

Management of External Assessments Standard Operating Procedure

Date		Version
September 2016		Version 1.3
Purpose		
<p>This procedure identifies the process through which the Trust gains assurance that it is responding appropriately to the recommendations and requirements arising from all external assessments, (including visits, inspections, accreditations, surveys and reviews). The register of external assessments provides a formal record of the key details of each external assessment.</p>		
Who should read this document?		
<ul style="list-style-type: none"> Care Group and Service Line Management Teams. Clinical and non-clinical managers, because they are likely to be the staff group that will be responsible for the administration of an external review, or at a more senior level, will be responsible for the outcome of the review. 		
Key messages		
<p>The Trust needs to be assured that there are reliable procedures in place to facilitate the completion of external reviews specific to the Trust, to report the results of those reviews to appropriate monitoring and decision making groups within the Trust and to act on the recommendations made where appropriate. Appointed Lead officers need to ensure that they keep the register of external reviews up to date.</p>		
Accountabilities		
Production	Deputy Head of Quality Governance	
Review and approval	Quality Assurance Committee	
Ratification	Director of Nursing	
Dissemination	Audit, Assurance and Effectiveness Team	
Compliance	Quality Assurance Committee	
Links to other policies and procedures		
<p>Risk Management Policy Claims Handling Standard Operating Procedure Inquests Standard Operating Procedure Management and Implementation of National Guidance and Enquiries Policy Managing and Responding to Formal Complaints Standard Operating Procedure</p>		
Version History		
1.0	November 2011	Formalisation of procedure in response to NHSLA recommendation
1.1	June 2012	Minor amendment to include reference to the Inquests SOP and provide more detail of the monitoring arrangements.
1.2	March 2015	Minor amendment to reflect revised Governance arrangements
1.3	September 2016	Planned document review. Amendments to reflect Service Line and Care Group responsibilities, changes to linked policies and shared responsibility within the Audit, Assurance and Effectiveness Team for this process.
Last Approval		Due for Review

September 2016

September 2021

PHNT is committed to creating a fully inclusive and accessible service.

Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff.

We will treat people with dignity and respect, actively promote equality and diversity, and eliminate all forms of discrimination regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/ maternity.

An electronic version of this document is available on the Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

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1 Introduction

This document sets out the process for managing and responding to the recommendations and requirements arising from external agency visits, inspections and accreditations specific to Plymouth Hospitals Trust.

The Trust receives a wide range of reviews and assessments from a variety of external agencies. The results of these visits represent a significant potential source of learning and often expert guidance. The Trust recognises the need to maintain a robust process for coordinating and evaluating the work of external agency visits, inspections and accreditations, to maximise the potential benefits.

The process should also help to control the burden on the Trust, by reducing overlap and highlighting potential gaps in assurance to be identified and addressed. As part of the Trust's internal control system, it should provide assurance to the Board that the Trust is addressing the outcome of all external reviews appropriately.

This procedure also encompasses recommendations arising from opinion surveys carried out on aspects of the Trust's organisation and services.

2 Purpose

In many instances, accreditation and registration reviews are only locally relevant to specific service areas. As such, they should be addressed locally, by managers and sub-committees of the Trust, under delegated authorities. In many clinical environments, the process of quality assurance, accreditation and registration is integral to the day to day operations and systems of those services. Reference is made to existing documentation, where local arrangements are covered by a specific procedural document.

Other reviews and inspections are likely to have a wider reaching impact and will need to be addressed on a more Trust-wide basis.

This procedure recognises that the framework for managing and monitoring assurance from external agency reviews needs to accommodate both the local and Trust-wide needs. This procedure recognises also that the Trust needs to be assured that the outcomes of all external agency reviews are responded to appropriately; and escalated where necessary.

Accordingly, this procedure requires the maintenance of a register of all external agency reviews and defines, in Appendix 1, the minimum content of this register in detailing the arrangements for reporting assurance locally and for escalating outcomes and recommendations, where necessary. This procedure:

- identifies key sources of assurance that the Trust receives;
- documents how assurances received impacts on key Trust objectives as recorded in the Trust's assurance framework;
- specifies that identified sources of assurance are assessed to understand the level of assurance provided;

- specifies that the results of external agency reviews are reported to the relevant sub-committee, or formal group of the Board;
- identifies how potential gaps in assurance are identified and addressed; and
- specifies the audit trail from the external agency review to actions planned and delivered to address any recommendations arising.

