	Reference Number: PHW47/CD01 **Version Number:** 1 **Date of Next review:** December 2026

Guidance for Governance and Management of Standard Operating Procedure (SOPs) in Public Health Wales

Introduction and Aim

This guidance supports the Corporate Policies, Procedures and Other Written Control Documents Management [Policy] and [Procedure] and provides detailed instructions and guidance for staff responsible for the governance, development and management of these documents.

This guidance outlines the overarching principles and governance arrangements which should be in place when developing Standard Operating Procedures (SOPs) in Public Health Wales.

This guidance seeks to:

- Confirm the principles that guide the development and review SOPs in Public Health Wales
- Establish standardised procedures to ensure that SOPs are developed, approved, monitored and reviewed consistently across the organisation

This guidance ensures that Public Health Wales:
- Has a clear supporting guidance in place for the review or development of SOPs.
- Clearly defines the role of those who have a role in developing / reviewing SOPs.
- Clearly outlines the requirements relating to consultation.
- Has consistent templates and format for recording and monitoring of local SOPs

Supporting Procedures and Written Control Documents

[All corporate policies and procedures are available on the Public Health Wales website]

Corporate Policies, Procedures and Other Written Control Documents Management Policy

Corporate Policies, Procedures and Other Written Control Documents Management Procedure

Data Protection Impact Assessment Procure and Template

Guidance on Retention of Documents

Scope

This guidance is applicable to all staff with responsibilities for the governance, monitoring and development of local SOPs.

Standard Operating Procedures (SOPs) are a standardised method of performing clinical or non-clinical tasks **specific to a directorate, division or team**. Local Procedures or SOPs are directorate, divisional or team specific and are stored locally. The governance, monitoring and development of these documents should follow a standardised process across the organisation.

A SOP provides a series of actions to be conducted in an agreed and consistent way to achieve a safe, effective outcome. This will ensure all concerned undertake the task in an agreed and consistent way. SOPs are considered mandatory.

Any procedure that is applicable to more than one Directorate is subject to the Corporate Policies, Procedures and Other Written Control Documents Management Policy and Procedure.

Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
Approved by	Leadership Team
Approval Date	11/12/2023
Review Date	11/12/2026
Date of Publication:	18/01/2024
Accountable Executive Director/Director	Executive Director of Quality, Nursing and Allied Health Professionals
Author	Integrated Governance Manager

Summary of reviews/amendments

Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1	2023	11/12/23	18/01/24	First version of document. Amendments made following consultation period of first draft. Final version incorporates suggestions.

Contents

1. Introduction

Public Health Wales maintains a large number of local procedures (Directorate, Division and Departmental Specific Documents) (SOPs). A local procedure provides a written means to instruct employees on how a particular procedure should be carried out and lays out boundaries of responsibility. It can be used to satisfy legal compliance requirements too. Where written control documents relate to a single Directorate or Division and there is no wider impact on the organisation, it is the responsibility of the Executive Director/Director to determine that an appropriate approval and scrutiny process in in place within the directorate.

This document provides guidance to Directorates on best practice for the development, approval and review of local procedures and Standard Operating Procedures (SOPs).

Public Health Wales has a statutory duty to ensure that appropriate policies (supported by procedures and other control documents) are in place in order to comply with legislation and regulation. Having effective, up to date and accessible corporate and local policies, procedures and other written control documents also helps to promote governance best practice, guide staff and minimise risks.

Any written control document which applies to two or more directorates is considered a corporate policy, procedure and other written control document and should be developed in accordance with the Corporate Policies, Procedures and other written control documents management procedure.

2. Roles and responsibilities

This section outlines the roles and responsibility for:
- Executive Directors/Directors
- Board Secretary and Head of Board Business
- Executive Director of Quality, Nursing and Allied Health Professionals
- Director(s) of the NHS Wales Collaborative
- Procedure Leads / Authors

2.1. Executive Directors/Directors

Executive Directors/Directors (including the Board Secretary) will make sure that their area of responsibility is supported by the necessary local procedures. They are responsible for determining that

an appropriate approval and scrutiny process is in place within the directorate for local procedures (SOPs).

