Northern Lincolnshire and Goole Hospitals NHS Foundation Trust actively seeks to promote equality of opportunity. The Trust seeks to ensure that no employee, service user, or member of the public is unlawfully discriminated against for any reason, including the “protected characteristics” as defined in the Equality Act 2010. These principles will be expected to be upheld by all who act on behalf of the Trust, with respect to all aspects of Equality.

Medical Director

POLICY FOR DEALING WITH SERIOUS UNTOWARD INCIDENTS (CLINICAL AND NON-CLINICAL)
Contents

Section..................................................................................................................Page

1.0 Purpose............................................................................................................4
2.0 Area ..................................................................................................................4
3.0 Definition of a ‘Serious Untoward Incident’ ....................................................4
4.0 Examples of ‘Serious Untoward Incidents’.......................................................4
5.0 Duties & Responsibilities ..............................................................................5
6.0 Procedure / Actions.......................................................................................5
6.1 Immediate Action ..........................................................................................5
6.2 Record Keeping .............................................................................................7
6.3 Subsequent Action .........................................................................................8
6.4 Designation of Incident Room .....................................................................11
6.5 Management of Information .......................................................................11
6.6 Communications/Media Relations ...............................................................11
6.7 Follow-up / ‘Closing the Loop’ ...................................................................13
6.8 Maternal Deaths ...........................................................................................13
6.9 Part 8 Case Reviews – Children Act 1989 ..................................................14
6.10 Information Governance ............................................................................14
7.0 Approval & Ratification ................................................................................14
8.0 Review & Revision ........................................................................................14
9.0 Implementation .............................................................................................14
10.0 Dissemination .............................................................................................14
11.0 Monitoring Compliance & Effectiveness......................................................15
12.0 Further Reading / Associated Documentation ..........................................15
13.0 References ...................................................................................................16

Appendices:

Appendix A - Serious Untoward Incident (SUI) Management Checklist..............17
Appendix B - Setting Up & Use Of ‘Helplines’ ................................................................. 18
Appendix C - Helpline Proforma .................................................................................. 21
1.0 Purpose

This policy is intended to formalise roles and responsibilities, for dealing with ‘Serious Untoward Incidents’, in order to ensure that such events are managed effectively and efficiently. It should be read in conjunction with the Trust’s Incident Reporting Policy & Procedure.

2.0 Area

This policy applies to all staff employed by or seconded to the Trust and to all Trust premises.

3.0 Definition of a ‘Serious Untoward Incident’

3.1 There is no absolute or perfect definition of a ‘Serious Untoward Incident’. The following definition, which has been adapted from NHS Executive and CNST guidance and adopted within the Northern Lincolnshire & Goole Hospitals NHS Foundation Trust, should therefore be used as a guide only.

3.2 A Serious Untoward Incident is “an incident or series of incidents (in which one or more patients are involved) which are likely to produce significant legal, media or other interest or give rise to large scale public concern and which, if not properly managed, may result in significant loss of the Trust’s reputation and/or assets”.

3.3 This includes incidents involving patients, members of staff (including volunteers), contractors and visitors to the Trust.

4.0 Examples of ‘Serious Untoward Incidents’

4.1 The following is not an exhaustive list but is intended to provide examples only:

- The unexpected death of, or serious injury to, any individual (including patients, staff, contractors or visitors) on NHS premises. This will include maternal deaths. Where patient(s) involved (other than maternal death), this may include death(s) following an adverse incident and which necessitated the involvement of the Police

- Suspicion of or actual large-scale theft or fraud or any incident which might give rise to serious criminal charges

- Impending large-scale litigation (including negligence claims)

- Repeated serious complaints about a member of staff or contractor (including primary care contractor)

- Suspicion of or an actual serious error or errors by a member of staff or contractor (including primary care contractor)

- A serious breach of confidentiality including loss of person identifiable information
• A number of unexpected/unexplained deaths (including apparent clusters of suicides of patients in receipt of psychiatric care)
• The suicide (or attempted suicide) of any person on NHS premises
• Death or injury where foul play is suspected
• Serious damage which occurs in NHS premises or any incident which results in serious injury to any individual or serious disruption to services
• Absconsion by patients detained under the Mental Health Act, 1983, who present a serious risk to themselves or to others
• An incident where it is suspected that defective drugs and/or equipment may have caused the serious injury/death which has occurred
• Bomb Threats (please see procedure for dealing with Bomb Threats and/or Suspect Packages)

4.2 For further information – please refer to the National Framework for Reporting and Learning from Serious Incidents Requiring Investigation.