The results of external investigations of specific adverse incidents, through reports and responses under Regulation 28 of the Coroners (Inquests) Regulations 2013 and the outcome of compensation claims against the Trust are addressed through the Claims Handling Standard Operating Procedure and the Inquests Standard Operating Procedure.

Similarly the outcome of Parliamentary and Health Service Ombudsman (PHSO) enquiries are addressed through the Managing and Responding to Formal Complaints Standard Operating Procedure.

The arrangements for learning from national confidential inquiries and enquiries are addressed in specific policies of the Trust and are therefore excluded from this SOP.

The Trust will use the results of external agency reviews to inform its risk and assurance framework, to seek assurance that recommendations from external agency reviews are being acted upon and that internal controls are in place and operating effectively. These assurances will inform the Trust's Statement on Internal Control.

3 Consequences of not complying with this Procedure

The Trust Board will be at risk of making, or approving decisions without having the benefit of the assurance gained from positive assessments, or an understanding of risks and improvement needs identified in critical assessments.

The Board will not be assured that the Trust's procedures are adequate, or that any control weaknesses identified are being addressed appropriately.

4 Definitions

- **External agency** - any organisation having a legitimate interest in the workings of the Trust and with which the Trust is required or requested to co-operate.
- **External agency review** - visits, audits, inspections and accreditations carried out by an external agency.
- **Accreditation / Registration** - a process in which certification of competency, authority, or credibility is presented. Normally, a periodic confirmation of accreditation is required to provide formal external authorisation for the service to continue to be delivered.
- **Inspection** – a formal review of aspects of the Trust's working arrangements, required by statute, or government regulations.
- **Audit** – a formal review completed by the Trust's internal or external audit providers.

- **Visit** – a semi-formal, or informal review of aspects of the Trust’s working arrangements, carried out by an external agency with expertise in the area of review.
- **Survey** – a process of collecting and analysing the views and experiences of groups and individuals who have experienced aspects of the Trust’s working arrangements.
- **Sub-committee (includes ‘groups’)** – a meeting of senior staff, which may include non-executive directors, established formally by the Trust, or under delegated authority by executive and associate directors of the Trust.
- **Register (of external agency reviews)** – the Trust’s record of all external agency reviews, providing details necessary to facilitate administration of the external review process, see Appendix 1.

5 Roles and Responsibilities

Trust Board and Chief Executive

The Trust Board is responsible for ensuring that the Trust has adequate systems and arrangements in place for ensuring and gaining assurance that all required external agency reviews are completed. It is responsible for ensuring that the outcomes of all external agency reviews are addressed appropriately, at Trust Board level, or under delegated authority by sub-committees of the Trust.

The Chief Executive is ultimately responsible for ensuring that the risks, controls, action plans and assurances are in place to address issues arising from external agency reviews. Responsibility for ensuring that this takes place is delegated to the Director of Nursing.

Quality Assurance Committee

The Quality Assurance Committee is responsible for seeking assurance, from the Director of Nursing and Deputy Head of Quality Governance, that the outcomes of all external agency reviews are addressed appropriately.

Director of Nursing

The director with responsibility for governance across the Trust is responsible for:

- ensuring that responsibility for each mandated external agency review is allocated to the most suitable director and through them to the relevant Care Group, formal working group, or committee; and
- providing annual reports to the Quality Assurance Committee on the progress of delivery of all external agency reviews.

Trust Directors

The relevant director provides oversight of the relevant statute, regulations, internal and external assessments that they are accountable for. The director may rely upon advice from the Care Group Management Teams, Appointed Lead or a nominated group or committee in overseeing the delivery of the external agency review and the Trust’s response to it.

A large number of reviews will be managed locally or within Service Lines with oversight at Care Group level as described below. Some will be Trust wide e.g. Care Quality Commission or there will be an expectation that the review will be managed at Trust corporate level for example Royal College reviews. A Director will have accountability for these reviews and will ensure that an appropriate Lead Officer and / or Group / Committee is appointed to manage the preparation for, and outcome of, such reviews.

Care Group Management Teams are accountable for ensuring that Service lines are responding appropriately to external agency reviews, both the preparation for review and the response to the outcome of a review.

