or did lead to, unintended or unexpected harm, loss or damage to staff, visitors, contractors or the services provided by the Trust.

*e.g. needlestick injuries*

3.3 Near Miss Incident

An incident leading to a *near miss* is an unplanned event that did not result in injury, illness, or damage - but had the potential to do so. Only a fortunate break in the chain of events prevented an injury, fatality or damage. Examples include:

**Clinical near miss:**
- Medicines prescribing error identified before a drug is administered.

**Non-clinical near miss:**
- Inadequate lighting levels leading to the potential for a slip trip or fall identified and corrected before this happens.

**Clinical and/or non-clinical near miss:**
- Faulty / dangerous equipment / devices (medical and non-medical) identified during routine checking.

3.4 Adverse Event Incident

An incident leading to an *adverse event* can be described as a situation where something untoward has happened, but without serious consequence, although minor injury, harm or loss (including loss of service, theft / vandalism of; e.g. equipment, premises etc.) may have been sustained. Examples include:

**Clinical adverse event:**
- Medication given in error; wrong route, wrong dose, wrong frequency of medication;
- Patient slips, trips and falls;

**Non-clinical adverse event:**
- Injuries as a result of manual handling activities;
- Staff, visitors, contractor etc. slips, trips and falls;
- Violence and aggression towards staff etc.;

**Clinical and/or non-clinical adverse event:**
- Administration of oxygen whilst patient has petroleum jelly on their lips,
- Medical devices / non-medical equipment not fit for purpose leading to injury / harm.

3.5 Serious Untoward Incident (SUI)

The principal definition of a serious untoward incident (SUI) is any incident on Trust premises which has:
- Resulted in serious injury or death (this includes deaths from suspected suicide/suicide or homicide) or was life-threatening or led to permanent long term harm;
- Contributed to a pattern of reduced standard of care;
- Involved a hazard to public health;
• Involved the absconding of a patient detained under the Mental Health Act, 1983/2007 and/or where a patient poses a significant risk to themselves or others;
• Caused serious disruption/damage to services/assets (including significant IT/telecoms/plant failure etc.);
• Involved fraud or suspected fraud;
• Major breaches of confidentiality such as the loss or theft of personal identifiable records or information;
• Hospital acquired grade 3 or 4 pressure sores;
• Security threat resulting in major contingency plans being invoked;
• Involvement of external investigation agencies (Police, HSE, CQC, MHRA,).
• Involved significant health care associated infections e.g. outbreaks, unit/ward closures or public health issue, especially if they require the involvement of the Health Protection Agency.

4. RESPONSIBILITIES

4.1 Statutory and Mandatory Responsibilities

The Trust has Statutory and Mandatory responsibilities to report some incidents to external agencies:

Statutory Responsibilities
- Health and Social Care Act, 2008
- Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995

Mandatory Responsibilities
- Care Quality Commission (CQC)
- Monitor
- National Reporting and Learning Service (NRLS)
- Strategic Health Authority (SHA)
- Police
- Coroner
- Medical Devices and Healthcare Products Regulatory Agency (MHRA)
- North West Medical Physics
- Information Governance Commissioner
- Local Authorities
- Safe Guarding Agencies
- Serious Hazards of Transfusion (SHOT)

4.2 Organisational Responsibilities

4.2.1 The Trust Board

The Trust Board will:

Receive a formal quarterly report on all of the incidents reported via the incident reporting system and can delegate authority for any further investigation, action or monitoring function to an appropriate Board Sub Committee:

Seek assurance that incidents are appropriately recorded, reported, escalated and investigated via the following Committee and/or Groups:

- Governance and Risk Committee
- Quality Improvement Committee
- Risk and Environmental Management Committee
Through the line management structure, ensure that this policy and associated procedures are applied within their areas of responsibility and promote a positive incident reporting culture throughout the Trust.

4.2.2 The Chief Executive

The overall responsibility for effective governance and risk management lies with the Chief Executive.

The Chief Executive will:

- Ensure that a suitable and effective incident reporting system is in place within the Trust to allow employees to record, report, escalate and investigate incidents as they occur;
- Seek assurance that this policy and associated procedures are embedded within the organisation.
- Seek assurance that incidents are appropriately recorded, reported, escalated and investigated in line with this policy and associated procedures.

The Chief Executive has entrusted to the Deputy Chief Executive/Director of Nursing and Performance, DIPC and the Medical Director the responsibility for ensuring there is an integrated system for the recording, reporting, escalation and investigation of incidents.

