



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

## HSE Procedure for developing Policies, Procedures, Protocols and Guidelines

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<b>Revision number</b>	<b>1</b>	<b>Document approved by</b>	<b>Office of Quality and Risk</b>
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## Acknowledgements

The policy, procedure, protocol and guideline working group wish to thank the following areas for submitting and sharing their work in relation to policy, procedure, and protocol and guideline development. Their documents have assisted in development of this procedure and template.

- Cork University Hospital Group
- Organisation Development Unit, North Eastern Health Board (NEHB)
- An Bord Altranais
- Lincolnshire Partnership Trust National Health Service (NHS) Foundation.
- Nursing Midwifery Planning Development Unit, South Eastern Area
- HSE Dublin Mid Leinster Quality and Clinical Audit Dept.
- The Adelaide and Meath Hospital Dublin, incorporating the National Children's Hospital
- Naas General Hospital
- Galway University Hospital
- Sligo General Hospital

## **1.0 Policy Statement**

The Health Service Executive (HSE) policy is that all policies, procedures, protocols and guidelines (PPPGs) are developed using the following procedure.

## **2.0 Purpose**

The purpose of this procedure is to provide a standardised methodology for the development of PPPGs throughout the HSE.

Policies, procedures, protocols and guidelines are an essential tool in improving the quality of health care provision. They articulate consistent approaches for best practice. They serve to:

- Promote best practice
- Standardise practice and service delivery
- Ensure that legislative and regulatory requirements are met
- Ensure employees and line managers are clear on their roles and responsibilities
- Facilitate effective staff induction
- Act as educational tools
- Act as a basis for audit and evaluation

## **3.0 Scope**

This procedure applies to all Health Sector employees.

## **4.0 Glossary of Terms and Definitions**

### **4.1 Policy**

A policy is a written statement that clearly indicates the position and values of the organisation on a given subject (HIQA 2006).

### **4.2 Guidelines**

A guideline is defined as a principle or criterion that guides or directs action (Concise Oxford Dictionary 1995)

### **4.3 Protocol**

A protocol is defined as a written plan that specifies procedures to be followed in defined situations; a protocol represents a standard of care that describes an intervention or set of interventions. Protocols are more explicit and specific in their detail than guidelines, they specify who does what, when and how (cited in An Bord Altranais 2000). Protocols are most typically used when developing instructions for drug prescription, dispensing and administration, i.e. drug protocols.

### **4.4 Procedure**

A procedure is a written set of instructions that describe the approved and recommended steps for a particular act or sequence of events (HIQA 2006).

### **4.5 Healthcare Audit**

Healthcare audit is audit of current practice against standards in any aspect of healthcare and includes both clinical and non-clinical audit (Clinical Audit Criteria and Guidance Working Group 2008).

### **4.6 Evaluation**

Evaluation is defined as assessment/appraisal of the degree of success in meeting the goals and expected results (outcomes) of the organisation, service, programme, population or patients/clients (Quality and Risk Taxonomy Governance Group report 2008).

### **4.7 Scope**

This includes both the target users and target population (only refer to a target population if the PPPG is referring to specific groups for example all service users aged 16 years and over) of the policy, procedure, protocol or guideline. It identifies to whom the policy, procedure, protocol or guideline applies.

### **4.8 Consultation**

The exchange of views and establishment of dialogue between either or both a) One or more employees or the employees' representative(s) and  
b) The employer.  
(Employees (Provision of Information and Consultation) Act 2006)

## **5.0 Roles and Responsibilities**

### **5.1 Roles**

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- Managers to ensure that employees are aware of this Procedure
- Managers to facilitate training for employees where necessary
- Managers to ensure that employees comply with this Procedure
- All employees to utilise this HSE Procedure and Template

## **5.2 Responsibility**

- Each health professional/HSE employee is accountable for their practice. This means being answerable for decisions he/she makes and being prepared to make explicit the rationale for those decisions and justify them in the context of legislation, case law, professional standards and guidelines, evidence based practice, professional and ethical conduct.
- It should be recognised that policies, procedures, protocols and guidelines represent a statement reflecting an expected standard of care and could be introduced in law as evidence of the standard of care expected. There may be occasions when it is acceptable to deviate from a PPPG but clinical judgement in such a decision must be clearly documented.
- The public may request access to policies, procedures, guidelines and protocols and public bodies may be called on to publish such documents under Freedom of Information Act (1997) and appropriate legislation.