5.0 Duties & Responsibilities

5.1 Whilst the Medical Director has overall responsibility for governance and risk management (supported by the Head of Governance), dependent on the circumstances of the incident, the appropriate Non-Clinical Director or Directorate Director/Directorate Manager* will assume specific responsibility for managing the incident. For example:

- Clinical Issues: Relevant Director**
- Medical issues: Medical Director
- Finance issues: Finance Director
- Estate issues: Director of Facilities

*Out of hours the on-call Director/Senior Manager will assume this responsibility.

**Supported by the Medical Director and/or the Head of Governance, as appropriate. However, dependent on the circumstancesSCALE of the incident (e.g., large scale patient re-calls) the Medical Director and/or the Head of Governance may need to assume responsibility for the management of the incident. This will be decided at the time the incident occurs.

6.0 Procedure / Actions

6.1 Immediate Action

6.1.1 Following a serious untoward incident, the person in charge of the ward/department should take any necessary and immediate remedial action to prevent a recurrence.
6.1.2 The occurrence of a serious untoward incident, with the exception of suspected fraud or corruption (see below), should be notified immediately to the Head of Governance. It is recognised that the relevant Director or Manager may already have been informed as part of pre-existing departmental working arrangements. Where this is not the case, the member of staff reporting the incident should ensure appropriate escalation within the Branch/Directorate to ensure that all relevant staff are aware.

Note: Incidents of fraud and corruption must be dealt with in accordance with the Trust’s Counter Fraud Policy, which is based on national guidance for counter fraud arrangements within the NHS.

Note: out of hours, the respective Site Manager should be contacted in the first instance. The Site Manager in turn will contact the on-call Director/Senior Manager (please also see point 6.1.5 below).

6.1.3 Initial notification of a serious untoward incident should be by telephone or in person. This should be followed up by the completion of an incident reporting form (including information on all persons involved and the immediate action taken after the occurrence and enclosing statements obtained from all those involved in the incident).

Note: ‘Guidelines on Preparing a Statement’ are available from the Risk Management webpage.

6.1.4 In respect of incidents, where foul play is suspected/has been confirmed, early consideration should be given, by the person in charge of the ward/department, in consultation with his/her Manager (or Site Manager if out of hours) if necessary, to involving the Police. In the event of such action being taken, the area should be isolated and any equipment involved should be retained until the Police have visited. Details of any witnesses to the incident should also be obtained in case this information is required by the Police. Should staff be unsure whether Police involvement is required, advice can be obtained 24 hours a day from the Police Advice Desk Sergeant on telephone (Grimsby) 01472 359171 or (Scunthorpe) 01724 282888. Note: It is recognised that the requirement to involve the Police may not become apparent until investigation of the incident has commenced/been completed. However, early contact with the Police is encouraged in order to obtain appropriate advice at an initial stage.

6.1.5 On notification of the incident, the Head of Governance will ensure that the following staff are or have already been notified:

- Appropriate Director
- Chief Executive
- Medical Director
- Chief Nurse
- Head of IT (Trust Information Security Manager), as appropriate
- Head of Car Parking, Transport & Security (Trust Security Management Specialist), as appropriate
• PR & Communications Manager

• Health & Safety Manager, as appropriate

If out of hours, the Site Manager will, in the first instance, notify the Director/Senior Manager on-call, who will then make a decision as to whether any of the above should be contacted.

6.1.6 The Head of Governance, or Site Manager, will ensure that the necessary immediate action has been taken to prevent a recurrence of the incident(s) where this is possible and/or appropriate. In respect of incidents involving defective ‘products’ (i.e. drugs, equipment etc.), this will involve ensuring that the item(s) have been isolated and retained (where this has not already occurred for the purposes of a Police investigation) and the relevant in-house personnel contacted (this is in line with the requirement to report incidents caused by defects in medicinal products; buildings and plant; and other medical and non-medical equipment and supplies to the relevant external authority).

6.1.7 In respect of clinical/patient safety incidents, the Head of Governance, or Site Manager, will establish what information has already necessarily been communicated to the patient(s) and his/her relatives and agree with the appropriate Director (or if out of hours the Director/Senior Manager on-call) the approach for further communication and the responsibility for this (e.g. responsible Consultant, Ward Manager, etc). For further information on ‘being open’ – please refer to the Trust’s ‘Policy on Being Open – Communicating with Patients and / or their Relatives / Carers Following a Patient Safety Incident’.

6.1.8 Depending on the circumstances of the incident and, as appropriate, the Health & Safety Manager will advise whether it is necessary to inform the Health & Safety Executive (HSE) and whether the area involved needs to be isolated until a HSE Inspector has visited.