4.2.3 Deputy Chief Executive/Director of Nursing & Performance, DIPC and the Medical Director

The Deputy Chief Executive/Director of Nursing and Performance, DIPC and the Medical Director are the appointed Executive Leads for safety within the Trust and will:

- Appraise the Chief Executive and Trust Board of any issues or concerns arising from all reported incidents;
- Ensure that an appropriate structure and system is in place for the recording, reporting escalation and investigation of all incidents and for appropriate staff support following an incident;
- Seek assurance that incidents are appropriately escalated through internal channels and that external reporting requirements have been adhered to where necessary;
- In the event of an actual or potential Serious Untoward Incident (SUI) determine membership for an Initial Review Meeting (IRM), appoint a competent Root Cause Analysis (RCA) investigator and formally sign off completed Root Cause Analysis reports when the investigation and associated Action Plan is complete.

4.2.4 Head of Quality and Safety

The Head of Quality and Safety is responsible for advising on and co-ordinating risk management activities within the trust. Supported by the Patient and Staff Safety Team the Head of Quality and Safety will:

- Ensure that an appropriate structure and system is in place for the operation and administration of the trust’s chosen incident reporting system – Datix web
- Ensure that an appropriate structure and system is in place for the recording, reporting escalation and investigation of all incidents;
• Ensure appropriate reports on all reported incidents are produced from the Datix Risk Management System by the appropriate person and that these are presented at the appropriate committee(s) / board;
• Appraise the Deputy Chief Executive/Director of Nursing and Performance, DIPC and the Medical Director of any reported incidents giving cause for concern which have been escalated by Divisions/Directorates, individuals and/or the Patient and Staff Safety Team;
• In the event of an actual or potential serious untoward incident (SUI), will attend the Initial Review Meeting (IRM) or nominate a suitable representative;
• Notify the Patient and Staff Safety Team of the outcome of the Initial Review Meeting.

4.2.5 Patient and Staff Safety Team (PSST)

The Patient and Staff Safety Team comprise of the Patient Safety Manager and Health and Safety Manager and their respective teams, who will:

• Administer and maintain the Datixweb Incident Reporting system;
• Liaise and work with the Divisional Governance Leads to develop their local arrangements for reporting, management and investigation of incidents using Datixweb;
• Provide training to identified divisional and directorate Datix web leads on the use of the system and the recording, reporting, escalation and investigation of all incidents;
• Advise and guide staff in the completion of Datixweb incident reports;
• Complete initial quality and accuracy check of all incidents submitted via Datix web on a daily basis (Monday to Friday 9am to 5pm) and make any necessary corrections required so that the right person has access to the right form containing all the correct basic details;
• Following completion of the initial quality and accuracy checks, change the reported incident status to ‘Still being reviewed, not yet sent for final approval’;
• Access the Datixweb incident reporting system to identify incidents that may require internal and/or external escalation, reporting and/or investigation;
• Ensure all statutory and recommended reporting procedures are undertaken;
• Provide regular reports to the Trust Board, Occupational Safety and Health Committee, Risk and Environmental Management Committee, Governance and Risk Committee and the Quality Improvement Committee relating to reported near miss, adverse event and serious untoward incidents;
• Develop and update the eCompulsory Risk Management module which incorporates the recording, reporting, escalation and investigation of incidents.

4.2.6 Responsibility of Associate and Deputy Directors and Divisional General Managers

Associate and Deputy Directors and Divisional General Managers will:

• Develop their local arrangements for reporting, escalation, management and investigation of near miss, adverse events and serious untoward incidents using Datixweb;
• Ensure there are local arrangements in place to communicate to and appraise the Patient and Staff Safety Team and the Head of Quality and Safety of any reported incidents giving cause for concern which may require escalation for consideration as a potential Serious Untoward Incident;
• Foster a positive incident reporting and fair blame culture and ensure there is a consistent approach in order to allow lessons to be learned, corrective actions to be taken and the avoidance recurrence, as far as is possible.

Note: The National Patient Safety Agency (NPSA) Incident Decision Tree is a valuable and recommended tool, which can be accessed via the NPSA website, www.npsa.nhs.uk

• Ensure staff are appropriately supported following involvement in or reporting of an incident,
this includes the administration of first aid;

- Ensure that reported incidents progress through the Datixweb incident reporting system in a timely manner in compliance with required timescales (see incident reporting and investigation procedure for further information).
- In the unlikely circumstances that the incident was caused by a malicious act or gross misconduct on the part of an individual employee of the Trust, the Divisional General Manager/Head of Service or appropriate professional clinical lead should immediately discontinue the investigation process and notify the individual and the relevant Human Resources Business Partner, that a referral to the disciplinary process will be made.