They will achieve this by:
- identifying a Lead/ Author for each document making sure that if the Lead/ Author leaves the organisation or moves into another role it is clear who assumes responsibility for the ongoing review and development of the document,
- Ensure all documents within their delegated area are reviewed and updated in a timely manner,
- Ensure that all documents within their delegated area have been developed in accordance with the process outlined in this document,
- Making sure that consultation has taken place and impact assessments, including for Welsh language, equality and health impact, have been completed where necessary. Where these have not been undertaken a reason for this will be provided,
- Making sure that where a process of audit and/or review has been agreed this is maintained and reported on,
- Provide updates as requested to the Integrated Governance Manager to ensure local procedures are being managed appropriately across the organisation.

2.2. Board Secretary and Head of Board Business Unit

The **Board Secretary and Head of Board Business Unit** is responsible for the governance and assurance of compliance with corporate policies, procedures and other written control documents.

2.3. Executive Director of Quality, Nursing and Allied Health Professionals

The **Executive Director of Quality, Nursing and Allied Health Professionals** is responsible for ensuring there are governance processes in place for the development and monitoring of Local Procedures and Standard Operating Procedures (SOPs).

2.4. Director(s) of Hosted Bodies

The **Director(s) of a Hosted Body**, responsibilities equate with that of an Executive Director/Director as detailed in 2.1.

2.5. Local procedure Leads / Authors

Local procedure Leads / Authors are employees who job role has responsibility for the task of writing or reviewing a local written control document.

They must:
- Make sure that documents are reviewed in line with the review date or as a result of changes to practice, organisational structure or legislation,
- Liaise with the appropriate Divisional/Team lead before embarking on developing a written document to clearly establish whether there is a need for the written document and, if so, how it will be developed,
- Ensure that appropriate consultation has taken place with the Executive Director/Director of any learning, education or development needs and resource implications which must be considered before approval can take place,
- Engagement with the relevant individuals and groups as part of the review,
- Undertake the necessary impact assessments, including an Equality and Health Impact Assessment as standard.
- Consider the findings and make sure that appropriate action has been taken in response to equality and health impact assessments and Data Protection impact assessments,
- **Post approval:** liaise with Executive Directors/Directors to make sure that local procedures/SOPs are implemented appropriately and, where necessary, compliance with these documents is formally audited.
- Responsible for any training and development requirements of staff to implement the document including ensuring appropriate promotion of the document to the relevant individuals.

If a Lead/ Author leaves the organisation or takes up another post, the responsibility for the ongoing maintenance of the document is taken on by the new post holder. Where no direct role replacement is appointed, responsibility reverts to the post holder's line manager. The Executive Director/Director will be informed of the situation to allow them to identify a replacement author if it is not appropriate for the responsibility to stay within that department. The Executive Director/Director should refer to 2.1 above.

3.   Definitions

Local Procedures (Including Standing Operating Procedures)	A standardised method of performing clinical or non-clinical tasks **specific to a directorate, division or team**. Providing a series of actions to be conducted in an agreed and consistent way to achieve a safe, effective outcome. This will ensure all concerned undertake the task in an agreed and consistent way. Local Procedures are stored locally and are considered mandatory in the area specified in the procedure.

Some elements that a Local procedure provides includes:
- Transparency
- Signals uniformity in approach
- Enables comparison to review quality issues
- Helps employees understand what they need to do so the process can be reproduced by others
- Reduces variation in quality of risk assessments
- Improvement in data capture and monitoring
- Assurance in situations where a safe system of work can only be achieved by performing the task(s) in a sequence
- Opportunity to reduce ambiguity in instructions – makes clear what must be done
- Guidelines for those who need to be trained in carrying out effective risk assessment

4.   Local Procedures (SOPs): Review Process

(To include the development of a new document and the review of existing document).

The Local Procedures (SOPs) development and review process should follow a seven stage model (see below). This ensures that the cycle is continuous with regular monitoring and review, allowing Public Health Wales to adapt to change. This follows the same cycle as that used for Corporate Policies, Procedures and other written control documents.

Figure 1: Local Procedures (SOPs) Cycle

The following sections outlines each stage of the cycle

4.1. Review

A need for a new Local Procedure/ SOP may be initiated from a number of sources, including a change in working practice, change in legislation or the service lead identifying the need.

Key questions to ask as part of this review include:

- **What are the objectives of the procedure?**

- **Scope of the procedure – What are you trying to achieve?**

- **Outside the scope - What is not being covered in the procedure?**

- **Who is the procedure aimed at?**

- **Who are the key users of the procedure?**

- **What other local procedures/SOPs or corporate written control documents are there that impact on this procedure?**
  In order to establish precedent and inform the process, research must be conducted into existing local procedures /SOPs or similar external examples.