Note: Where the incident occurs out of hours, the Director/Senior Manager on-call, who at this point will assume responsibility for managing the incident from the Site Manager, will need to satisfy themselves that all necessary and appropriate action has been taken to prevent a recurrence and ‘manage’ the incident (points 6.1.1 – 6.1.8 above refer).

6.2 Record Keeping

6.2.1 It is essential that records of the investigation/actions taken throughout the management of a serious untoward incident are maintained and kept secure (tips for information gathering and collection/collation are available in the Trust’s Root Cause Analysis (RCA) Toolkit). The relevant Director/Manager with responsibility for the management of the incident will ensure that:

• all documentation relating to the incident is retained/secured for future reference in the event of (i) an external independent investigation; (ii) legal proceedings being issued; and (iii) a criminal investigation
• (in respect of clinical/patient safety incidents) the medical records are ‘secured’. Where records are required for the purposes of an external investigation, i.e. an inquest or criminal investigation, copies should be retained on the hospital site. Where records may be required for ongoing treatment, copies may need to be provided for the purposes of the investigation process.

6.3 Subsequent Action

6.3.1 The relevant Director/Manager assuming responsibility for managing the incident will, at the earliest opportunity after the incident, convene an urgent ‘incident review meeting’ of all relevant parties so that all are fully briefed on the circumstances surrounding the incident.

Note: In respect of incidents which occur out of hours, in the majority of cases it will not be necessary to hold the ‘incident meeting’ during the night, although this meeting should be held at the earliest opportunity during the next working day. The on-call Director/Senior Manager on-call should, however, ensure that the relevant Director/Manager is fully briefed on the circumstances surrounding the incident and the action taken to ‘manage’ the situation (if necessary on an on-going basis and, in any event, prior to the ‘incident review meeting’). Should it be necessary to hold such a meeting out of hours, however, the Director/Senior Manager on-call should ensure that all relevant parties (as per point 6.1.5 above) are notified to attend.

6.3.2 The purpose of the ‘incident review meeting’ should be to:

• Determine whether the incident requires reporting to the relevant external Stakeholders including the relevant PCT and Monitor. In all instances, reporting to the external stakeholders should be discussed and agreed with the Medical Director and/or the Head of Governance. The Head of Governance will assume responsibility for reporting to PCTs (and Monitor/CQC as required). Where reporting to other external stakeholders may become necessary, responsibilities for this will be agreed at the time of the incident.

• Identify the staff member(s) or group who will carry out fact finding for the Trust response, reporting back to the relevant Director/Manager and above group to find out what occurred and why.

• In cases where the HSE/Police or other enforcement agencies are involved, these organisations may initiate their own investigation and request interviews with and information from Trust staff. The Head of Governance/Health & Safety Manager will act as the Trust ‘Co-ordinator’ (as appropriate) in such instances.

• Agree the terms of reference/timescale of a formal internal investigation and to subsequently formulate a report/action plan. This will need to include any recommendations made by other agencies involved (i.e. HSE/Police). The group should also consider to whom the investigation report will be submitted.
Note: Whilst the timescale for the completion of a formal investigation and the formulation of a report/action plan may vary, depending on the nature and extent of the incident, staff responsible for leading the investigation should aim to complete this process within 6 – 8 weeks of the incident occurring. Where this initial timescale needs to be extended (e.g. where external expert opinion may be required – see below), those involved (including any affected patients and staff and relevant stakeholders) should be kept fully informed.

- Agree the need for external expert opinion/involvement in the investigation and the approach to be adopted. The need to involve an external expert will depend on the circumstances of the incident and, for this reason; it is not possible to outline in this policy the detailed criteria for obtaining such input. Examples of where external expert opinion may be helpful include where the cause is not clear or is disputed or where an objective/independent view is considered helpful in providing reassurance to the patient and/or relatives and/or others involved.

- Make an initial assessment of the likely long-term implications of the incident(s)

- Establish a lead role responsibility for on-going liaison with other agencies, as appropriate (i.e. Police/Coroner/HSE, etc)

6.3.3 The relevant Director/Manager assuming responsibility for managing the incident will also ensure that:

- the necessary arrangements are in place for individuals involved in incident(s) to receive the necessary counselling and support, as required/appropriate – for further information in this regard please refer to section 8.3 & Appendix D: 2.3.1 & 2.3.2 of the Trust’s Incident Reporting Policy/Procedure

- the Trust’s legal representatives are advised of the incident/possibility of legal proceedings being issued and receive ongoing updates, as necessary. The Trust’s legal representatives will in turn advise on any further action to be taken to minimise the risk involved