## 6.0 Procedure

### 6.1 Plan/setting the agenda

The mission and vision of the HSE along with the priorities of the Transformation Programme and the Quality and Risk Management Framework should drive and underpin PPPG development.

To facilitate co-ordination and consistency, organisations should have a core management committee that approves and authorises all policies, procedures, protocols and guidelines formulated in the organisation. This can be an existing committee for example Self Assessment Team for the Quality and Risk Framework, Clinical Governance Team, Quality and Risk Team. This core management committee will ensure that PPPG developers have adhered to the National HSE template prior to authorisation. It is NOT the remit of this committee to review the actual content of the PPPG. All committees developing PPPGs in the organisation should link in to the core committee when obtaining final authorisation for PPPGs.

APPENDIX I lists the professional disciplines who should be a member of the Core Management Committee.

When the need for a PPPG has been identified, and the mandate for the development of same has been received from either local or national management, the person or team responsible for the drafting of the PPPG should initially identify the following:

- The background for the development of the policy should be outlined.
- The overall purpose and objectives of the policy, procedure, protocol or guideline must be described.
- The people and services to which the policy applies must be identified.
- The extent of involvement of all stakeholders needs to be identified.
- The resources required to develop the policy should be determined.
- The consultation process to meet our legal obligations to be followed.
- The communications process to support the early stages of policy development needs to be outlined.

- The process of reaching consensus is crucial to ownership by employee

## **6.2 Review the available evidence/analysis**

After the initial stage, a review and/or analysis should be undertaken. This review and or analysis may include any or all of the following:

- Review similar policies, procedures, protocols or guidelines devised by other groups or organisations. Other groups may have looked at this issue and reviewed evidenced based material relevant to the PPPG under development. It is acceptable to draw on PPPGs prepared by other groups provided that due permission and acknowledgement is sought and given and the content is deemed appropriate and reliable by experts in the area.
- Conduct a review of the literature if required. In the case of Clinical guidelines the AGREE instrument can be used to appraise evidence (See appendix II list of useful resources)
- Consult with experts in the area.

### **6.3 Devise the PPPG**

The PPPG should be written using the HSE PPPG Template (Appendix III) and the accompanying template user manual/guidance notes (Appendix IV).

### **6.4 Format of PPPG**

It is important that the document is accessible to users in terms of layout and language. Recommendations from the National Adult Literacy Agency (NALA) should be followed.

- Type of Font – Verdana
- Type size – Headings 12 Text 10
- Align the text throughout the document to the left
- Use single line spacing
- Use double spacing between paragraphs
- Section Headings – boldface typed
- Every entry in a guideline, policy or protocol must be numbered
- Paragraphs are structured so that each main subheading represents a separate heading
- Each subheading is represented by equal indentation.
- Abbreviations should be kept to a minimum.
- When working with draft documents ensure a draft number and date is identified clearly on the cover page.
- Include definitions for all terms used in the text.
- A local logo can be inserted on the front cover on the right hand side.

Due regard should be given to the Official Languages Act 2003.

### **6.5 Devise an Implementation Plan**

An implementation plan that outlines how the PPPG will be put into practice and resources needed will be required. The following should be considered:

- Assignment of responsibility for implementation (named person/job title). This should be documented on the first page of template (Cover)
- Identify training needs
- Identify realistic resources required to implement

- Identify the most effective method to communicate the PPPG to all relevant staff.