- **What corporate policy and procedure does this SOP relate to?**

- **Has there been any legislative changes that need to be taken into account in this area?**
  All developments should be undertaken in line with current legislation, national and professional guidance. Documentation should also be based on sound evidence and be appropriately referenced.

- **Is this existing procedure still required?**
  As part of the review, the document author should, in liaison with the Service lead, consider whether there is still a requirement / need for the document.

  If it is considered that the document is still required, the review should be undertaken in accordance with the guidance set out in this document.

  If it is decided that there is no longer a requirement for the document e.g. it has been superseded by and/or incorporated

into another document, a record of that decision should be made on a local procedures/SOPs register. An example register is available at [SOP's Register Template example](#)

4.2. Implementation

When developing or reviewing a document it is important to consider how it will be implemented.

Implementation Plans which set out the actions needed to enable the delivery of the document should be developed and referenced within the document. Any training requirements and references to supporting documents should be included.

4.3. Impact Assessments

When developing and reviewing a local procedure/SOP, you must consider the impact of the document on the following areas as a minimum:
- Equality
- Health
- Data Protection

An Integrated Equality and Health Impact Assessment (EHIA) has been developed to streamline Equality, Welsh and Health Impact Assessments. It does not replace the need to undertake full assessments for more complex procedures.

In addition to the EHIA, you must consider the impact of the document on Data Protection and Socio Economic Duty, and where appropriate complete a full assessment in these areas where there is significant impact identified.

The Data Protection Impact Assessment procedure and template is available on the internet [DPIA Procedure](#) [DPIA Template](#)

Below is a summary of the requirements to consider as part of your assessment of each area:

Equality	The Equality Act 2010 requires the undertaking Equality Impact Assessments (EIAs). All Public Health Wales policies will require an EIA. This is a process by which we can conduct an analysis of any 'policy' change. EIAs play an important role in improving the quality of our health services and to meeting the needs of staff and those using our

	services. They are a process to find out whether a 'policy' will affect people differently on the basis of their 'protected characteristics': age, disability, gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion, sex or sexual orientation and if it will affect their human rights. It also takes account of the Welsh Language. It is designed to ensure that we are taking into consideration the needs of all individuals who work for us and/or access our services. Where a procedure or other written control document has been developed in support of a policy it may not be necessary to undertake a further EHIA where it is applicable. If an EHIA has not been completed the reason for this will be explained at the beginning of the document. Where an EHIA has been completed the impact will be included in the document. The EHIA Template is included EHIA Template
Health	A Health Impact Assessment (HIA) is a process that assesses the potential impact of any change or amendment to a policy, service, plan, procedure, or programme on the health of the population and on the distribution of those effects within the population, particularly within vulnerable groups. HIAs help identify how people may be affected differently on the basis of where they live and potential impacts on health inequalities and health equity. HIAs increase understanding of potential health impacts on those living in the most deprived communities, improves service delivery to ensure that those with the greatest health needs receive a larger proportion of attention and highlights gaps and barriers in services. The findings of the HIA are incorporated within the policy/control document objectives/aims. The EHIA Template is included EHIA Template

Data Protection	If the local procedure will involve the processing of personal data in any form, then consideration must be given to conducting a Data Protection Impact Assessment. The Data Protection Template is included as available on the internet [DPIA Template](#)

4.4. Drafting: Document Format / Content

A document template has been developed which contains the mandatory sections that must be included. The template is available here: [Local Procedure SOP Template](#). Where a Directorate/Division is using IPassport or other document management system, the template, including mandatory sections, is available within the software system.

Procedure

> **Procedure Definition:**
>
> A standardised method of performing clinical or non-clinical tasks that is relevant organisation-wide.
>
> Providing a series of actions to be conducted in an agreed and consistent way to achieve a safe, effective outcome; or a step-by-step account of specific arrangements that apply in particular circumstances. This will ensure all concerned undertake the task in an agreed and consistent way. These are often the documents detailing how a policy is to be achieved.

The procedure should be used to describe a mandatory process by which the identified staff must follow and should include: roles and responsibilities, scope, process steps.

The Public Health Wales Local Procedure/SOP Template [Local Procedure SOP Template](#) must be used.

Further guidance on the content of the procedure is contained within the template.