- the Chief Executive is kept advised of developments/action taken. The Chief Executive and/or the Medical Director and/or the Head of Governance, will be responsible for notifying the Trust Chairman and Non Executive Board Members either directly or at the next available Board meeting

- the PR & Communications Manager is kept fully informed of developments/action taken

- dependent on the circumstances of the incident, consideration is given, as appropriate, as to whether it is appropriate to report the incident to the relevant professional body (e.g. UKCC, GMC etc) or ‘Confidential Enquiry’
6.3.4 As part of the formal internal investigation, the relevant Director/Manager will be responsible for:

- Identifying the immediate cause of the incident (i.e. how it happened) and the underlying or root cause of the incident (i.e. why it happened). For serious untoward incidents, a detailed investigation/root cause analysis (RCA) will be required

Note: For further information on investigation & RCA of incidents, please refer to the Trust’s Policy on the Grading & Investigation of Incidents/Accidents, Complaints & Claims and the Trust’s RCA Toolkit, which are available on the Risk Management webpage under ‘documents’.

Note: Unless the causes of adverse incidents are properly understood, lessons will not be learned and suitable improvements will not be made to secure a reduction in the risk of harm to future patients, staff and visitors.

- Compiling a written report including conclusions and recommendations highlighting learning points and action required to prevent a recurrence

- Implementing agreed action measures

- Ensuring feedback to the patient(s) and/or relatives and/or staff and/or member(s) of the public of the outcome of the investigation/lessons learned and the action taken/proposed. In respect of clinical/patient safety incidents, in addition to the formal written response to the patient/relatives outlining the investigation findings, consideration should also be given to offering a meeting with the senior staff involved in the investigation process

Note: In the event that, following a serious clinical incident, concurrent related internal investigations are ongoing (e.g. disciplinary investigation involving staff); such investigations will NOT delay the resolution of the clinical issues including the final response to the patient/relatives.

- Agreeing with relevant parties any additional media notification, as necessary/appropriate

- Ensuring that arrangements are in place for the relevant external stakeholders, to be notified of the outcome of the investigation/lessons learnt and the actions taken or proposed

6.3.5 Whilst staff involved in managing serious untoward incidents should always refer to the full guidance outlined in this policy document, a management checklist has been provided and is attached at Appendix A.

---

1 DOH, National Patient Safety Agency publication ‘Doing Less Harm’
6.4 Designation of Incident Room

Where it becomes apparent that the management of a serious untoward incident is likely to generate large scale storage and management issues, for example where large numbers of patients are involved, the major incident room (Main Boardroom) on the respective site will be utilised as the 'incident room'.

6.5 Management of Information

In the event of a large-scale serious administrative and/or clinical error affecting large numbers of patients, the need to develop a dedicated database should be considered at an early stage. It should be stressed, however, that the process of setting up and managing such a database should be project managed from the outset by a local designated expert lead supported by a core group of relevant IT/information staff.

6.6 Communications/Media Relations

6.6.1 At the initial meeting convened by the relevant Director/Manager a media/communication strategy should be agreed. This will include:

- clarification of lead role responsibility of "media spokesperson" (although the PR & Communications Manager will be responsible for on-going liaison with the media)

- agreement of briefing responsibilities, requirements and timescales. This should include lead role for:

(a) Contacting or further contacting the affected patient(s) and/or relatives or member(s) of the public (e.g. where the affected person may be a visitor) prior to release of statement/information to the media

N.B. There should be no proactive release of information to the media until every effort has been made to contact affected patients and/or relatives or member(s) of the public. However, where there are tight timescales within which the Trust must contact patients and/or relatives, the need to balance the imperative of contacting affected patients and/or relatives against the likely sensitivities around the method and timing of the contact must be considered.

(b) In the event of a serious untoward incident affecting a member or members of staff, the same principles should apply as in (a) above

(c) the setting up of an advice/helpline for dealing with enquiries from patients/relatives/the wider public, where this is considered necessary/appropriate (please refer to Appendix B for further information on setting up an advice/helpline)

(d) as appropriate, briefing of:

Internally:

- Directors-Managers
- Trust Governance Committee
- Trust Board
- Trust Staff (including those directly involved)
- PALS
- Governors
- Unions

**Externally:**
- MPs
- other hospitals/Trusts
- legal representatives – ongoing briefing
- Monitor
- National Patient Safety Agency
- Medicines & Healthcare Products Regulatory Agency (MHRA)
- Primary Care Trust(s)/GPs (if patients affected)

**N.B. Given the wide catchment area covered by the Trust, care should be taken to ensure that all relevant PCTs are briefed on the incident.**
- Emergency Planning Officer – Local Authorities
- Local Authority Health Scrutiny Lead(s)
- Social Services
- Emergency Services
- National Health Service Litigation Authority
- Police
- Coroner
- Health & Safety Executive
- Public Health
- Local Supervising Authority (ref. maternal deaths – see section 6.8 below)
- Information Commissioner
- Care Quality Commission
6.6.2 As indicated in point 6.2.1 above, it is essential that records of the investigation/actions taken throughout the management of a serious untoward incident are maintained – this will include the need for any information given to staff, patients or the public to be fully documented.