Service Line Management Teams are responsible for overseeing the preparation for review, the response to the outcome of an external review and for providing assurance of this to the Care Group. They are responsible for ensuring that:

- a lead officer is appointed and informed of their responsibilities for managing the Trust's facilitation of the external agency review;
- any risks to the successful preparations for, or positive outcome of, an external agency review are assessed in line with the Trust's risk management framework and escalated through to the Care Group and Trust Board, as necessary;
- all required and commissioned external agency reviews are supported and facilitated adequately by the appointed lead, so that the maximum benefit can be gained from the minimum cost;
- all required and commissioned external agency reviews are completed and reported upon within required and agreed timescales and costs;
- the outcome of each external agency review, including positive reports, is considered, through receipt of reports and actions proposed;
- the results of each external agency review and any recommendations arising from it are addressed appropriately;
- any adverse conclusions and risks identified are assessed in line with the Trust's risk management framework and escalated through to the Care Group and Trust Board, as necessary;
- advice and support, on improving the impact and effectiveness of specific external agency reviews and the Trust's response to them, is provided to the appointed lead officer;
- relevant assurance gained is taken into account in service and organisational planning; and
- any opportunities for wider organisational learning are communicated and followed up appropriately.

These responsibilities will be assigned to the Care Group for reviews that encompass multiple services or to a relevant committee or group where the review sits outside the Service Line and Care Group structure.

Appointed Lead Officer

Each external agency review, listed in the register, must have a nominated lead officer identified against it. The lead officer is responsible for:

- informing the Audit, Assurance and Effectiveness Team (plh-tr.External-Assessments@nhs.net) of all new external agency reviews and providing the details required to complete the entry in the register;
- informing the Audit, Assurance and Effectiveness Team (plh-tr.External-Assessments@nhs.net) of any changes to the process of the external agency review, such as frequency of reviews, change in statutory/regulatory output of reviews, change in responsible sub-committee;
- informing the Service Line and Care Group Management Teams and Audit, Assurance and Effectiveness Team (or the Director of Nursing), immediately, of all unannounced external agency reviews;
- manage and maintain the process of the external agency review, including the schedule of review dates and timetable of the review;
- ensure that all systems recording data relevant to external agency review is kept up to date;
- coordinate the review of and agree the content and accuracy of reports produced by the external agency;
- report formally the results of the external agency review, including wholly positive outcomes, to the responsible sub-committee, within the timeframe agreed. Identify specifically any risks and recommendations identified that might have a wider impact on the Trust;
- send a copy of the responsible sub-committee minutes, recording its consideration of the outcome of the external agency review, to the Audit, Assurance and Effectiveness Team (plh-tr.External-Assessments@nhs.net);
- ensure that the Trust's risk register is populated with risks identified in the preparation for, or outcome of, external agency reviews, in accordance with the Trust's risk management policy; and
- manage the development and delivery of action plans to implement any recommendations made as a result of reviews and report progress against these to the responsible sub-committee, in line with the frequency set by that sub-committee.

Further responsibilities, relevant to the administration of the external review process, are set out in the section: Scheduling and managing visits.

Deputy Head of Quality Governance

Responsible to the Director of Nursing, the Deputy Head of Quality Governance has responsibility to ensure that the Audit, Assurance and Effectiveness Team:

- maintains the register of external agency reviews, including seeking annual confirmations and updates of records from each of the Trust's senior managers; and

- maintains a record of completed external agency reviews, reported to the responsible sub-committee. Seek explanation from the nominated lead officer for external agency reviews overdue, reviews not yet reported or agreed actions arising from reviews that have not been implemented within agreed timelines.

All members of staff

All staff are required to deliver the tasks allocated to them in line with expected quality outcome standards.

6 Identification of External Organisations

Through complying with this SOP, the Trust will maintain a register of all external agencies undertaking reviews specific to the Trust. This includes local inspections for specialist services as well as organisational reviews.

The following list, which is not exhaustive, identifies the types of external agencies that are likely to undertake reviews that should provide assurance to the Trust:

- Care Quality Commission.
- NHS commissioning and strategic bodies.
- External and internal audit (statutory and in-house audit programmes).
- United Kingdom Assurance Service.
- Health and Safety Executive.
- MHRA (Medicines and Healthcare Products Regulatory Agency) (compliance against legislation for Pharmacy, Blood Transfusion, Laboratory and all Research & Development practices).
- HTA (Human Tissue Authority) (compliance against legislation for all transplant activity, and storage / retention of all tissue and bone).

