Healthier Communities, Outstanding Care

INCIDENT REPORTING POLICY

POLICY

Reference	G/IR-01
Approving Body	Patient Safety Committee
Date Approved	November 2023
For publication to external SFH website	**Positive confirmation received from the approving body that the content does not risk the safety of patients or the public:**

YES	NO	N/A
X		

Issue Date	February 2024
Version	V8.0
Summary of Changes from Previous Version	• Review and update undertaken to bring into line with Patient Safety Incident Response Framework and the Trusts Patient Safety Incident Response plan. • Job titles/ roles and Trust committee/ group names updated as applicable. • Roles and responsibilities updated to reflect current requirements. • Appendix A (PSIRF Flow Chart)
Supersedes	V7.0
Document Category	• Governance
Consultation Undertaken	• Clinical Director for Patient Safety • Deputy Director of Nursing Quality & Governance • Quality Governance Leads • PSIRF Implementation Group • Divisional Leadership Teams • Datix Manager • Associate Director of Nursing, Patient Experience and Complaints • Patient Safety Partners
Date of Completion of Equality Impact Assessment	October 2023
Date of Environmental Impact Assessment (if applicable)	Not Applicable
Legal and/or Accreditation Implications	Regulatory requirement with CQC
Target Audience	• This document will apply to all staff, contract staff and third parties working on behalf of the Trust. It applies to all areas in support of the Trust's business objectives both clinical and corporate. • The policy applies to all premises owned and operated by the Trust, or at other locations where work is carried out by or on behalf of the Trust. The policy also applies where employees are required to work in the community or travel between locations as part of their job.
Review Date	October 2026
Sponsor (Position)	Medical Director
Author (Position & Name)	Director of Nursing Quality & Governance Candice Smith

Lead Division/ Directorate	Corporate
Lead Specialty/ Service/ Department	Nursing/ Governance Support Unit
Position of Person able to provide Further Guidance/Information	• Director of Nursing Quality & Governance • Quality Governance Leads

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
• CSTO Serious Incident SOP • Medicine Division Serious Incident SOP • Surgery Division Serious Incident SOP • Urgent and Emergency Care Division Serious Incident SOP • Women and Children's Division Incident, Trigger and Serious Incident Process SOP • PSIRF policy • PSIRP • Mortality Management Policy (Learning from deaths) • Duty of Candour Policy • Risk Management and Assurance Policy • Maternity Services Risk Management Procedure • Speaking Up Policy (previously Raising Concerns – Whistleblowing Policy and Procedure) • Information Governance Policy • Management of Work Related Stress Policy **TOOLKIT** • Datix Incident Reporting Form (DIF-1) (Hard copy form to use for business continuity purposes)	All in date at time of this review/ update The toolkit provides the standard/ specialist subject scoping and investigation report templates and other additional guidance for staff – all have been reviewed and updated where necessary during 2020 and 2021. All are in-date. Last updated Feb 2020
Template control	June 2020

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1.0 INTRODUCTION

1.1 This policy is issued and maintained by the Medical Director (the sponsor) on behalf of the Trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.

1.2 This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Sherwood Forests Hospitals NHS Foundation Trust (hereafter referred to as 'the Trust') approach to developing and maintaining effective systems and processes for reporting and responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

1.3 The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management. This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF:

- compassionate engagement and involvement of those affected by patient safety incidents.
- application of a range of system-based approaches to learning from patient safety incidents.
- considered and proportionate responses to patient safety incidents and safety issues.
- supportive oversight focused on strengthening response system functioning and improvement.

1.4 In accordance with national guidance and legislation, the Trust is required to record all incidents (adverse events / patient safety incidents) and 'near misses', which may be observed and reported by staff/patients or the general public, whether they are:

- major/ minor;
- clinical or non-clinical;
- affect one person or more persons and related to patients, staff, students, contractors or visitors to the Trust premises;

1.5 The Trust is committed to identifying incidents and near misses to enable the Trust to identify opportunities for learning from reported incidents, and ensure appropriate action is taken to avoid recurrence, including making changes to practice, systems and process, and/or the environment to improve patient, staff and public safety

This policy together with its associated standard operating procedures (which describe the divisional processes) and toolkit (which includes additional guidance and scoping/ investigation templates), is intended to ensure that:

- All incidents or 'near misses' which occur on Trust premises or in the course of the employees duties are recorded.
- Incidents or 'near misses' are investigated at an appropriate level.
- Action is taken to prevent or reduce the risk of reoccurrence.
- A prompt and accurate report of incidents and 'near misses' are made available to appropriate external agencies.
- Staff who may have been directly or indirectly affected by the incident are supported.
- The Trust enacts it responsibilities to the Duty of Candour in relation to being open with patients and or their family/representative, commissioners, inspectors and regulators.

1.6 The following external documents must be used in conjunction with this policy:

1. Never Event list 2018 (NHS Improvement, 2018) last updated Feb 2021
2. Never Events Policy and Framework (NHS Improvement, revised January 2018)

2.0 POLICY STATEMENT

2.1 The Trust aims to take an integrated approach to learning from all incidents in order to improve its services, whether clinical or non-clinical.
The Trust is committed to ensuring an effective approach to the reporting, investigating, learning lessons, implementing and sustaining change as a result of investigation findings and analysis of incidents in order to provide safe, high-quality care to our patients and a safe environment for our staff and members of the public. The Trust recognises that identifying risks and ensuring these are managed effectively, provides opportunities to improve patient care and safety.