6.7 Follow-up / ‘Closing the Loop

6.7.1 A key requirement of the follow-up/closing the loop process and, in order to bring about real improvements with the Trust’s services, is the sharing of lessons learned arising from incidents with the staff involved and, where relevant, the wider organisation and external stakeholders.

6.7.2 Within NLG, lessons learnt arising from incidents (including SUIs) will be shared via the following routes:

- **Branch / Directorate Level:**
  - Branch Governance Groups/Minutes
  - Staff Meetings
  - Newsletters etc

- **Trustwide:**
  - ‘Learning the Lessons’ Newsletter
  - Internal Safety Alerts
  - Risk Fora (e.g. Trust Governance Committee, Health & Safety Committees etc)
  - Serious Untoward Incident Reports submitted to the Trust Governance Committee and Trust Board (as agreed)

6.8 Maternal Deaths

Instances of maternal death will be classified as Serious Untoward Incidents and should be reported as such. It should be noted, however, that the Trust has in place a separate policy/procedure to be used following an instance of maternal death in accordance with National guidelines. These require that a ‘confidential enquiry’ is made into every maternal death and the Director of Public Health has responsibility for initiating this inquiry in conjunction with the Trust concerned. In the event of a maternal death the on-call Supervisor of Midwives is informed immediately. This individual starts the process of investigation as per Local Supervising Authority Guidelines. Maternal Deaths are then reported to the Local Supervising Authority Midwifery Officer who liaises with the nominated Supervisor of Midwives for Maternal Deaths for the Trust. This Supervisor of Midwives acts in a co-ordinator role for the Trust throughout the whole investigation. Documentation is completed in accordance with the Guidelines. The confidential enquiry held into a maternal death will therefore be in place of, or complimentary to, the Policy/Procedure for Dealing with Serious Untoward Incidents.
6.9 **Part 8 Case Reviews – Children Act 1989**

The Trust has a separate policy for discharging its responsibilities under the Children Act 1989, where a child dies or is seriously injured and abuse is suspected or confirmed. These are known as Part 8 Case Reviews. Where injury/harm to the child occurs on Trust premises, the Policy/Procedure for Dealing with Serious Untoward Incidents would apply.

6.10 **Information Governance**

Where a serious breach of confidentiality occurs – including loss of person identifiable information, such incidents will be dealt with in accordance with this policy and relevant national guidance.\(^2\) Those more serious incidents (rated as ‘category 3-5 incidents’ within the above guidance) will be reported by the office of the Head of Governance & Trust Secretary to the Information Commissioner and Monitor.

7.0 **Approval & Ratification**

The Trust Governance Committee will be responsible for the ratification of this procedure.

8.0 **Review & Revision**

This procedure will be reviewed every three years or sooner should the need arise in the light of experiences/lessons learned in the management of serious untoward incidents within the Trust.

9.0 **Implementation**

Training for staff in managing serious untoward incidents, where this is a requirement of their role, is provided via the SUI training sessions, the Risk Management Study Day and the Root Cause Analysis Training.

10.0 **Dissemination**

Copies of these procedures will be disseminated in hard copies and electronically via the intranet. Copies will also be issued to Directors/Senior Managers on-call.

---

\(^2\) Reporting Serious Untoward Incidents (SUIs) Relating to Actual or Potential Breaches of Confidentiality Involving Person Identifiable Data (P.I.D), including Data Loss
11.0 Monitoring Compliance & Effectiveness

11.1 The Trust Governance Committee (who have designated responsibility on behalf of the Trust Board) will be advised of all new SUIs and will be kept informed of progress with and the outcome of the investigation/lessons learned and the action taken or proposed following SUIs. For further information – please refer to the Trust’s ‘Incident Reporting Policy/Procedure’. Where requested by the Trust Governance Committee (i.e. in instances where there is the potential for significant media interest and/or the involvement of external agencies), the Trust Board will also be notified of SUIs and will monitor progress with the implementation of agreed remedial actions.