As a minimum the principles listed below must still be followed:
- SOP Reference number should follow the guidance from the records management programme e.g SOP – Making a cup of tea v 1.0 – October 2023
- Document must have a clear heading

- The scope and objectives must be defined
- The status of the document must be clear, for example, guidance/mandatory requirement
- Instructions/guidance must be logically recorded
- Date of approval shown
- Date of review shown
- Author(s) - Job title details
- Pages numbered
- Version control

Style

The following principles should be used when drafting the documents:
- All documents need to be user friendly.
- The language used for all documents should be plain English, using short sentences and where possible avoiding technical terms so it can be easily understood by those using it.
- If technical terms are used, they should be explained using a glossary or footnotes.
- All reference material should be listed in full at the end of every document in Harvard style.
- Abbreviations: State in full in first usage with abbreviation in brackets.
- Page numbering to be included in the footer on every page after first page. It will include the page number and total number of pages (page x of x).
- Use titles rather than names for staff: Individuals with particular responsibilities will be identified by their job title only.
- Documents to state 'Draft' as watermark whilst in development together with version number of draft.

4.5. Consultation

Local procedures/SOPs must not be written in isolation

All local procedures/SOPs should be developed in consultation with their target audience involving appropriate stakeholder, managerial, clinical and Trade Union/staff representation.

Please consider consultation with the following groups
- Relevant professional groups and/or individuals;
- Staff representatives specifically affected by the document;
- Stakeholder representatives/organisations/groups;
- Service user representatives/groups (if relevant);
- Subject matter experts from across the organisation for example Information Governance;
- Trade Unions; and

- Staff Networks.

All consultations will be led by the author and must be completed before the procedure begins the approval process.

Review of Consultation outcomes

Comments should be included in any approval process, including rationale given for accepting/rejecting comments. An audit trail of comments should be kept by the author.

4.6.   Approval Process

It is necessary to ensure that all Local Procedures/SOPs undergo the appropriate scrutiny and consultation prior to their approval. An example timeline is included SOP's Document Development flowchart timeline example

When submitting a Local Procedure/SOP for approval, the author must provide a summary of the way in which the document has been developed. This could be achieved through completion of a cover sheet.   A template is provided SOP's Approval Cover Sheet. This includes
- The reasons for the review of the document, such as impact of legislation;
- A summary of the major changes made since the last revision;
- A summary of the consultation that has taken place and the groups that have considered the document prior to being submitted for approval;
- Summary of the impact assessments that have been undertaken, including reference to those that have not been undertaken or where there is no impact; and
- An implementation plan.

Approving Bodies

It is the responsibility of the Executive Director/Director to determine that an appropriate approval and scrutiny process is in place within the directorate. Each Directorate should have an identified body for approval of local procedures/SOPs. This could be the Directorate/Divisional senior management forum or a dedicated group specifically with the remit for approving local procedures.

It is also the responsibility of the Executive Director/Director to ensure that the appropriate Directorate, Division or Departmental specific documents are in place, are kept up to date and any training of staff to ensure compliance with any internal processes.

Records must be maintained at a local level to ensure that there is a full history and document archive. There must be a clearly documented audit trail to indicate where and by whom the document has been considered.

Amendments to documents following approval

No changes should be made to a local procedure/SOP after it has been ratified and approved.

4.7.   Publication and Dissemination

Directorates and Divisions should have a process for logging and documenting approved local procedures/SOPs. This should include allocation of a document number to each procedure. This should link to a local register and documents should be sorted and displayed for staff to access and what access rights are required.

Staff should be made aware of new/amended procedures.

4.8.   Local Procedures (SOPs) Review process

Year 1 Review
During the first year following implementation of a local procedure/SOP, work should be undertaken to monitor and assess its success and, where appropriate, minor revisions proposed. Generally, this will be undertaken by the Local Procedure Lead/Author and should include feedback from staff using the document on an operational level.

Ongoing Review
Once established, local procedures/SOPs are subject to a full review The review date is totally dependent on the SOP and is to be decided by the local area depended on the risk element and how frequently this procedure needs to be reviewed to remain compliant. They may also be reviewed or amended before their review date should the need arise.

Audit
All local procedures should be part of the Public Health Wales and/or Directorate auditing process to ensure that they:
- have been implemented effectively;
- are fit for purpose; and
- are being complied with.

Information regarding the frequency of the monitoring arrangements should be included within the local procedure.

It will be necessary to ensure that all documents are being produced, approved and disseminated in accordance with this guidance. Periodic 'spot checks' will be carried out in all areas to ensure that all local procedures comply with this guidance.   A template for audit is provided SOP's Audit Template.