2.2 The Patient Safety Incident Response Framework (PSIRF, 2020) provides the NHS with guidance on how to respond to patient safety incidents; with no distinction between incidents and 'serious incidents' for the purpose of learning. As such, it is relevant to all bodies involved in providing; commissioning, supporting, overseeing and regulating NHS-funded care.
Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

2.3 A patient safety incident is investigated or reviewed under this framework to understand the circumstances that led to it, for the purpose of system learning and improvement. There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes, such as claims handling, invited external reviews, human resources investigations into employment concerns, professional standards investigations, coronial inquests and criminal investigations, exist for that purpose. The principle aims of each of these processes differ from those of a patient safety response and are outside the scope of this policy. Where there are legitimate concerns about individual and/or organisational accountability including criminal or civil proceedings, disciplinary procedures, employment law, or professional standards and organisational or professional regulators need to be involved, they must be informed, and their relevant protocols.
This policy applies to all permanent and temporary staff employed, or those working under contract for services or under service level agreement, within the Trust. The policy also describes the arrangements for the management of incidents where more than one provider is involved.

2.4 The initial recording and review of these incidents will follow the process outlined in this policy. The level of investigation will be determined in line with the Trusts Patient Safety Incident Response Plan (PSIRP)

2.5 Some incidents with wider implications are to be reported to various outside agencies. Executive leads, with the support of the Governance Support Unit (GSU), will report according to the process detailed within this policy and the PSIRP.

2.6 All staff work to fulfil the Trust's commitment to the Trust vision for healthier communities and outstanding care for all to the best of their ability and within available resources. Occasionally despite our best efforts things go wrong and it is important to emphasise that the Incident Reporting Policy is about promoting a just, fair and responsible culture which fosters learning and improvements as a result of mistakes.

2.7 Being open and honest with the patient and or their representative that an incident has

occurred is an integral part of incident management. For further information see the Trust's Duty of Candour Policy.

2.8 The Trust is committed to adhering to a just culture, yet we reserve the option to apply the disciplinary policy if deemed necessary.

3.0 DEFINITIONS/ ABBREVIATIONS

3.1 Definitions	
The Trust / SFHFT	Means Sherwood Forest Hospitals NHS Foundation Trust
Staff	Means all employees of the Trust including those managed by a third party organisation on behalf of the Trust
Duty of Candour	Principles that healthcare staff should use when communicating with patients, their families and carers following an incident.
Adverse Event	Any untoward medical occurrence in a patient.
Hazard	Means a source of potential harm or a situation with a potential to cause loss.
Patient Safety Incident	Any unintended or unexpected incident(s) that could have or did lead to harm for one or more person(s) receiving NHS funded healthcare.
Near Miss	Means any event, which does not, but has the potential to result in harm, injury, damage or loss.
Incident	Means any event that has given, or may give rise to actual or possible personal injury, to patient dissatisfaction, or to property loss or damage
Never Event	Never Event is an incident that meets the criteria of the Never Events list and is a serious largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.
DIF 1	Datix Incident Form 1 (for reporting an incident)
DIF 2	Datix Incident Form 2 (management form to log the investigation)
3.2 Abbreviations	
ASMS	Accredited Security Management Specialist
CQC	Care Quality Commission
DOC	Duty of Candour
GSU	Governance Support Unit
HSSIB	Health Service Safety Investigation Body
MNSI	Maternity and Newborn Safety Investigations Special Health Authority
ICB	Integrated Care Board
IRMER	Ionising Radiation (Medical Exposures) Regulations
MASH	Multi-Agency Safeguarding Hub
MHRA	Medicines and Healthcare products Regulatory Agency
NHSI	NHS Improvement
NPSA	National Patient Safety Agency.
NRLS	National Reporting and Learning Systems
LFPSE	Learning From Patient Safety Events
PSC	Patient Safety Committee
PSII	Patient Safety Incident Investigation
PSIRF	Patient Safety Incident Response Framework
PSIRP	Patient Safety Incident Response Plan
QC	Quality Committee
PSIRG	Patient Safety Incident Review Group
SABRE	Serious Adverse Blood Reactions and Events
SHOT	Serious Hazards of Transfusion Scheme

PSIRF	Patient Safety Incident Response Framework
StEIS	Strategic Executive Information System

4.0 ROLES AND RESPONSIBILITIES

4.1 Chief Executive

- The Chief Executive has overall responsibility for the management of health and safety and being open within the Trust. The Chief Executive has delegated responsibility for the incident reporting systems within the Trust to the Medical Director.

4.2 Medical Director/Chief Nurse

- Under the Trust's scheme for delegation, the Medical Director has overall responsibility for ensuring that the Trust has a system in place for reporting, recording and analysing incidents.
- The responsibility for defining and verifying an adverse event as a PSII rests with either the Chief Nurse or the Medical Director (or their Deputy in their absence) as part of the PSIRP.
- The responsibility for the sign off for PSII rests with either the Chief Nurse or the Medical Director (or their Deputy in their absence)

4.3 Director of Nursing Quality & Governance

- Develop strategies, design and implement systems to raise awareness of incident reporting, risk assessment, risk registers, investigation processes including training in learning response tools and implementing the 'Being Open and Duty of Candour Policy

- Manage the Trust's central Incident reporting database 'Datix' to ensure access to timely and accurate information on the Trust Incident profile and in mandatory reporting to external agencies e.g. Learning from Patient Safety Events Service (LFPSE).