4.2.7 Responsibilities of Heads of Nursing, Heads of Service and Departmental Managers

Heads of Nursing, Heads of Service and Departmental Managers will:

- Provide assurance to the General Manager(s) and the relevant Divisional /Directorate Governance/ Quality/Service Improvement Teams/Group, that incidents and concerns are reported, that appropriate actions are/were taken and the appropriate level of escalation and investigation was undertaken in response to the nature or severity of the incident.
- In consultation with Divisional General Managers, identify an appropriate Incident Reporting Lead or Leads within their Divisional/Directorate/Service/Specialty to co-ordinate the recording, reporting, escalation and investigation of near miss, adverse events and serious untoward incidents.
- Regularly liaise and seek assurance from Incident Reporting Leads that incidents are appropriately recorded, reported, escalated and investigated.
- Ensure staff are appropriately supported following involvement in or reporting of an incident, this includes the administration of first aid;
- Ensure that the local systems in place enable reported incidents to be reviewed, appropriately investigated and achieve final approval status within the required timescales for the review, investigation and final approval.

4.2.8 Responsibility of Matrons and Ward / Line Managers

The Matrons and Ward / Line Managers will:

- Ensure that this policy and associated procedures for the recording, reporting, escalation and investigation of incidents are applied within their area of responsibility;
- Ensure the safety of patients, staff, visitors and the environment (including preserving the scene where necessary or referring for medical help) in the event of all incidents;
- Take appropriate action to limit the possibility of recurrence, if this seems likely, and/or if there appears to be an avoidable reason;
- When an incident involves a patient, ensure that patient and next of kin/carer, as appropriate, are informed and that this is documented in the patient's record.
- When an incident involves a patient, ensure that details of the incident, side effects, injury, outcome etc. and any medical review, investigation and treatment are documented in the patient records.
- Remove from use any medical device, electrical or mechanical equipment that is suspected or confirmed as being directly attributable to the incident and arrange secure storage pending further investigation.
- Support staff to enable the timely reporting of near miss, adverse events and serious untoward incidents;
- Ensure staff are appropriately supported following involvement in or reporting of an incident, this includes the administration of first aid;
- Ensure that reported incidents progress through the Datixweb incident reporting system in a timely manner in compliance with required timescales for review and investigation in readiness
for final approval by themselves or the identified divisional/directorate/service leads with responsibility for final approval, investigation (see incident reporting procedure for further information);

- Escalate actual and potential serious untoward incidents at the earliest opportunity in line with supporting procedures.

4.2.9 Responsibility of Individuals

Each member of staff has an individual responsibility to:

- Ensure they report all near misses, adverse events and serious untoward events.
- Submit a record of the incident via the electronic incident reporting system known as Datixweb, found on the Trust’s Intranet Homepage.
- Inform the person in charge at the time the incident occurs and the Ward / Line Manager of the incident as soon as it is appropriate and practical to do so.
- Undertake eCompulsory Risk Management training module which incorporates the recording, reporting, escalation and investigation of incidents as per the training needs analysis (TNA) and within the required update frequency.

The individual employee involved in, witnessing or having an incident reported to them is responsible for ensuring:

- Witness statement(s) and any further information are provided as requested or required.
- They co-operate and assist in any investigation of all reported incidents.

If staff are anxious or uncertain about reporting any incident, they can first discuss the incident, in confidence, with any of the Executive Directors, the Patient and Staff Safety Team or HR Department.

5 REPORTING PROCEDURE FOR NEAR MISS, ADVERSE EVENTS AND SERIOUS UNTOWARD INCIDENTS

5.1 From 1 April 2010 all incidents including Serious Untoward Incidents have been required to be reported using the electronic incident reporting form via the Datixweb Incident Reporting System on the Trust Intranet homepage.

5.2 The person who identifies or is involved in the incident, in the first instance, should report to the person in charge of the ward, clinic or department at that moment in time and complete an on-line Datixweb incident form.

5.3 In the event of any incident giving immediate cause for concern or believed to be an actual or potential Serious Untoward Incident during the hours of Monday to Friday 9am to 5pm the completion of the Datix web incident reporting form should be backed up with a phone call to the Patient and Staff Safety Team or Head of Quality and Safety and the appropriate senior manager.

5.4 In the event of any incident giving immediate cause for concern or believed to be an actual or potential Serious Untoward Incident outside the hours of Monday to Friday 9am to 5pm the completion of the Datix web incident reporting form should be backed up with a phone call to the on call Manager and email to the Patient Safety Manager, Health and Safety Manager and the Head of Quality and Safety.

5.5 When completing a Datix incident form:

- All the information recorded must be **factual** and **should not include** any assumptions, speculation, hearsay or personal opinion.
As much factual detail as possible should be entered before it is submitted and forwarded to the relevant people for review.