## **6.6 Devise Monitoring, Audit and Revision Plan**

Monitoring of the PPPG by means of regular audit and review is necessary to ensure it is meeting its intended purpose and objectives. A named person and title must be identified as the lead for this process. Document this individual's name/job title on first page (cover) of the template. A schedule for regular **monitoring**, e.g. monitoring procedures such as safety checks on the emergency trolley, should be developed at the time the procedure is written and the schedule should be designed so as to ensure that assurance is given to management that the safety checks are being monitored as per the policy – this could mean that all safety check sign off check sheets are monitored for completeness once a month. A schedule for regular **audit** on high risk or high volume PPPGs should be developed at the time the PPPG is being developed – this may mean six monthly or yearly audits by, for example, direct observation or chart review.

## **6.7 Sign-off Procedures**

A three-step formal process is required to ensure that appropriate governance arrangements are in place to sign off a policy, procedure, protocol and guideline in advance of final approval/sign off.

### **6.7.1 Peer Review and key stakeholder review sign-off of PPPG**

The purpose of this is to review and agree the **content and recommend approval** of the PPPG.

- The Chair of the development group must identify and consult with individuals either within or outside the organisation who can provide assurance regarding the content (clinical, non-clinical, legal etc.) of the PPPG (Appendix V).
- The PPPG will then be sent to the managers of all those who have a stake in the PPPGs, in advance of approval of the PPPG, in order to confirm to the development group that they have seen and agree to the PPPG (Appendix VI).
- The final document then needs to be signed off by the Chair of the development group and forwarded for approval to the Core Management Committee.

### **6.7.2 Final Approval of PPPG.**

The purpose of this is to **assure** that the HSE National template has been adhered to and **approve** the PPPG for use in the organisation. When an organisational level policy has been developed then it must be authorised by the Chair of the Core Management Committee. The PPPG along with the above documentation (Appendices V and VI) are sent to the Core Management Committee.

A signed Master Copy should be retained in an agreed central location with all of the above signatures where it will be document controlled before dissemination. A dissemination list should be retained to facilitate retrieval of PPPGs when necessary for example when reviewing updating PPPGs.

It is not necessary to have the written signatures on the PPPG that will be disseminated as long as the Master Copy with signatures (either written or electronic) is retained as above.

The members of the Development Group should be documented at the back of the PPPG as an appendix.

### **6.8 Action Implementation Plan**

- Relevant employees must be informed of PPPG
- Disseminate the PPPG to relevant employees
- All staff members must sign a signature sheet to confirm they have read, understand and agree to adhere to the PPPG. (Appendix VII Signature sheet in template)

### **6.9 Action Monitoring, Audit and Revision Plan**

The monitoring, audit and revision must take place on a consistent, planned ongoing basis, as referenced on the review date on the cover of the PPPG. This review and audit date must be agreed by the development committee.

The feedback from the audit must be communicated to the relevant people in order to ensure continuous improvement. This will facilitate the sharing of best practice and learning from experiences and knowledge of what works best in the organisation.

The feedback must also be used to address any barriers to implementation and influence future development of the PPPG.

A review will be carried out on a two-yearly basis unless for example, an audit, serious incident, organisational structural change, scope of practice change, advances in technology, significant changes in international best practice or legislation identifies the need to update the PPPG.

## 7.0 References

- An Bord Altranais (2000)  
<http://www.nursingboard.ie/en/policies-guidelines.aspx?page=2> (accessed 10/08/08)
- Concise Oxford Dictionary. (1995). Oxford. Oxford University Press.
- Health Information and Quality Authority (2006). *Hygiene Services Assessment Scheme*
- Health Service Executive, Office of Quality and Risk (2008). *Quality and Risk Taxonomy Governance Group Report on Glossary of Quality and Risk Terms and Definitions (2008) Taxonomy report.*
- NHS Scotland (2005) Clinical Governance and Risk Management: Achieving Safe Effective patient Focused Care and Services. Edinburgh: NHS Quality Improvement Scotland.
- Official Languages Act (2003). Dublin: Government Publications
- The Oireachtas (2006). *Employees Act. Provision of Information and Consultation.* Dublin: Government Publications
- Health Care Audit Criteria and Guidance (2008).  
[http://hsetnet.hse.ie/HSE\\_Central/Office\\_of\\_the\\_CEO/Quality\\_and\\_Risk/Documents/OQR014\\_2\\_Healthcare\\_Audit\\_Criteria\\_and\\_Guidance.pdf](http://hsetnet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/OQR014_2_Healthcare_Audit_Criteria_and_Guidance.pdf) (accessed 18/05/09)