- Oversight of the development and management of the PSIRP within the Trust. Along with the Chief Nurse and Medical Director, responsible for advising the Care Quality Commission and NHS England about incidents where applicable.

- In conjunction with Human Resources and Organisational Development colleagues, create and provide an appropriate just and restorative learning culture and support infrastructure for staff involved in incidents.

4.4 Patient Safety Partners

As part of our commitment to working with members of the public we have embarked on a Patient Safety Partner (PSP) programme. This is where members of the public support our Quality and Safety Improvement work.
Initially starting with four PSP's, those who support us in Safety and Quality Improvement have expectations as part of their contribution to the PSIRF to:

- Undertake the training required to the national standard for their role as specified in the National Patient Safety Syllabus as well as other relevant training.
- Be active members of oversight groups, committees and workstreams with the aim of helping us design safer systems of care and prioritise risk.
- Co-design information material for patients and the public.
- Encourage Patients, Families and Carers to play an active role in their safety.

- Contribute to safety recommendations following investigation, particularly around actions that address the needs of patients.

4.5 Governance Support Unit

- Screen reported incidents within 2 working days and where possible verify the severity coding of incidents to help detect incidents that required further investigation or significant trends and themes that required investigation / escalation to the Divisional Governance Forums**.**

- Support the process of discharging the Trust's Duty of Candour in relation to incidents that require investigation. Following an incident the Governance Support Unit may be required to assist other key stakeholders in their investigation as appropriate.

- Review and identify complaints that require further investigation / inclusion into thematic reviews. Where necessary an incident will be raised on Datix and managed accordingly. Will provide a level of validation of the management of incidents by handlers.

- Ensure the appropriate internal and external reporting is carried out and the investigation commences in accordance with this policy and procedure.

- Analyse trends and triangulate incidents, claims, learning from Death and complaints data in order to identify key risk themes and subsequently ensure these are assessed and managed, added to the Datix Risk Register as appropriate and considered for inclusion in the trusts Patient Safety Incident Response Plan (PSIRP)

- Manage the processes for sharing incidents that require further investigation by other NHS providers.

- Monitor and manage a process through the clinical governance forums to ensure actions have been progressed through to closure and fully implemented as necessary. Timely completion of actions will be monitored and escalated through the Trust's Quality Assurance groups via the Patient Safety Committee Quality Metrics Dashboard.

- Support staff to undertake annual Continuing Professional Development relating to PSIRF.

- Establish processes to ensure incident analysis reports provide themes and trends that enable the Board, Executive Teams and Divisions to ensure the effective management of risks associated with incident trends.

4.6 Patient Safety Committee

- The Patient Safety Committee (PSC) has oversight of the highlight reports. The committee should feedback at each meeting on our progress against the PSIRP. Where there are concerns about the robustness of actions identified, or the progress on implementation, the Chair of PSC will seek assurances from the divisions that risks are being adequately addressed. Where there are remaining concerns these will be escalated to the Quality Committee.

4.7 Quality Committee

- The Quality Committee has responsibility to seek and gain assurance that the actions and learning resulting from patient safety incident investigations are appropriate and timely and any challenges to implementation are escalated. The Committee should feedback at each meeting on our progress against this PSIRP.

4.8 Patient Safety Incident Review Group

- PSIRG is a multi-disciplinary forum to review incidents warranting escalation beyond divisions due to them meeting the criteria for further response detailed in the trusts PSIRP. It will meet weekly to discuss incidents escalated by Divisional leadership teams for consideration for a PSII.

- PSIRG will oversee that the most effective proportionate learning response tool is selected and triangulate Incidents, Inquests and any complaints linked to these, to ensure they meet all statutory requirements and have clear key lines of enquiry for the review.

- PSIRG will review and comment on all draft PSII reports to ensure that they have met with the terms of reference, meet the national standards required and sign off completed PSII reports. By doing so will accept the safety recommendations made and ensure these inform the transformation and quality improvement work of the organisation

- The ICB will be represented at this group to enable them to have oversight of the learning response activity being undertaken and to identify incidents or issues that require a cross-system learning response.

- The PSIRF oversight group will meet quarterly to review the incidents within their divisions within the last quarter.

4.9 Divisional Leadership Teams

- Divisional leadership teams are required to foster a culture of shared learning from incidents and encourage all disciplines to report incidents and near misses via the Datix incident reporting system.

- Ensure that each ward and department has a nominated handler and deputies for the management of the incidents through the Datix incident reporting system, for receiving and taking action on incident reports.

- Are responsible for establishing Clinical Governance Forums at divisional and specialty level which will receive incident reports and action appropriately

- Are responsible for assessing incidents against the PSIRP and identifying (with assistance from the GSU) the appropriate response. Notes will be taken of the discussion, decision and rationale for the selected learning response which will be kept with the incident record on Datix.