5.6 The details listed below must be entered on the Datix web incident reporting form:

- Hospital or site, division and/or directorate, ward/clinic/department
- Name and address of patient or visitor, contractor
- Name and work address of staff members permanent, agency or locum
- Date and time of Incident
- Date and time incident reported
- Full description of the incident including any known cause/contributing factors
- Details of injury, harm or loss sustained
- Result of any medical review/treatment, especially x-rays
- Actual or possible staff absence of three days or more
- Name and contact details of person completing the incident report

5.7 Any additional information, action or consequence of the incident arising after the Incident Reporting Form has been submitted should be recorded in the 'investigation detail' field of the Datix web incident form as soon as possible after it is known.

5.8 In the unlikely circumstances that the incident was caused by a malicious act or gross misconduct on the part of an individual employee of the Trust, the Divisional General Manager/Head of Service or appropriate professional clinical lead should immediately discontinue the investigation process and notify the individual and the relevant Human Resources Business Partner, that a referral to the disciplinary process will be made.

Once this has been done, the incident recording, escalation and investigation process should be continued in order to identify any systems and processes which could be improved to promote safety and reduce any future risk to patients or the organisation.

6.0 INVESTIGATION PROCEDURE FOR NEAR MISS, ADVERSE EVENTS AND SERIOUS UNTOWARD INCIDENTS

An investigation must be completed for all reported incidents.

A thorough investigation is crucial to the prevention of similar incidents in the future. The level of investigation and detail involved in the investigation will be determined by the nature of the incident, the extent of any injuries sustained etc. and the potential for a recurrence.

6.1 Investigation of Adverse Events and Near Misses

Responsibility for the investigation of near miss and adverse event incidents lies with the named Datix web investigation leads within each Division / Directorate or Service. The investigation must be fully completed within 10 days of the incident being notified.

There are 5 main steps to the investigation process:

Step One: Incident notification and review - the identified Datix web Investigation Leads will review all incidents notified to them within 5 days of the incident being reported. They will review all mandatory fields (which are highlighted by a red asterisk) ensuring they are populated appropriately and correctly.

Step Two:
**Incident investigation** - the identified Datix web investigation leads will co-ordinate the investigation and collection of evidence. The investigation must be fully completed within 10 days of the incident being notified. This should include the following stages:

- **Information gathering** should consider:
  - People involved (injured person / witnesses affected by the incident etc.);
  - Events leading up to, and the location where the incident happened;
  - Environment, equipment, medications, substances etc. involved in the incident;
  - Procedures and paperwork, which will give sufficient information for an effective investigation e.g. policies, procedures, risk assessments, other documentation e.g. nursing paperwork, work requisitions etc.

- **Conducting formal interviews** with all of the people involved, to establish the facts, not to apportion blame. It is ideal to interview witnesses as soon as possible at the scene of the incident, before memory fades or information becomes distorted through collaboration, rumour and speculation. Obviously an interview with the injured party may not be appropriate / possible until much later.

- **Physical evidence gathering** where necessary (and most commonly during non-clinical investigations):
  - Taking photographs
  - Taking measurements
  - Details of any other physical evidence

  (Assistance in this process can be sought by contacting the Patient and Staff Safety Team).

- **Inspecting the environment, equipment, medications, substances etc** involved in the incident for any signs of damage. Where medical devices are involved please refer to section 7.

- **Identifying any procedures, standard operating procedures (SOPs) and guidance** that need review which were in place at the time of the incident. These may include; risk assessment, maintenance records, induction courses, training, certification records, and policies etc.

All of this information may assist in identifying the underlying cause(s) of the incident. Evidence must therefore be referenced and provided as supporting documentation to the investigation of the incident.

**Step Three:**

- **Analyse the information** - analysis of the above evidence must be undertaken to help identify the facts leading up to the incident, to establish why it happened and to prevent it from happening again. Analysing the information gathered will assist in identifying a sequence of events, contributing factors and circumstances of the incident in order to identify root cause(s) and actions required to reduce the risk of recurrence.

**Step Four:**

- **Completing the investigation** – all investigation findings must be recorded on Datix web and an appropriate action plan developed to address lessons learned and implement any required control / risk reduction measures. The investigation must be fully completed within 10 days of the incident being notified.

**Developing an action plan**

Any recommendations and action plans developed to address lessons learned and required control / risk reduction measures should be clear and concise.