11.2 Monitoring of agreed action measures will be undertaken as part of the wider Incident Reporting System arrangements via the Trust Governance Committee. It will be the responsibility of the relevant Director/Manager to ensure escalation of significant risk issues/incidents to the Trust Governance Committee and for keeping these committees advised of progress against agreed action plans.

11.3 The Trust's performance with regards to the management of SUIs will also be undertaken as part of its commissioning arrangements with its local PCTs and also by Monitor.

12.0 Further Reading / Associated Documentation

12.1 The following documents are available for reference in the management of serious untoward incidents.

12.1.1 Incident Reporting Policy (MDP058).

12.1.2 Procedure for the Grading & Investigation of Incidents/Accidents, Complaints & Claims (Appendix D of the above document).

12.1.3 Procedure for the Reporting of Adverse Incidents involving Medical Devices to the Medicines and Healthcare Products Regulatory Agency (MHRA) (MDR019).

12.1.4 Guidelines on Preparing a Statement (MDG014).

12.1.5 Root Cause Analysis Toolkit (MDM002).

12.1.6 Policy on Being Open with Patients and/or their Relatives/Carers following a Patient Safety Incident (MDP006).
13.0 References


13.6 Never Events Framework – Update for 2010/11.

13.7 National Framework for Reporting and Learning from Serious Untoward Incidents.

The electronic master copy of this document is held by Document Control, Office of the Medical Director, NL&G NHS Foundation Trust.
Appendix A

Northern Lincolnshire and Goole Hospitals NHS Foundation Trust

SERIOUS UNTOWARD INCIDENT (SUI) MANAGEMENT CHECKLIST – REVISED VERSION May 2011

This document is intended as an ‘aid memo’ for Directorate staff to be used throughout the management / investigation of an SUI. On completion of the SUI investigation, a copy of this checklist MUST be submitted to Risk Management along with the investigation / RCA report and action plan.

<table>
<thead>
<tr>
<th>Actions</th>
<th>Completed (Yes / No / N/A) &amp; Date (where applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUI REFERENCE NO.</td>
<td></td>
</tr>
<tr>
<td>Immediate Action:</td>
<td></td>
</tr>
<tr>
<td>o immediate safety and care of the people involved ensured;</td>
<td></td>
</tr>
<tr>
<td>o area made safe / scene preserved;</td>
<td></td>
</tr>
<tr>
<td>o patient / relatives informed and apology given (+ need for designation of ongoing ‘family liaison’ considered)</td>
<td></td>
</tr>
<tr>
<td>NB. Ensure documentation of discussions with patients / relatives – refer ‘Being Open Policy’;</td>
<td></td>
</tr>
<tr>
<td>o support mechanisms identified for staff involved and need for involvement of designated ‘Senior Clinical Counsellor’ considered to support staff through the ‘being open’ process;</td>
<td></td>
</tr>
<tr>
<td>o incident notified immediately to the Head of Governance or Trust Risk Manager or Site Manager (if out of hours) and to the relevant Director / appropriate staff within the Directorate.</td>
<td></td>
</tr>
<tr>
<td>NB. Initial report to central governance team to confirm whether incident involved a doctor in training to ensure notification to the relevant Foundation Director and the Y&amp;H Deanery (for F &amp; F1 doctors) to ensure support and learning. Where the incident involved other training grade doctor(s), the relevant Director / Clinical Director should be notified as part of existing Directorate escalation arrangements following SUIs;</td>
<td></td>
</tr>
<tr>
<td>o initial verbal reporting followed up with Incident Report Form.</td>
<td></td>
</tr>
</tbody>
</table>

‘Incident / Root Cause Analysis (RCA) Review Group’ convened particularly where large numbers of patients are involved and / or where the incident is cross-Directorate. NB. Where the incident involves another Branch / Business Unit or Directorate and where a Review Group is not convened – you MUST inform / involve the relevant staff within those areas, particularly where remedial action may be required.

Investigation / RCA commenced and statements and other relevant information / documentation obtained.

NB. Refer to NLS Incident Reporting Policy” (Appendix D – Incident Investigation), Root Cause Analysis Toolkit and Guidelines on Preparing a Statement.

Where incident involves large numbers of patients (e.g. patient recalls) need for the following considered:
| o setting up of ‘helpline’;                                           |                                                     |
| o designation of ‘incident room’;                                    |                                                     |
| o development of dedicated database                                  |                                                     |

Debrief / support / counselling offered to staff involved (and is ongoing as required).

Notification of incident to Branch Governance Group or Directorate equivalent.

Investigation / Root Cause Analysis completed & report and action plan (with leads and clear timescales) submitted within 6 – 8 week deadline.