## 8.0 Appendices

Appendix I	Members of the Core Management Committee
Appendix II	Useful Resources
Appendix III	Template
Appendix IV	Template user manual/Guidance notes
Appendix V	Peer Reviewer Statement
Appendix VI	Key Stakeholder Reviewer Statement
Appendix VII	Signature Sheet
Appendix VI	Members of the PPPG Working Group

## **Appendix I Members of the Core Management Committee**

- Clinical Director
- Heads of Discipline (NHO/LHO)
- Chairs of relevant committees for example Quality and Risk Committee, Haemovigilance committee, Infection Control Committee

## **Appendix II List of useful links and resources**

- Improving Our Services. A Users Guide to Managing Change in the HSE (2008).
- The AGREE Instrument. The Appraisal of Guidelines for Research and Evaluation
- <http://www.agreecollaboration.org/instrument/>
- Healthcare Audit Criteria and Guidance
- [http://hsenet.hse.ie/HSE\\_Central/Office\\_of\\_the\\_CEO/Quality\\_and\\_Risk/Documents/](http://hsenet.hse.ie/HSE_Central/Office_of_the_CEO/Quality_and_Risk/Documents/)
- National Institute of Clinical Excellence  
<http://www.nice.org.uk/>
- Scottish Intercollegiate Guidelines Network (SIGN)  
<http://www.sign.ac.uk/>

LOCAL LOGO



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**Appendix III      Template**

**Title**

<b>Document reference number</b>		<b>Document developed by</b>	
<b>Revision number</b>		<b>Document approved by</b>	
<b>Approval date</b>		<b>Responsibility for implementation</b>	
<b>Revision date</b>		<b>Responsibility for review and audit</b>	

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## Table of Contents:

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- 1.0 Policy**
- 2.0 Purpose**
- 3.0 Scope**
- 4.0 Legislation/other related policies**
- 5.0 Glossary of Terms and Definitions**
- 6.0 Roles and Responsibilities**  
**Monitoring and Audit**
- 7.0 Procedure/Protocol/Guideline**
- 9.0 References**
- 9.0 Appendices**

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## Appendix IV Template User Manual

### Page One (Cover):

**Title:** title of the Policy, Procedure, Protocol or Guideline

### Document Development and Control:

- **Document reference number:** To be agreed nationally
- **Revision number:** To be agreed nationally
- **Approval date:** date when the PPPG has been approved
- **Revision date:** date the PPPG is due for revision
- **Document developed by:** This should be the name of chair of the development group. The members of the working group should be listed as an appendix.
- **Document approved by:** This is the name of the Chair of the Core Management Committee who has final sign off.
- **Responsibility for Implementation:** identify and name the individual who is responsible for rolling out the implementation of the PPPG. This individual's job title should also be documented.
- **Responsibility for revision and audit:** Identify and name the person(s) with responsibility for revision and audit. This individual's job title should also be documented.
- **How to insert a Footer:** On toolbar select, View – Header and Footer – Select Footer – Insert the following information as it pertains to document:

Title, document reference number, revision number, approval date

## **Page Two (Table of contents):**

This is usually completed when the PPPG is fully developed. The electronic template which is available to download from the HSEnet has been formatted to formulate a table of contents.

To set up an automatic table of contents:

- Place the cursor where you want to insert the table of contents. On toolbar select: Insert - Index and Tables- Table of Contents- Format: formal- Show levels: 1

## **Page Three (section headings):**

**1.0 Policy Statement:** This is a written statement that clearly indicates the position of the organisation regarding the Procedure, Protocol or Guidance that follows for example; It is policy of the HSE to use this procedure in the development of all PPPGs.

**2.0 Purpose:** This describes the objective for writing the PPPG. It provides the rationale for why the PPPG is required. It should be comprehensive and concise in its meaning.

**3.0 Scope:** This identifies the users of the policy, procedure or guideline. It identifies to whom the PPPG applies. (only refer to a target population if the PPPG is referring to specific groups for example all service users aged 16 years and over).