They should clearly identify, who is responsible for carrying them out and within prescribed timescales. The Datix web investigation lead is also responsible for monitoring the effectiveness of any recommendations and actions required.
Recording your findings

Every stage of the investigation should be recorded in the ‘Investigation Details’ section of Datix web, within the ‘Action Taken’ field. The following fields must also be completed:
- Outcome of Investigation (adverse event, near miss, serious untoward incident)
- Lessons Learned
- Date investigation started and completed
- Name of Investigator
- Complete the ‘Action Plan’ field registering the name of the person nominated to address the recommendations within the action plan.

All hard copy documentation gathered and associated reports developed during the investigation process should be attached to the relevant incident form using the ‘Documents’ facility found on Datix web in the left hand menu of the incident form.

Step Five:
Final Approval of Reported / Investigated Incidents – within 10 days of the incident being notified (unless identified as an SUI or Divisional RCA Investigation)

- All incidents should be available for final approval by the person who has been authorised to give final approval status to reported / investigated incidents
- Approval status should remain at ‘awaiting final approval’ until the incident report and any investigation has been checked to confirm an appropriate level of investigation has been undertaken and all mandatory requirements met.
- The authorised final approver should, when satisfied that the incident has been reported and investigated in line with policy, give the incident ‘final approval’ status and save this to the Datix web system
- The final approval of all incidents is required within 10 days at the latest unless identified as an SUI or Divisional RCA Investigation

6.2 Investigation of Serious Untoward Incidents (SUI)

In the case of Serious Untoward Incidents before any investigation begins, the initial stage is the completion of an SBAR (Situation, Background, Assessment, Recommendations) Proforma in readiness for an Initial Review Meeting (IRM) which will be chaired by the Deputy Chief Executive/Director of Nursing and Performance, DIPC and/or the Medical Director.

6.2.1 All potential Serious Untoward Incidents are considered at an Initial Review Meeting (IRM) and a decision made based on the SBAR and information provided by the IRM attendees.

6.2.2 Once the facts have been considered, the executive chair will determine if the incident is to be investigated as a StEIS SUI (Strategic Executive Information System SUI) that requires executive monitoring and sign off or as a Divisional RCA Investigation.
- StEIS SUI is reportable to StEIS under the Strategic Health Authority and/or Department of Health SUI requirements.
- Divisional RCA Investigation is non-reportable to StEIS but requires a full Divisional root cause analysis investigation

6.2.3 The Director of Nursing/Medical Director will identify an appropriate person to lead the investigation regardless of this being a StEIS SUI or Divisional RCA Investigation.

6.2.4 StEIS SUIs and Divisional RCA Investigations require a completed summary report and any identified action plan to be submitted to the Deputy Chief Executive/Director of Nursing and Performance, DIPC and/or the Medical Director with a copy to the Patient and Staff Safety Team.
6.2.5 The Deputy Chief Executive/Director of Nursing and Performance, DIPC and/or the Medical Director will identify the appropriate committee or board to receive and monitor progress against the completed StEIS SUI and Divisional RCA Investigation Report and Action Plans.

6.2.6 SteIS SUIs and Divisional RCA Investigations must be completed within 40 working days of the incident notification. In the event that this is not achievable, the chair of the IRM and Head of Quality and Safety must be immediately informed.

7.0 EXTERNAL AGENCY REPORTING ARRANGEMENTS

The Trust is required to report some incidents to external agencies. Such reports will usually be made by the Patient and Staff Safety Team unless otherwise stated.

7.1 Monitor
Monitor is the organisation, which, authorises and regulates NHS foundation trusts and supports their development, ensuring they are well-governed and financially robust. This done via the ‘Compliance Framework.’

One of the requirements of Monitor is that the trust submits notifications and regular reports in relation to identifying, escalating, investigating and taken action in response to serious untoward incidents and evidence that the Board is aware of such incidents.

These information submissions and notifications are made by the Board Secretary on behalf of the trust.

7.2 Care Quality Commission (CQC)

The Care Quality Commission monitors the performance of health and social care providers against the ‘Essential Standards of Quality and Safety’.

In line with this, the trust is required to provide the Care Quality Commission with regular updated information and notifications including reported incidents data relating to specific quality and safety issues detailed within the ‘Essential Standards of Quality and Safety’.

The incident information submission is made by the Head of Quality and Safety on behalf of the Trust.

7.3 Strategic Health Authority (SHA) Serious Untoward Incidents

The SHA require the Trust to report serious untoward incidents within a maximum of 48 hours after the incident has been identified as a Serious Untoward Incident (SUI).

Where the authorised named individual in the Trust believes that the incident has significant implications for the NHS in terms of clinical, managerial or media issues, and warrants the immediate involvement of the SHA out of hours, the SHA on-call executive can be contacted.

Verbal reports are followed up with information being electronically inputted onto the SteIS system (Strategic Executive Information System) within 72 hours of the incident occurring, or as soon as known following notification.