NB. 1. Where an investigation is not completed within the required 6-8 week deadline, an interim progress report should be submitted including details of expected date of completion. 2. The final investigation report & action plan MUST have Director level sign-off.

Action plan being monitored via Branch Governance Group or Directorate equivalent.

Action plan implemented and all actions complete.

Lessons learned and any areas of ‘good practice’ shared (within immediate team & wider Directorate), as follows:

☐ Branch Governance Group   ☐ Staff / Team Meeting   ☐ Staff Newsletter

☐ Staff Notice Board   ☐ Other ......................................................... (please include)

The lessons learned arising from this incident are applicable to and have been shared with the following staff groups within the Ward / Department / Directorate (please list):

Outcome of investigation conveyed to patient / relatives – refer ‘Being Open Policy’;

Audit of actions agreed, as follows (please include the date the audit will be completed in the right hand column and details of the group or committee which will receive and monitor progress with the completion of any recommended action below):

Name & Designation of person completing this checklist.

Notes:
1. Not all of the above actions will be applicable to all SUIs – a judgement will therefore need to be made based on the individual circumstances of the incident.
2. This checklist is not intended to be exhaustive – please also refer to the full Policy for Dealing with Serious Untoward Incidents (Clinical & Non- Clinical) and other relevant documents referred to above as required.
Appendix B

SETTING UP & USE OF ‘HELPLINES’

1.0 Introduction

1.1 It is recognised that the setting up of advice/information helplines by NHS organisations can be invaluable where there is likely to be large-scale public concern generated over a health related issue. This will usually be following an adverse incident or series of adverse incidents within an organisation / the NHS (please also refer to the Trust’s Policy on the Management of Serious Untoward Incidents).

1.2 The primary purpose of a helpline will be to provide an immediate and accessible point of contact for the provision of information/reassurance to concerned patients and/or relatives who may be affected by a particular adverse incident or series of incidents. However, calls will also inevitably be received from patients / relatives / the wider public not directly affected but who may still be concerned.

1.3 Examples where a helpline may be used include:

- Healthcare worker found to be HIV positive
- Large scale public concern directed at a particular Trust but which impacts on other organisations within the NHS (e.g. organ retention issue)
- Large scale serious administrative and/or clinical errors affecting large numbers of patients (e.g. cervical cytology screening errors)
- Repeated serious complaints against an individual
- Closure of services/hospitals

1.4 This document has been provided as an ‘aide memoir’ where the setting up of a helpline is being considered within the Northern Lincolnshire and Goole Hospitals NHS Foundation Trust. Note: It will be the responsibility of the Non-Clinical Director or Directorate Director/Directorate Manager in charge of managing the situation/incident, in conjunction with other key staff involved, to decide whether a helpline needs to be established and for ensuring that the necessary arrangements are made.

2.0 Procedure

2.1 Ensure that the PR & Communications Manager is fully briefed on the issue/incident to ensure that he is prepared for media interest and can include the helpline number in any press release issued.

2.2 Co-ordinate the setting up of the helpline through the Switchboard as a dedicated/new number and extra phone lines may be required to be installed. Switchboard will also need to be aware so that any calls that are received on the general hospital number or by other areas can be re-directed to the designated helpline number.
2.3 Consideration will need to be given to the anticipated number of calls as this will dictate the hours during which the helpline may need to be available/which office the helpline is managed from (if this is different from the ‘incident room’ – see section 6.4 of the Trust’s ‘Policy on the Management of Serious Untoward Incidents’)/how many handsets/staff to manage the calls will be required. The length of time the helpline needs to remain in place should be kept under review. Depending on the number of calls and the duration of the helpline arrangements, a staffing rota may need to be devised.

2.4 Dependent on the issue/circumstances or where it may not be possible to provide an immediate response to callers, a recognised approach is to have ‘front line’ staff taking the calls/details with a view to the caller being contacted at a later time/date with a response. Clinical staff may however need to be on stand by to answer queries where the caller may be distressed and/or requires an immediate response/reassurance. Again this will depend on the circumstances of the issue/incident. A judgement will also be required as to whether the circumstances of the incident dictate the need for clinical staff to take the calls.

2.5 Where ‘front line’ staff are taking the calls, ensure that the staff concerned have been fully briefed on the issue/incident, are prepared and able to deal with potentially difficult/distressed callers and know the answers which they are permitted to provide. It may be helpful to provide a list of Q&As and a copy of the press release to the staff concerned.