**4.0 Legislation/other related policies:** List any relevant legislation and policies.

**5.0 Glossary of Terms and Definitions:** Explanation of key technical terms or terminology that are referred to in the PPPG.

- List definitions in alphabetical order. If this is an exhaustive list then they may be included in an appendix.

- Definitions used should be in accordance with Quality and Risk Taxonomy Governance Group Report on Glossary of Quality and Risk Terms and Definitions (2008) where applicable.

**6.0 Roles and Responsibilities:** Clearly define the appropriate personnel to fulfill the following roles and responsibilities in relation to the steps outlined in this PPPG:

- those responsible for complying with the PPPG
- those responsible for ensuring compliance to the PPPG

**7.0 Procedure/Protocol/Guideline:** Outline the steps to be taken to achieve the objectives of the PPPG. This will be titled either a Procedure OR a Protocol OR a Guideline as is applicable.

**8.0 Implementation Plan:** PPPGs should be disseminated and implemented in ways that take into account the particular audiences they are for. They need to be disseminated in such a way that users become aware of them and are able to easily access and make use of them. For example:

- those responsible for rolling out (implementation) the PPPG
- For staff- what education and training will be required in order to implement the PPPG?
- For the service user (if applicable) – what education and training will be required for the patient or client in order to implement the PPPG?
- Before an organisation can implement a PPPG, an assessment of the resource and cost implications that this may have on their services must be undertaken.

**9.0 Revision and Audit:** The PPPG should be reviewed and audited at an appropriate time after the PPPG has been disseminated and implemented – this revision and audit date should be agreed by the committee developing the PPPG at the time of final sign off.

- those responsible for revision the PPPG
- those responsible for auditing the PPPG and providing feedback to relevant employees

**10.0 References/bibliography:** List all references used in the policy, procedure or guideline and include in the bibliography.

The following are some examples of references:

Reference to a Journal article

Evans DT (2000) Homophobic in evidence based practice based practice. *Nurse Researcher*. 8 (1), 47-51

Reference to a book

Mercer, P.A. and Smith G, (1993). *Social dimensions of software development*. 2<sup>nd</sup> ed. London.

Reference to a website

[www.abcdefg.ie](http://www.abcdefg.ie) (accessed 19/10/08)

Reference to a corporate body e.g. Government department

Department of Health and Children (2001) *Quality and Fairness: A Health System for you*. Dublin: Government Publications.

For further details on the Harvard referencing system please see

<http://www.ucd.ie/library/guides/pdf/blackrock/BICGuide27HarvardReferencing.pdf>

**11.0 Appendices:** Additional information is included in this section that will support and provide a rationale for the procedure. This could include:

- Relevant diagrams
- Flow charts
- Models
- Each appendix should be incrementally numbered using roman numerical script (e.g. Appendix I, II, III, IV etc.)

## **Page Four (Signature Page):**

All persons must sign and date this page after they have read and understood the PPPG.

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## Appendix VII Signature Sheet:

*I have read, understand and agree to adhere to the attached Policy, Procedure, Protocol or Guideline:*

<b>Print Name</b>	<b>Signature</b>	<b>Area of Work</b>	<b>Date</b>

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## **Appendix VIII**

## **Membership of the Working Group**

Ms. Marie Kehoe, Lead for Quality Function, Office of Quality and Risk (Chair)