7 Scheduling and Managing Visits

Where possible, the nominated lead officer should seek to schedule external agency reviews so that they cause minimum disruption to work and do not overlap with other external or internal reviews of the same service area.

The nominated lead officer should prepare adequately for the external agency review. The approach to this is likely to vary according to the focus of the external agency review. However, the standard good practice that is expected to be followed and evidenced is shown in Appendix 2 for guidance.

In all instances, the nominated lead officer is required to agree a timetable for the key milestones of the external agency review, which will include:

- dates of visit;
- receipt of draft conclusions and recommendations;
- agreement of final conclusions and recommendations;
- preparation of action plan in response to the conclusions and recommendations; and
- presentation of the conclusions and recommendations and the Trust's action plan to address these, to the responsible sub-committee.

The nominated lead officer is required to review the findings and conclusions of the external agency review and seek expert confirmation, from within the Trust, of the accuracy of those findings and conclusions.

Once the findings and conclusions are agreed, the nominated lead officer is required to draw up an action plan to address the recommendations arising or any risks and gaps indicated by the findings and conclusions. This action plan will include timeframes and responsibilities for the delivery of the improvements identified.

The nominated lead officer is also required to enter any risks identified from the review and associated actions onto the Trust's (Datix) risk register, in accordance with the Trust's risk management framework.

The nominated lead officer is required to report immediately and directly to the responsible (executive) director, Service Line and Care Group Management Teams any significant breach of the expected outcome of external agency reviews, such as failed or qualified accreditations. The nominated lead must also inform the Deputy Head of Quality Governance at the earliest opportunity.

8 Monitoring and Reporting Compliance and Effectiveness

The Audit, Assurance and Effectiveness Team will continuously maintain and review the register of external agency reviews and request evidence of the outcome of completed external agency reviews, reporting of the outcome to the relevant sub-committee and where relevant, request copies of action plans developed in response to a review.

Action plans will be monitored by the Audit, Assurance and Effectiveness Team through to completion through monitoring of the relevant sub-committee meeting minutes. Explanation will be sought from the nominated lead officer for external agency reviews overdue, reviews not yet reported or agreed actions arising from reviews that have not been implemented within agreed timelines. Adverse developments, such as breaches in expected outcomes will be reported to the Director of Nursing as soon as they are notified to the Deputy Head of Quality Governance.

The Director of Nursing and Deputy Head of Quality Governance will provide reports to the Quality Assurance Committee, at least once per year, summarising the Trust's performance in addressing external agency reviews and highlighting

any significant issues arising from these reviews. The Quality Assurance Committee may seek confirmation, from the responsible (executive) director, Appointed Lead Officer or Care Group Management Team that action plans for addressing significant risks are being delivered within the timescales set.

The Board will receive reports by exception.

9 Consultation and Approval

The design and process of review and revision of this document will comply with the Trust's formal policy on policy and procedural documents (The Development and Management of Trust Wide Documents).

The review period for this document is set as five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the SOP.

This document will be approved by the Quality Assurance Committee and ratified by the Director of Nursing.

Non-significant amendments to this document may be made, under delegated authority from the Director of Nursing, by the Deputy Head of Quality Governance. These must be ratified by the Director of Nursing and should be reported, retrospectively, to the Quality Assurance Committee.

Significant reviews and revisions to this SOP will include an extensive consultation with all senior managers in the Trust, particularly those that have direct involvement in external agency reviews. For non-significant amendments, informal consultation will be restricted to staff groups who are directly affected by the proposed changes.

The expected minimum content of the register of external agency reviews is detailed in Appendix 1 to this policy. The actual register will be subject to ongoing review and update.

10 Dissemination and Implementation

Following approval and ratification, this document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

All nominated leads, identified in the register of external agency reviews, will be sent an electronic copy of the ratified document.

Document control arrangements will be in accordance with the Trust's formal policy on policy and procedural documents (The Development and Management of Trust Wide Documents).

11 References and Associated Trust Documentation

The following approved Trust documents should be referred to in conjunction with this policy:

- Risk Management Policy

- Claims Handling Standard Operating Procedure
- Inquests Standard Operating Procedure
- Management and Implementation of National Guidance and Enquiries Policy
- Managing and Responding to Formal Complaints Standard Operating Procedure

The following documents are referred to in this policy, or provide additional sources of reference material:

- NHSLA Risk Management Handbook, 2011/12. **NHS Litigation Authority**, February 2011.
- NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care, 2011/12. **NHS Litigation Authority**, January 2011.