7.4 National Reporting and Learning System (NRLS)
Clinical incidents or non-clinical incidents that impact on patient care and services are reportable to the NRLS.

The Patient Safety Manager will export reported incidents from the DATIX system directly to the National Reporting and Learning System (NRLS).

7.5 Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)

The Trust has a legal duty under RIDDOR to report certain work-related injuries, diseases or dangerous occurrences to the Health and Safety Executive (HSE) within prescribed timescales, via the Incident Contact Centre. This is in addition to the requirements of the Trust’s incident reporting procedure.

RIDDOR only applies to injuries, diseases and dangerous occurrences which occur at work or as a direct result of an ‘at work activity’.

The Health and Safety Team have developed a RIDDOR Reporting Procedure which details the circumstances which require reporting. This can be accessed via the Trust’s Policy Library available on the Intranet.

7.6 Medical Devices and Healthcare Products Regulatory Agency (MHRA)

Medical device / equipment, medicines and blood related incidents may be reportable to the MHRA.

7.6.1 Medical Devices / Equipment

The Medicines & Healthcare Products Regulatory Agency (MHRA) should be informed of incidents involving medical devices and equipment even if they appear to be caused by human error as:

- It may be partly (or wholly) due to deficiencies in the design of the equipment or instructions for use;
- It will help prevent repetition of the same mistake. The MHRA may possibly issue national alerts. Manufacturers may improve the design of devices / equipment in the future.

Medical Devices / Equipment are used for:

- Diagnosis, prevention and/or treatment of disease
- Monitoring patients
- Assisting patients and users

General workshop equipment and general purpose laboratory equipment is not included.

Medical device / equipment incidents should, in the first instance, be reported via the Trust’s Datixweb Incident Reporting System.

Reportable medical device / equipment incidents include the following occurrences:

(i) Defect
A defect is a perceived deficiency in a product that has the potential to or has actually caused an adverse incident.

(ii) Incident
An incident is an event that gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, users or other persons. Incidents in medical devices may arise due to:

- Shortcomings in the equipment or manufacture of the equipment itself
- Inadequate manufacturers instructions for use
- Inadequate staff training leading to incorrect user practice
- Inadequate servicing and maintenance
- Problems caused by locally initiated modifications or adjustments
- Inappropriate management procedures
- Unsuitable storage arrangements
- Recommendation / selection of inappropriate device for the purpose

Conditions of use may also give rise to adverse incidents, e.g.:

(i) Environmental conditions such as electromagnetic interference (e.g. mobile phones)
(ii) Location (e.g. equipment designed for hospitals may not be suitable for use in the Community or ambulances)

When a Medical device / equipment incident occurs and the Datix web incident form has been submitted:

- It should then be reported directly to the MHRA: www.mhra.gov.uk.
- All items, together with relevant packaging materials, should be quarantined
- Do not repair the device, return it to the manufacturer or discard it until advised by the MHRA
- Do not send devices to the MHRA unless specifically asked to do so.
- Copies of all correspondence to and from the MHRA should be forwarded to the Patient and Staff Safety Team.

If staff are in doubt about reporting to the MHRA, they can check with the Patient and Staff Safety Team, Medical Electronics Department, Supplies Department

### 7.6.2 Medication Incidents

Incidents involving medications may be reportable to the MHRA. The Chief Pharmacist is responsible for notifying the MHRA when required.

### 7.6.3 Blood Transfusion Incidents

The UK Blood Safety & Quality Regulations, 2005 and the EU Blood Safety Directive require that serious adverse events and serious adverse reactions related to blood and blood components are reported to MHRA, the UK Competent Authority for blood safety via the Serious Advice Blood Reactions & Events (SABRE) reporting system.

The Blood Transfusion Department/Hospital Transfusion Team is responsible for notifying the MHRA via SABRE when required.

### 7.78 The Coroner

When a patient dies, and the circumstances of the death are unexpected or in any way suspicious the police should be contacted and the doctor involved in certifying the death should contact the Coroner. Out of hours the police fulfil the role of the Coroner’s office.
8. HUMAN RIGHTS ACT:

Implications of the Human Rights Act have been considered and are as follows:
As far as I am aware there is no implication on the Human Rights Act

9. EQUALITY & DIVERSITY:

The Policy has been assessed against the Equality Impact Assessment Form from the Trust’s Equality Impact Assessment Guidance and, as far as the author is aware, there is no impact on any Equality Target Group.

In implementing this policy managers must ensure that all staff are treated fairly and within the provisions and spirit of the Trust’s Equality, Diversity and Inclusiveness Policy.