- Have an oversight of Patient Safety incident Investigations (PSII's) incidents that met the national priority for escalation and thematic reviews that directly and indirectly affect their areas of responsibility.

- Have systems and processes in place at divisional level for approval of investigation reports including those requiring subsequent submission for executive sign off at the trusts Patient Safety Incident Review Group (PSIRG)

- Oversee that the most effective proportionate learning response tool is selected and triangulate incidents, inquests and any complaints linked to these, to ensure they meet all statutory requirements and have clear key lines of enquiry for the review

- Will have systems and processes in place to monitor the completion of action plans and sign off the evidence as applicable.

- Where appropriate introduce a programme of audit or monitoring to ensure that changes as agreed in the action plans are embedded within practice.

- Ensure incidents are escalated to the appropriate department in order to be reported externally as required e.g., SHOT, IRMER, HSIB and that the relevant specialist is involved in the investigation.

4.10 Heads of Service

- Heads of Service must ensure that they, and the staff for whom they are responsible, are fully aware of the Trust's Incident Reporting Policy, The PSIRP and that staff are able to report incidents using the Datix incident reporting system accessed via the homepage of the Trust intranet site.

- Heads of Service with the Support of the Specialty Clinical Governance Lead/ Handlers will investigate incidents as appropriate and have systems and processes in place at specialty level to monitor the completion of actions plans for local investigations.

- Heads of Service are responsible for ensuring Clinical Governance Forums are taking place at specialty level which will receive incident reports and action appropriately and escalate concerns to the Divisional Clinical Governance Forums as necessary.

4.11 Line Managers

- Line managers must ensure that they and the staff for whom they are responsible are fully aware of the Trust's Incident Reporting Policy, The PSIRP and that staff are able to report incidents using the Datix incident reporting system access via the Trust intranet site.
- Ensuring incident reporting arrangements are implemented within their service areas. Following an incident, take immediate action within the scope of their remit to prevent recurrence and/or eliminate or reduce any identified risks i.e. make the individual or environment safe.

- Line managers or their designated deputy will provide support for staff that have been affected by an incident, encouraging an 'open, just and restorative' culture within their service area Support can be found via the Trust's Occupational Health or counseling

services, as well as the Trust's Policy for Managing Work Related Stress. Where incidents meet TriM criteria line managers can refer the staff to the TriM team for ongoing support.

4.12 Specialist Leads

- The specialists will be able to view the incident and it is their role to support the investigation as required or on the request of the handler.

- Specialist leads when assigned to lead the investigation have the responsibility to complete investigations within the agreed time frame.

- Specialists will receive email notification of incidents that fall within their areas of responsibility or specialist knowledge. The name of the specialist lead is made available to the handler through the notifications list within the DIF2 investigation form.

- All communications should be completed through the communication section within the Datix incident reporting system; this will ensure an auditable evidence trail.

- Specialists are required to ensure incidents are reported externally as required e.g., SHOT, IRMER, HSIB

4.13 Reporter (all staff groups)

- The reporter will report an incident or near miss as close to the incident as possible and identify the level of harm and the severity of the incident. Guidance is available on SFHFT intranet via the Datix incident reporting system home page.

- The reporter has the responsibility of ensuring that any consequence of the incident is assessed to reduce any risks that may endanger patients, employees or members of the public. The assessment of the situation should be delegated to the most senior member of the Ward/Department.

- All staff groups must ensure that appropriate escalation of incidents should be completed in a time sensitive manner, through the Trust's management structures. This will enable the most senior member of staff to judge if the incident requires escalation outside the immediate ward or department.

- Once the investigation into the incident/near miss has taken place the reporter should expect to receive feedback from the Handler with regard to action taken and lessons learnt. The reporter should only use their NHS.net account when completing the DIF1 as feedback can only be given to a secure email address to prevent an information governance breach.

4.14 Datix System Manager

- The role of the Datix System Manager is to act as the in-house expert for the Datix incident reporting system and provide on-going support and training on the use of the system. This includes ensuring optimum and innovative use of the system, data analysis, supporting the production of reports (with the emphasis on training individuals to access reports) and improving data quality. The Datix System Manager is to ensure all reporting complies with requirements of external agencies e.g. NRLS / LFPSE whilst maintaining the integrity and security of the Datix incident reporting system.

5.0 APPROVAL

This policy (v7.1) has been approved by the Trust's Patient Safety Committee.

6.0 DOCUMENT REQUIREMENTS (POLICY NARRATIVE)

Please also use the relevant divisional standard operating procedures in conjunction with this policy:

1. CSTO Serious Incident SOP
2. Medicine Division Serious Incident SOP
3. Surgery Division Serious Incident SOP
4. Urgent and Emergency Care Division Serious Incident SOP
5. Women and Children's Division Incident, Trigger and Serious Incident Process SOP

6.1 How to Raise and Manage an Incident on the Datix Incident Reporting System

Identifying an incident or near miss is the first stage of risk management. Immediate action to be taken following an incident is described below.

Any member of staff present when an incident is discovered must take immediate action to reduce further risk and in maintaining safety, ensure that their own safety is not compromised.

Once the immediate situation has been addressed, it is the responsibility of all members of staff to bring an incident or near miss to the attention of the most senior member of staff on duty in the designated area.