2.6 Ensure that a call proforma is available (see section 3 below). This will ensure that the maximum amount of relevant information on the call/caller is collected for reference/record/learning and follow-up and to ensure that a thorough response to all issues raised can be provided. **Note:** Details of any advice/information given at the time of the call should also be recorded on the pro-forma. Similarly any subsequent communication with/correspondence to callers should be retained (with the incident file) for future reference/record. Consideration should also be given to developing a database of calls received/information given or alternatively including this information on the database set up as part of the management of the wider serious untoward incident (see section 6.5 of the Trust’s ‘Policy on the Management of Serious Untoward Incidents’).

2.7 Where a full response cannot be given at the time of the initial call, it should be confirmed with the caller how they wish subsequent information communicating to them. This could be via a telephone call, face to face meeting or in writing. **Note:** Where face-to-face meetings are planned, particularly off site, care should be taken to ensure the safety of the staff involved (i.e. the use of lone staff should be avoided).

2.8 Where the caller has requested a written response to their enquiry, consideration should be given to the postal arrangements for this correspondence. For example, where the content of this correspondence is likely to cause significant distress, consideration should be given to the correspondence being ‘double enveloped’. The inner envelope should contain the correspondence, the outer a letter explaining that the content of the correspondence in the inner envelope may cause distress and that consideration may need to be given by the recipient to having a relative/friend present for emotional support when opening. The letter in the outer envelope could also contain a telephone number to ring for access to counselling or support (if different to the helpline number). This method was used to respond to callers to the Trust’s Organ Retention Helpline. **Note:** The use of this method would be the exception rather than the norm. The timing of the sending of the
correspondence should also be considered (e.g. where possible avoid sending correspondence which is likely to arrive over a weekend unless the helpline is still in place or other arrangements are in place to ensure that there is someone available to take follow-up calls from distressed/anxious callers).

2.9 Where the issue affects more than one organisation, agreement will need to be reached as to who will manage the helpline so as to avoid confusion.

2.10 It is essential that Caldicott principles be adhered to at all times throughout the handling of helpline enquiries. Issues which may need to be considered include:

- Where someone is calling on behalf of an affected patient, care must be taken to ensure that the patient is aware of the enquiry and consents to the release of information to the caller;

- Where information may need to be passed to other agencies, the patient’s consent for this should be obtained save in exceptional circumstances. *(Note: There may be occasions where it is necessary in the patient best interests to disclose the information e.g. where there are possible child abuse allegations. Each case should be carefully considered.)*

- Where information from the helpline is subsequently collated for the purposes of ‘learning lessons’/’closing the loop’, care should be taken to anonymise this information;

**NB.**  *Patient identifiable information should only be shared on a strict ‘need to know’ basis.*

2.11 Dependent on the circumstances of the issue/incident, the staff manning the helpline may require support and/or counselling. This should be managed/monitored throughout the period that the helpline is in place and at the conclusion of the exercise. *Note: Please refer to HR for details of the counselling services available to the Trust (‘Confidential Care’).*

2.12 Further advice/assistance on the setting up of helplines can be obtained from within the Head of Governance and from the PR & Communications Manager (where the relevant staff are not already aware and involved with the issue).

3.0 **Helpline Pro-forma**

3.1 The pro-forma attached at Appendix C is an example of a form which has been used by the Trust where previous helplines have been put in place. This form can be used or adapted to suit the particular circumstances of the situation or incident.
## HELPLINE PRO-FORMA

### CALLER DETAILS

**CALLER**

**CALLER’S NAME & ADDRESS**

**DAYTIME PHONE NO:**   **EVENING PHONE NO:**

**DATE OF CALL:**   **TIME OF CALL:**   **(am/pm)**

**RELATIONSHIP TO PATIENT**

(NB. Is patient aware of call?)  **YES**  **NO**

**CALL TAKEN BY**

### PATIENT DETAILS

**PATIENT’S NAME & ADDRESS**

**DAYTIME PHONE NO:**   **EVENING PHONE NO:**

**HOSPITAL UNIT NO:**   **NAME OF GP:**

**CONSULTANT PATIENT UNDER:**

**HOW CONCERNS RAISED (as applicable)**

(a) I am one of the affected patients and was contacted by the Trust/my GP
(b) I am the relative of one of the affected patients
(c) I heard the news on the radio
(d) I saw the news on the TV
(e) I read the news in the paper
(f) Someone told me the news

Call referred to:  **(if applicable)**

---

Printed copies valid only if separately controlled
<table>
<thead>
<tr>
<th>ISSUES RAISED</th>
<th>RESPONSE GIVEN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OUTCOME:**

1. Caller satisfied - no further information required

2. Where response could not be given at time of initial call, does the patient want:
   - ☐ telephone response
   - ☐ written response
   - ☐ face to face meeting

Has patient/caller previously raised these issues. If so with whom/when/outcome, please detail:

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________