Ms. Elizabeth Adams, Office of the Nursing Service Director, HR Directorate

Ms. Helen Lambert, Information Communications Technology

Ms. Breege Kelly, Human Resources

Ms. Mary Boyd/Marie Fitzgerald Cork University Hospital

Ms. Georgina Morrow, Cavan Monaghan Hospital Group

Mr. Tony Fitzpatrick, Mental Health Act Implementation Group

Ms. Denise McCarthy Office of Quality and Risk

Mr. Theo Neijenhuis, Office of Quality and Risk

Ms. Mary Gorry, Human Resources, Head of Employee P&Ps

Ms. Noreen O'Regan, Primary Community and Continuing Care

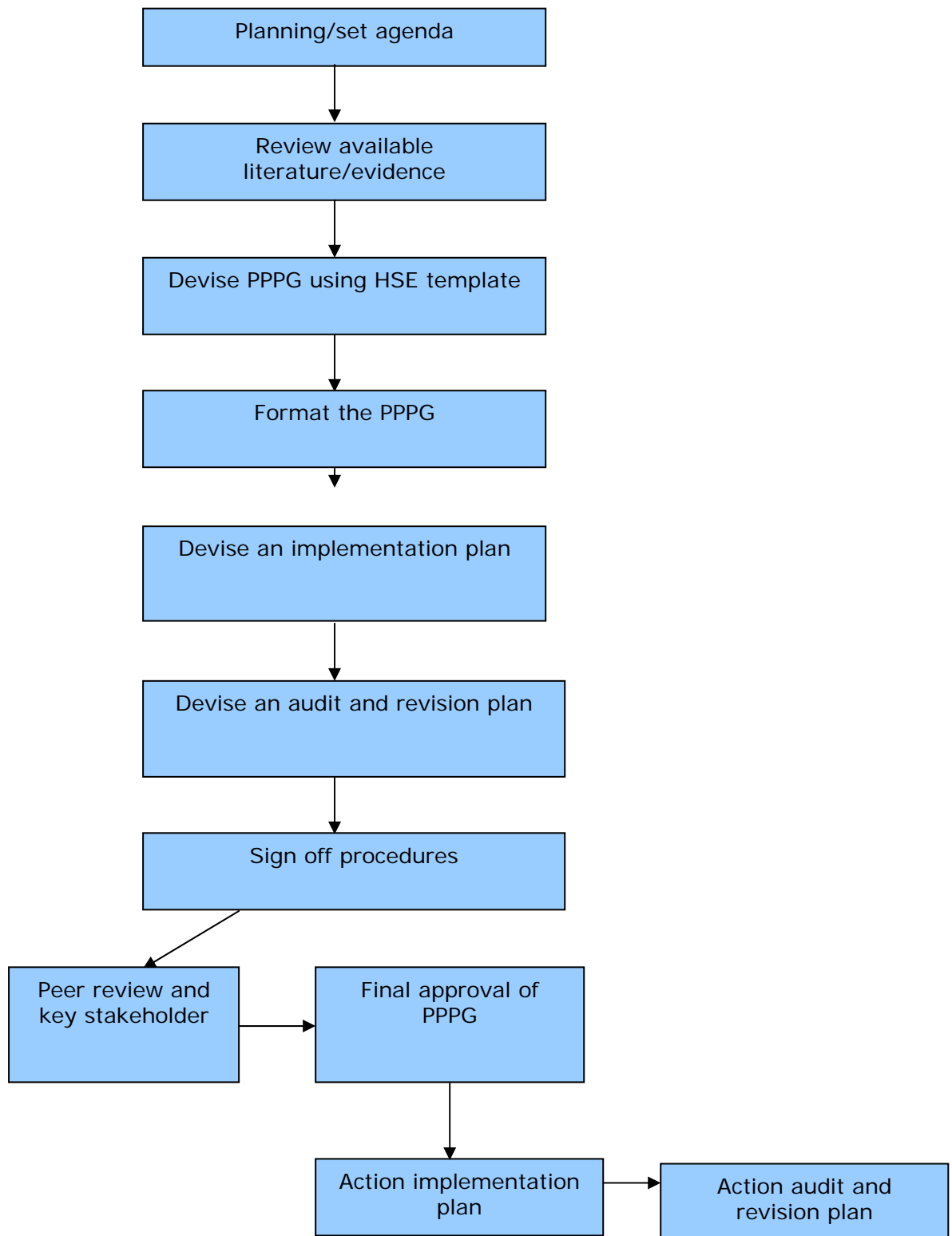
Ms. Dymphna Bracken, Communications

Mr. Patrick Lynch, Transformation Programme

Commissioner:

Ms. Anne Carrigy, Director, Serious Incident Management Team

## Appendix IX Flow chart summarising the steps involved in the PPPG development



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