10. MONITORING AND REVIEW:

10.1 The effectiveness of this policy will be evaluated against the Trust incident reporting system and monitored by the Quality Improvement Committee and the Risk and Environmental Management Committee via quarterly reports.

10.2 Compliance with the process of NRLS reporting is monitored by the production of bi-annual reports by the NPSA showing Trust activity on incident reporting and is measured against the overall national reporting of incidents.

10.3 The Board will receive monthly reports in respect of ‘Never Events’

10.4 RIDDOR reportable incidents are investigated locally within wards and departments and monitored by the Health and Safety Team. Quarterly reports are produced and communicated to managers via the Risk and Environmental Management Committee and Occupational Safety and Health Committee.

10.5 The Board will receive management reports in relation to Divisional performance against the agreed incident reporting and investigation deadlines.

10.6 The Policy will be reviewed every 2 years or sooner in the event of any significant changes to which it relates and approved at Quality Improvement Committee or Risk and Environmental Management Committee.

11. ACCESSIBILITY STATEMENT:

This document can be made available in a range of alternative formats e.g. large print, Braille and audiocassette.

For more details, please contact the HR Department on 01942 77(3766) or email equalityanddiversity@www.nhs.uk
References and Further Information:

- Health and Safety at Work, etc. Act, 1974
- Reporting of Injuries Diseases and Dangerous Occurrences Regulations (RIDDOR), 1995
- The Ionising Radiation (Medical Exposure) Regulations, 2000 (IRMER)
- Care Quality Commission: Guidance about Compliance - Essential Standards of Quality and Safety, March 2010
- Safety First: A Report for Patients, Clinicians and Healthcare Managers, DoH, December, 2006
- Building a Safer NHS for Patients: Implementing an Organisation with a Memory, DoH, April 2001
- An Organisation with a Memory, DoH, 2000
- 7 Steps to Patient Safety, NPSA, 2004
- Root Cause Analysis, NPSA, 2004
- NHSLA Risk Management Standards

Useful Web Sites:

Care Quality Commission (CQC)
www.cqc.org.uk

NHS Litigation Authority (NHSLA)
www.nhsla.com

Medicines and Health Products Regulatory Agency (MHRA)
www.mhra.gov.uk

Health & Safety Executive (HSE)
www.hse.gov.uk

National Patient Safety Agency (NPSA)
www.npsa.nhs.uk

Serious Hazards of Transfusion (SHOT)
www.shotuk.org
Related Policies and Procedures

- Risk Management Strategy and Policy
- Incident Reporting Procedure
- Investigation of Incidents, Complaints and Claims Policy and Procedure
- Analysis of, and Learning from, Incidents, Complaints and Claims Policy
- Health and Safety Policy
- Major Incident Planning Policy
- Raising Concerns Policy and Procedure
- Being Open Policy and Procedure
APPENDIX 3

Information Governance Incident Reporting

An Information Governance related incident involves a breach of information security and / or the confidentiality of personal information which could be anything from users of computers sharing passwords, to a piece of paper found on the high street containing patient personal details. Other examples of incidents can be located on the Information Governance intranet pages.

Staff must complete an on-line Datixweb Incident Form so that the Information Governance Co-ordinator can update the Information Governance Incident and Risk Log.

All personal data related incidents need to be classified, in line with DoH guidance, in terms of severity on a scale of 0-5 of either / both risk to reputation and risk to individuals as per table below:

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Risk to Reputation</th>
<th>Risk to Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No significant reflection on any individual or body. Media interest very unlikely.</td>
<td>Potentially serious breach. Less than 5 people affected or risk assessed as low, e.g. files were encrypted.</td>
</tr>
<tr>
<td>1</td>
<td>Damage to an individual’s reputation. Possible media interest e.g. celebrity involved.</td>
<td>Serious potential breach and risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected.</td>
</tr>
<tr>
<td>2</td>
<td>Damage to a team’s reputation. Some local media interest that may not go public.</td>
<td>Serious breach of confidentiality e.g. up to 100 people affected.</td>
</tr>
<tr>
<td>3</td>
<td>Damage to a services reputation / low key local media coverage.</td>
<td>Serious breach with either particular sensitivity e.g. sexual health details, or up to 1000 people affected.</td>
</tr>
<tr>
<td>4</td>
<td>Damage to an organisation’s reputation / local media coverage.</td>
<td>Serious breach with potential for ID theft or over 1000 people affected.</td>
</tr>
<tr>
<td>5</td>
<td>Damage to NHS reputation / national media coverage.</td>
<td></td>
</tr>
</tbody>
</table>

Incidents rated at a severity rating of 0 need not be reflected in annual reports but logged on local risk and incident logs.