The following factors should be taken into account in order to determine the necessary escalation:

- The extent of harm caused and the immediate first aid and support needed to the injured or traumatised
- The adequacy of the immediate nursing, medical and management response, and the need for specialist advice/support
- The safety of the situation and the potential for further harm
- The need to inform the patient/s and or their family/representative.
- The need to support service users, staff and others affected by the incident.

The Trust has implemented the Datix incident reporting system which is accessed through the intranet homepage using the following icon: 

All incidents and near misses should be reported on the Datix incident reporting system as close to the time of the incident as practicably possible. To support the interrogation of trends and themes the reporter is required to allocate the incident a category and sub-category. As the reporter is usually the person who witnessed the incident they are in a unique position in understanding the events.

Having the correct category and sub-category supports the process of mapping the Trust's patient related incidents to the national data base

Assistance for completing the initial DIF1 can be accessed here: How to report an incident.

6.2 General Incident Reporting Procedure

As a minimum all mandatory fields marked by a red asterisk on the online Datix form must be completed. These include:

- Nature of incident is (e.g. actual event or near miss - wrong drug given, delay in patient

receiving treatment).

- What happened (severity of actual or potential harm, people and equipment involved)
- Who was affected by the incident (patient's name, hospital number, date of birth, etc.
- If the person affected is a staff member it is not necessary to include details of their home address or date of birth etc). person reporting the incident. where did it happen (location/speciality).
- When did it happen (date and time). how did it happen (immediate or proximal causes). what action was taken or proposed (managers actions - immediate and longer term).
- Any documents capturing a staff members recollection of events provided should be legible, signed, dated and timed and must be attached to the Datix system.
- Where urgent action is indicated out of hours, the Site Manager should be informed who may need to escalate to the manager on-call. Where the incident involves a patient or visitor, a member of staff will complete the online incident form.

Indicative level of harm assigned following the NRLS levels of harm guidance, which is on the Datix form, this will change to LFPSE levels of harm guidance when published

6.3 Reporting incidents resulting in severe harm or death

In addition to the completion of an incident form the member of staff should:

- Report the incident immediately and verbally to the most senior manager of the department or service. For out of hours this will include the Site Manager, who will contact the Director on call who will escalate to the Executive on Call.
- Keep a concise and contemporaneous record of events. This should include decisions taken and by whom, and details of any witnesses or conditions at the time ensure the physical security of all healthcare records making photocopies if necessary and any faulty equipment or other evidence in preparation for a full investigation.

The senior manager should: review the support that the patient and/or family members and staff require following the incident. Ensure staff involved or witness to the event document their recollection of events whilst they are fresh. Ensure staff and the patient, relative or carers are kept informed and supported through the event as necessary. Inform Divisional leadership teams and GSU.

For additional information see:

- Appendix A – PSIRF Flow chart

6.4 Never Events

All Never Events will be investigated as a Patient Safety Incident Investigations (PSII) in line with National Guidance and the trusts PSIRP, although not all Never Events necessarily result in serious harm or death. A Never Event is an incident that meets the criteria of the Never Events list and is a serious largely preventable patient safety incident that should not occur if the available preventative measures have been implemented.

See Revised NHS England Never Events Policy and Framework (NHS England, January 2021) for the national definition and further information

6.5 Reporting Incidents to the Medical Education Centre

The Trust is required to ensure incidents relating to *Doctors in Training* are fed through to the Medical Education Centre. To enact this, the Medical Lead will receive alerts from Datix and will take action as required.

6.6 NHS Screening Programmes & Screening Quality Assurance

Quality Assurance (QA) is the process of checking that national standards are met (ensuring that screening programmes are safe and effective) and encouraging continuous improvement.

NHSE is responsible for the NHS Screening Programmes and the Screening Quality Assurance Service (SQAS).

If any incidents occur relating to screening programmes then the following guidance should be considered alongside the trust procedures: Managing Safety Incidents in NHS Screening Programmes (updated 16th July 2021). The guidance applies to all organisations that provide NHS Screening Programmes in England whether an NHS trust, NHS foundation trust, general practitioner or private provider. A Screening Incident Assessment Form (updated June 2021) should be completed within 5 days of the suspected incident being identified.

The guidance details the accountabilities for reporting, investigating and managing NHS screening programme safety incidents.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Compliance with policy	Internal Audit	Internal Audit	Minimum every 3 years	Minimum every 3 years
Activity against agreed PSIRP	Activity and assurance reports	Activity and assurance reports	Monthly	PSC / QC
Compliance against PSR timelines	Performance and Assurance Framework	Performance and Assurance Framework	Monthly	Datix team

8.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix I
- This document is not subject to an Environmental Impact Assessment

9.0 EVIDENCE BASE (Relevant Legislation/ National Guidance)

Evidence Base:

Care Quality Commission (2009) Guidance about compliance with the Health and Social Care Act (registration Requirements) Regulations London: CQC
Care Quality Commission (2016), Briefing: 'Learning from serious incidents in NHS acute hospitals', a review of the quality of investigation reports, June.
Department of Health (2000) An organisation with a memory: Report of an expert group on learning from adverse events in the NHS. London: DH
Department of Health (2001) Building a Safer NHS for Patients: Implementing an organisation with a memory. London: DH
Department of Health (2008) High Quality Care for All - NHS Next Stage Review Final Report, London: DH
Department of Health (2008) instruction relating to information governance and data loss London: DH
Department of Health (2004) Chief medical Officer Annual Report, 2004.
Learning how to Learn - Compliance with Patient Safety Alerts in the NHS: London: DH
Department of Health (2006) Guidelines for the NHS: in support of the Memorandum of Understanding London: DH
Department of Health, Association of Chief Police Officers, Health and Safety Executive (2006) Memorandum of Understanding London: DH, ACPO, HSE Equality Act (2010), Gov.co.uk
Francis Report (2013), Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Gov.co.uk
Health & Safety Executive (2013) Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 [online] HSE.
Health and Safety Executive, Health and Safety Guidance (HSG) (93)13 Reporting incidents relating to medical devices.
Management of Health and Safety at Work Regulations 1992
National Patient Safety Agency (NPSA) (2004) Seven Steps to Patient Safety. London: NPSA
National Patient Safety Agency (2005) Building a Memory: preventing harm, reducing risks and protecting patient safety London: NPSA
National Patient Safety Agency (2004) Seven Steps to Patient Safety. London: NPSA
Parliamentary and Health Services Ombudsman (2016), 'Learning from Mistakes', July. NHS Patient Safety Strategy (2019) NHS England.
Patient Safety Incident Response Framework (2020) NHS England.
Policy Guidance on Recording Patient Safety Events and Levels of Harm (2023), NHS England

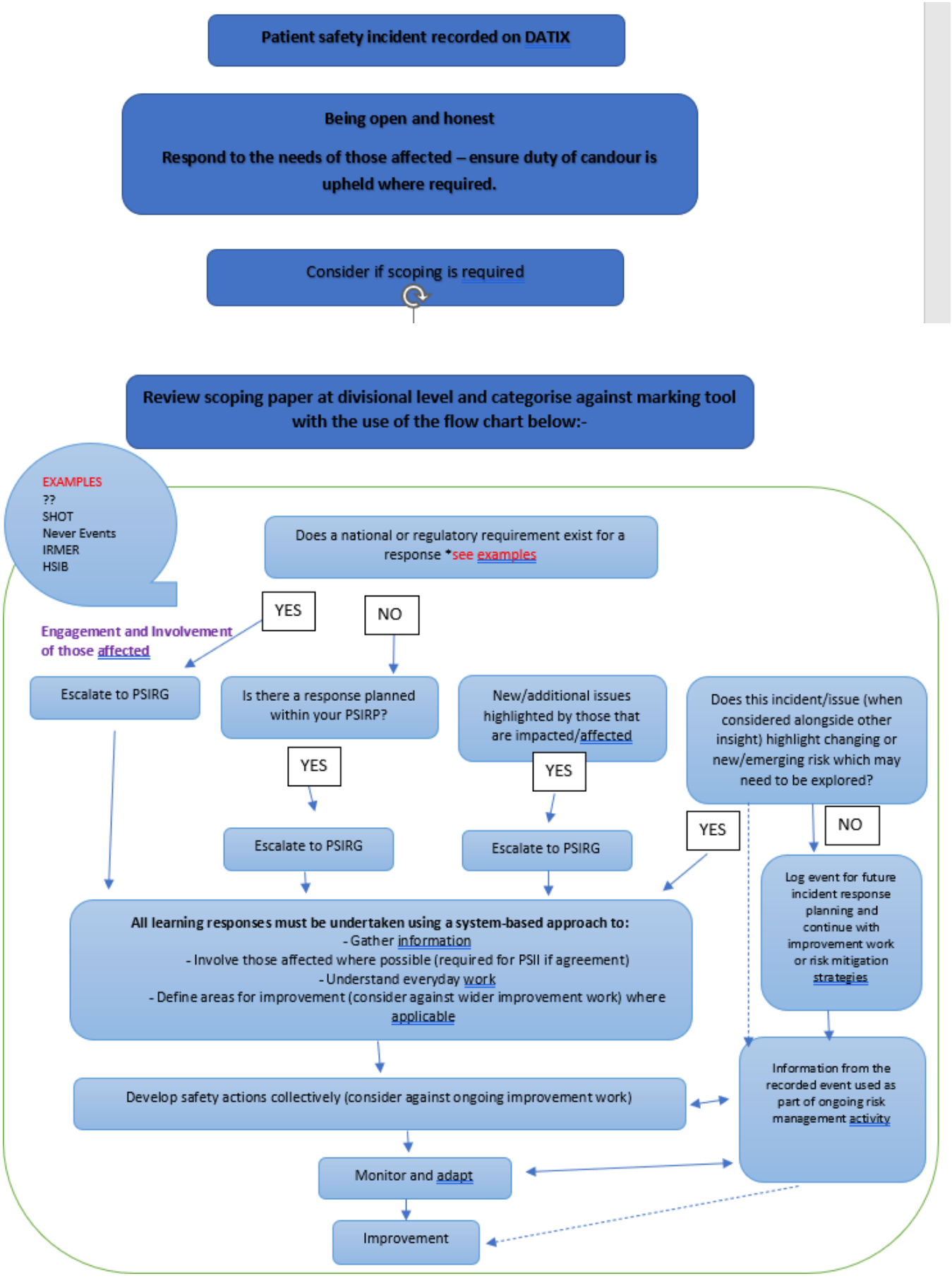
10. APPENDICES

Appendix A PSIRF Flow chart

Appendix B Guidance for the Coordination of Independent Investigations / Seeking an Expert Opinion.