The register will evolve over time and will include the following as a minimum:

Details of the review

- Review title
- Review agency / body
- Coverage of review (specialty, site, trust-wide etc)
- Output of review (accreditation, registration, certificate, informal etc)
- **Details of Trust officers and committees/groups**
 - (executive) director
 - Care Group
 - Service Line
 - Nominated committee
 - Nominated lead officer
- **Review history**
 - Frequency of review (years)
 - Date of completion of last review
 - Deadline for completion of next review
 - Date of reporting of outcome to nominated committee
- **Outcome of review**
 - Pass, fail, qualified pass etc.
 - Any significant actions arising
 - Datix risk references

It is likely that the locally relevant interpretation of the requirements and expectations that the external agency will assess the Trust against will be set out in a Trust document (policy, procedure, protocol, guidance).

The following is a checklist of good practice indicators that the lead officer responsible for facilitating an external agency review should consider, throughout the year, as well as in advance of an imminent review visit.

Compliant operational procedures

Throughout the year, the nominated lead officer, along with relevant key staff, should:

- identify and review the Trust's compliance with the requirements to be subject to the external agency review, to ensure that the local document remains up to date and valid;
- review compliance of systems and processes with the expectations and identify actions needed to ensure compliance is delivered;
- define what tasks operational areas need to complete to meet regulations and the expected quality standards the Trust is aiming for and ensure that these are effectively communicated to appropriate operational managers;
- ensure that these sources of assurance are captured and held centrally on a regular basis (monthly, quarterly, yearly depending on assurance source); and
- ensure that appropriate risks, controls and assurances are identified, implemented and monitored, forwarding reports as required by the Executive Lead, Service Line or Care Group management team or line manager.

In preparation for the visit and at the start of the external agency review, the nominated lead officer should:

- ensure clear lines of communication are established with the lead assessor, or inspector to facilitate a satisfactory inspection experience;
- define what assurance (KPIs, clinical audit, internal audit etc.) they need to evidence compliance against the relevant regulations and other assessments; and
- verify that compliance with expectations can be evidenced, collecting relevant evidence together, if experience from previous external agency reviews indicates that this will be beneficial to the review process.

Preparation for the visit

The nominated lead officer should:

- identify themselves to the external agency as the point of contact for all correspondence;
- agree a timetable for the review and its completion and reporting, with the external agency and responsible (executive) director, responsible sub-committee, Service Line or Care Group management team;
- agree dates for the external agency visit and ensure that key staff are available for the period of the review, or for specific times during the review;
- agree the methodology of receiving feedback from the external agency and make arrangements to facilitate this;
- arrange suitable working accommodation and facilities for the external agency staff for the duration of the review;
- arrange meetings for key stages in the review (e.g. introduction, draft findings, formal close);
- agree with the external agency the specific evidence to be provided in support of the review; and
- brief all staff working in areas to be covered by the review, particularly those that the external agency may wish to speak to.

Preparation for the report and responses

The nominated lead officer should:

- agree the timescale for receipt of the report from the external agency;
- inform appropriate personnel (Service Line and/or Care Group management teams, other affected service lines, Trust Board, Audit, Assurance and Effectiveness Team) of any initial findings arising from the closing meeting in advance of the report;
- arrange meetings with key personnel to disseminate the content of the report and share a copy with the Audit, Assurance and Effectiveness Team;
- in the event of non-conformance arising from the report, agree a manageable plan for remedial, corrective and preventative activity as required. Timescales should be agreed and monitored;
- agree a timescale for resolution and reporting with the external agency;
- track all post-inspection activity to provide assurance that findings have been resolved as agreed. This information should be shared with key personnel including the Audit, Assurance and Effectiveness Team; and

- provide assurance to the external agency that all findings have been resolved.

Dissemination Plan

Appendix 3

Core Information				
Document Title	Management of External Assessments Standard Operating Procedure			
Date Finalised	September 2016			
Dissemination Lead	Head of Clinical Governance Systems			
Previous Documents				
Previous document in use?	Yes, electronic version on Trust Documents Network Share Folder			
Action to retrieve old copies.	To be managed by the Information Governance Team			
Dissemination Plan				
Recipient(s)	When	How	Responsibility	Progress update
All Trust staff	Sept 2016	Vital Signs	Information Governance Team	
External Assessment Leads	Sept 2016	Email	Audit, Assurance & Effectiveness Team	