Incidents classified at a severity rating of 1-2 should be aggregated and reported in the annual report.

Incidents classified at a severity rating of 3-5 are those that should be captured as Serious Untoward Incidents (SUI’s) and should be reported to SHAs and the Information Commissioner.
Glossary of Terms

IRM – Initial Review Meeting
SUI – Serious Untoward Incident
NRLS – National Reporting and Learning Service
DoH – Department of Health
HSE – Health and Safety Executive
SHA – Strategic Health Authority
StEIS - Strategic Executive Information System
### EQUALITY IMPACT ASSESSMENT FORM

#### STAGE 1 – INITIAL ASSESSMENT (PART 1)

<table>
<thead>
<tr>
<th>Division:</th>
<th>Nursing and Operations</th>
<th>Department:</th>
<th>Patient &amp; staff Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person(s) completing this form:</td>
<td>Pat O’Brien</td>
<td>Tel No:</td>
<td>01942 264413</td>
</tr>
<tr>
<td>Others involved:</td>
<td></td>
<td>Start date of this assessment:</td>
<td>15/02/10</td>
</tr>
<tr>
<td>Title of policy being assessed:</td>
<td>Policy and Procedure for the Reporting of Near Miss, Adverse Event and Serious Untoward Incidents</td>
<td>Policy implementation date:</td>
<td></td>
</tr>
<tr>
<td>What is the main purpose (aims / objectives) of this policy?</td>
<td>To promote and support an active and positive incident reporting culture throughout the Trust</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the policy existing &amp; being reviewed or a new policy? (tick the relevant box)</td>
<td>Existing &amp; Being Reviewed</td>
<td>✓</td>
<td>A NEW Policy</td>
</tr>
<tr>
<td>Will patients, carers, the public or staff be affected by this policy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Carers</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Staff</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If staff, how many individuals / Which Groups of Staff are likely to be affected?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have patients, carers, the public or staff been involved in the development of this policy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Carers</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Staff</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If yes, who have you involved and how have they been involved:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>What consultation method(s) did you use?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For example: focus groups, face-to-face meetings, questionnaires etc.</td>
<td>N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How are any changes / amendments to the policy communicated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For example: Meetings / Focus / Email etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### EQUALITY IMPACT ASSESSMENT TABLE

<table>
<thead>
<tr>
<th>Equality Target Group</th>
<th>Positive Impact</th>
<th>Negative Impact</th>
<th>Reason/Comments for Positive Impact</th>
<th>Reason/Comments for Negative Impact</th>
<th>Resource Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
<td>Low</td>
<td>None</td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>Men</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Younger People (17-25) and Children</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Older People (60+)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race or Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning Difficulties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hearing Impairment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visual Impairment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Disability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Health Need</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gay/Lesbian/Bisexual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transgender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faith Groups (please specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Group (please specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applies to ALL Groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**High:** There is significant evidence of a negative impact or potential for a negative impact.

**Low:** Likely to have a minimal impact / There is little evidence to suggest a negative impact.

**None:** A policy with neither a positive nor a negative impact on any group or groups of people, compared to others.
INITIAL ASSESSMENT (PART 3)

(a) In relation to each group, are there any areas where you are unsure about the impact and more information is needed?

N/A

(b) How are you going to gather this information?

N/A

(c) Following completion of the Stage 1 Assessment, is Stage 2 (a full assessment) necessary?

Have you identified any issues that you consider could have an adverse (negative) impact on people from the following Equality Target Groups?

<table>
<thead>
<tr>
<th>Group</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Younger People (17-25) and Children / Older People (60+)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Gender (Men / Women)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Race</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Disability (Learning Difficulties / Hearing Impairment / Visual Impairment / Physical Disability / Mental Illness)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Religion / Belief</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Sexual Orientation (Gay / Lesbian / Bisexual / Transgender)</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Carer</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Other</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

Any Other Comments

N/A

Assessment Completed By: Pat O’Brien    Date Completed: 15/02/2011

IF ‘NO IMPACT’ IS IDENTIFIED Action: No further documentation is required.

If required, the Full Equality Impact Assessment Form Template can be downloaded from either the Policy Library Intranet Page or the Equality & Diversity Intranet Page.

PLEASE RETURN COMPLETED FORMS VIA E-MAIL TO:
DEBBIE JONES, EQUALITY AND DIVERSITY PROJECT LEAD (for Service related policies)  
debbie.jones@wwl.nhs.uk

EMMA WOOD, EQUALITY AND DIVERSITY PROJECT LEAD (for HR / Staffing related policies)  
emma.wood@wwl.nhs.uk