Appendix C Safeguarding Section 42 and Section 47 Process

APPENDIX A – PSIRF FLOWCHART



Appendix B

Guidance for the Coordination of Independent Investigations / Seeking an Expert Opinion

1. Introduction

This guidance is intended to describe, and to clarify, the process for the coordination of independent investigations or occasions whereby an expert opinion is required to support an internal investigation; from the point of such an investigation being commissioned right through to the sign off of the resulting action plan as fully implemented.
The main objectives of the guidance are to ensure that:

- An Independent Investigator / Expert is properly supported in their role
- Trust staff receive appropriate support and advice
- Good communication takes place between all parties
- Recommendations are implemented in a timely and effective manner
- Risk to the Trust's reputation is minimised

The guidance is based on the current Trust Incident Reporting Policy and current implementation, monitoring and oversight practices, which in turn are informed by guidance from the National Patient Safety Agency (NPSA) and our commissioners.

2. Responsibilities

The Medical Director and the Chief Nurse are the Board leads for PSII's, including those high level investigations which may result in an independent investigations or whereby it is deemed an expert opinion will support the internal investigation process. In relation to concerns regarding fitness to practice the decision makers are the Medical Director, the Chief Nurse, the HR director and the Chief Executive. They have overall responsibility for coordination of investigations which are deemed to require an expert opinion, and will be supported by the Director of Nursing Safety, Quality and Governance / Clinical Director for Patient Safety and GSU Team.

The Patient Safety Incident Review Group receives all completed PSII reports and will include independent investigation reports on behalf of the Patient Safety Committee. The Patient Safety Committee is the Trust group with overall responsibility for monitoring the management of PSII's and for ensuring that learning takes place from all incidents.

3. Criteria for Independent Investigations

- Independent investigations are required where the integrity of the internal investigation and its findings are likely to be challenged or where it will be difficult for an organisation to conduct a proportionate and objective investigation internally due the individuals or number of organisations involved. Independent investigations avoid conflicts of interest and should be considered if such conflicts exist or are perceived to exist.

- An independent investigation can be used as a means of assessing whether an account of an incident has been fairly presented to give credit to the findings and assurance that lessons will be learnt to prevent recurrence, or it can be used to obtain an objective assessment of the nature and causes of an incident irrespective of whether or not any investigative work has been or is to be undertaken.

4. Commissioning the investigation

For those occasions when the Trust identifies that an external expert is necessary for providing assurance of oversight and remedial actions for example if there is concern that an event may represent significant systemic service failure or to supplement our own internal PSII investigation; this would be commissioned by the executive team after due consideration at the Patient Safety Incident Review Group.

5. Support and communication systems

When the Trust identifies there may need to be an independent investigation / expert opinion commissioned, staff should be informed and given information to describe the process.

When the Trust is notified by the ICB (or other external body) that an independent investigation is being commissioned, the GSU will inform all relevant staff/managers.

The executive team will discuss the support to be put in place for staff, including the need for specialist external advice. The exact nature of support to be put in place will vary according to the nature and scope of the independent investigation, and the circumstances of the particular incident. It may include some of the following:

- A briefing meeting at the outset of the investigation
- Provision of written information outlining the process
- Support in statement writing and at interviews
- Access to local managers/professional leads/executive directors
- Access to unions and professional bodies
- Access to the Employee Assistance Programme and occupational health services
- Individual meetings as appropriate
- A meeting prior to publication of the report

The Trust's Duty of Candour Policy will apply.

6. Initiating, conducting and supporting the investigation

At the outset of the scoping of the PSII investigation or at the Patient Safety Incident Review Group a meeting will be arranged with all stakeholders to agree timescales, ground rules, sharing of information and terms of reference. This will include specifically what information is shared with the expert to support their investigation for example, medical records, statements already obtained as part of initial investigation and access to any relevant clinical and non-clinical databases.

The GSU will be the Trust's lead contact for the investigation manager, and will ensure that all requests for documentation, meetings and other evidence is supplied in a timely manner.

The investigation manager will be requested to send any correspondence via GSU to individual staff and ensure appropriate support can be put in place for staff.

7. Receipt of the draft report

The Trust will be provided with a copy of the draft report and asked to respond to matters of factual accuracy. Any concerns regarding individual members of staff that are criticised in the report, will be shared with the executive team regarding fitness to practice. The staff member(s) will be given the opportunity to respond to the findings. A meeting will normally be held with the member of staff to support them during this stage of the process.

The Trust will receive a final draft, and will prepare an action plan in response to recommendations made (which are relevant to the Trust). This will be led by the Chief Executive, Chief Nurse, Medical Director, HR Director and any other relevant staff.

The Trust's response will be approved by the Medical Director and the Chief Nurse.

The final draft report and action plan will be submitted for formal Trust sign off to the Patient safety incident review Group and will be communicated to all members of staff interviewed during the investigation.

8. Implementing the action plan and monitoring implementation

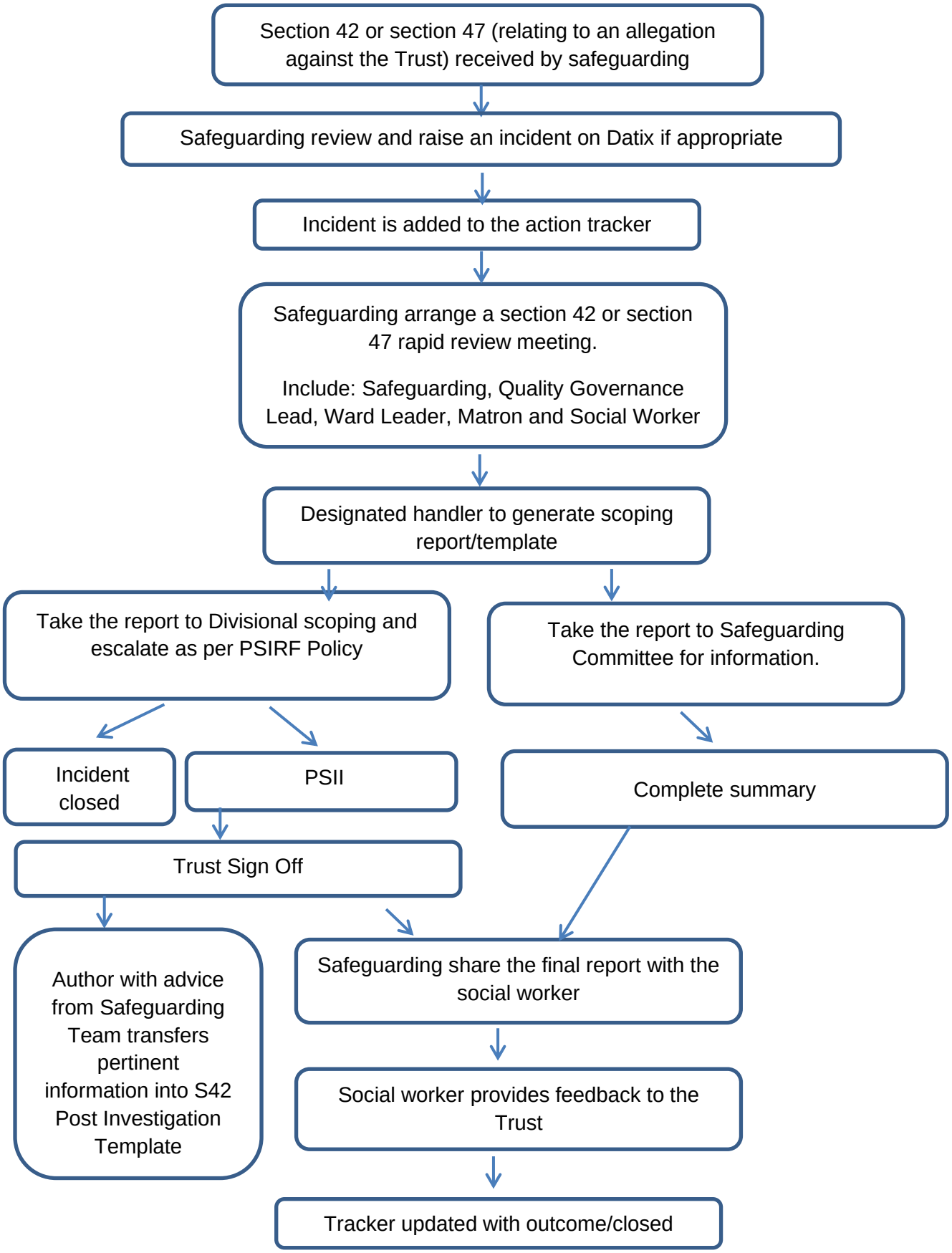
The responsibility for implementation of action plans sits with the respective Divisions/ Departments. GSU monitors and manages a process through the clinical governance forums to ensure actions have been progressed through to closure and fully implemented as necessary. Timely completion of actions will be monitored and escalated through the Trust's Quality Assurance groups via the Patient Safety Committee Quality Metrics Dashboard.

9. Archiving

All documentation relating to any investigation including independent investigations must be stored electronically on the Datix incident reporting system.

Appendix C

Safeguarding Section 42 and Section 47 Process



APPENDIX I – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: INCIDENT REPORTING POLICY			
New or existing service/policy/procedure: Existing			
Date of Assessment: New date			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None known	Applies to all patients irrespective of protected characteristic group.	None known
Gender	None known	As above	None known
Age	None known	As above	None known
Religion	None known	As above	None known
Disability	None known	As above	None known
Sexuality	None known	As above	None known
Pregnancy and Maternity	None known	As above	None known
Gender Reassignment	None known	As above	None known
Marriage and Civil Partnership	None known	As above	None known
Socio-Economic Factors (i.e. living	None known	As above	None known

in a poorer neighbourhood / social deprivation)			

What consultation with protected characteristic groups including patient groups have you carried out?

- **None required as the policy applies to all patients irrespective of protected characteristic group.**

What data or information did you use in support of this EqIA?

- **None required as the policy applies to all patients irrespective of protected characteristic group.**

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- **None**

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Candice Smith

Signature:

Date: New date