Trust Policy

University Hospitals Plymouth NHS Trust

The introduction of new clinical devices and procedures

Issue Date	Review Date	Version
June 2018	August 2021	6

Purpose

The purpose of this policy is to ensure that the implementation of new clinical devices and procedures is appropriately governed.

Who should read this document?

All staff who intend to introduce new clinical practice through new clinical devices or procedures. In particular this includes Service Line Management Teams and Clinical Governance Leads.

Key Messages

The decision to introduce new clinical practice through new clinical devices or procedures should be considered in conjunction with:

- National best practice/best evidence such as National Institute of Clinical Excellence NICE), Royal Colleges, National Patient Safety Agenda (NPSA), Medicines and Healthcare Products Regulatory Agency (MHRA).
- Health Service Circular HSC 2003/011
- NICE Interventional Procedures Programme
- Financial implications and business case
- Training and competency
- Ongoing monitoring through audit

Core accountabilities	
Owner	Assistant Medical Director for Quality and Safety/Deputy Audit, Assurance and Effectiveness Manager
Review	Clinical Effectiveness Group
Ratification	Medical Director/ Assistant Medical Director for Quality and Safety
Dissemination (Raising Awareness)	Clinical Effectiveness Group
Compliance	Clinical Effectiveness Group

Links to other policies and procedures

Management and Implementation of National Guidance and Enquiries Policy
Clinical Audit Policy

Version History

4	July 2008	Approved by the Clinical Governance Steering Group
5	August 2015	Approved by the Clinical Effectiveness Group
6	June 2018	Minor amendments to job titles, roles and monitoring.

The Trust 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, 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 Trust Documents on StaffNET. Larger text, Braille and Audio versions can be made available upon request.

1 Introduction

The Trust is committed to delivering safe and effective care to its patients and so encourages the developments in clinical care.

As new and aspiring practice and technology develops and evolves it is important that there is a well governed and consistent approach to the consideration, approval, evaluation and implementation of new clinical technologies and procedures.

2 Purpose

This policy sets out the roles and responsibilities for all those who may be involved in the process of consideration, approval, evaluation and implementation of new clinical technologies or procedures.

3 Definitions

Interventional procedure - making a cut or a hole to gain access to the inside of a patient, gaining access to a body cavity, or using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light)

Medical Device – A medical device is an instrument, apparatus, implant, in vitro diagnostic, or similar used to diagnose, prevent, or treat disease or other conditions.

Clinical Practice – A professional clinical activity or the primary area of responsibility, depending on the profession.

National Best Practice – National best practice guidance is clinical guidance issued to the NHS from national government, professional and expert sources

Clinical Audit - clinical audit provides a method for systematically reflecting on and reviewing practice.

Proposer – The person who makes a formal request for a new clinical practice, procedure, intervention or device to be considered.

4 Duties

Medical Director/Assistant Medical Director for Quality and Safety

The Medical Director has overall accountability for the safe introduction of new clinical devices and procedures into clinical practice in the Trust. This includes ensuring that there is effective governance of the introduction of new clinical devices and procedures.

The Medical Director is responsible for the overall decision to implement all new practice, procedures, interventions and devices, and notify the NICE Interventions Procedure Project of any practice currently untested, undeveloped or not covered by best practice guidance. This responsibility is also delegated to the Assistant Medical Director for Quality.

The Medical Director and Assistant Medical Director for Quality chair the Clinical Effectiveness Group.

Clinical Effectiveness Group

The Trust has established the Clinical Effectiveness Group (CEG) to act as the lead forum for oversight of delivery of the Trust's effective care work stream. CEG will ensure that appropriate standards of governance and practice are met in the introduction of new practices and procedures in line with national guidance.

The Clinical Effectiveness Group reports to the Safety and Quality Committee on a bi-monthly basis.

Proposer
The proposer is responsible for ensuring that a new clinical device or procedure is considered with reference to this policy, that all relevant information is presented to CEG and for gaining approval from CEG and the Medical Director for trial and / or implementation. The proposer is also responsible for monitoring of implementation (audit) and for ensuring the continuation of outcome monitoring.

Clinical Governance Leads
The Clinical Governance Leads are responsible for overseeing that all relevant clinical guidelines are updated to reflect the implementation of new clinical devices and procedures and to be aware of any associated audit requirements to feed into service line clinical audit plans.

Service Line Management Teams
The Service Line Management Teams are responsible for ensuring that all decisions to consider and implement new clinical devices and procedures made at Service Line level are made in accordance with this Policy and that they are reported to the relevant Clinical Governance meeting for approval and oversight. It is also the responsibility of the Service Line Management Teams to prepare and submit a business justification template and gain approval for commissioning arrangements where required.

Care Group Management Teams
The Care Group Management Teams are responsible for ensuring that all decisions to consider and implement new clinical devices and procedures made at Care Group level are made in accordance with this Policy and that they are recorded and reported through to the relevant Clinical Governance meeting for approval and oversight.
It is also the responsibility of the Care Group Management Teams to oversee the submission of a business justification template and gain approval for commissioning arrangements.
The Care Group Management Teams are also responsible for ensuring that Service Line decisions are made in accordance with this policy.

CEG Secretary
The Clinical Effectiveness Group Secretary is responsible for ensuring an accurate record of all approved/non approved proposal decisions that are presented to group is maintained and that, where required, oversight of the implementation or outcomes of any new clinical devices or procedures is added to the forward work plan.

5 Process

The decision to introduce new clinical practice through new clinical devices or procedures should be considered in conjunction with:

- National best practice/best evidence such as National Institute of Clinical Excellence (NICE), Royal Colleges, National Patient Safety Agenda (NPSA), Medicines and Healthcare Products Regulatory Agency (MHRA).
- Health Service Circular HSC 2003/011
- NICE Interventional Procedures Programme
- Financial implications and business case
- Training and competency
- Ongoing monitoring through audit

The flow chart in Appendix 1 has been devised to ensure staff are aware of the appropriate process to follow. Appendix 2 New clinical devices and procedures Form must be completed in advance of the Clinical Effectiveness Group for members to review ahead of the meeting.

To introduce new clinical practice through the introduction of a new clinical device or procedure that is not currently in use within our Trust, the Proposer must ensure that a Business Justification Template has been completed and that it has received Service Line approval. If a procedure or intervention has associated NICE guidance the proposed practice must comply with this guidance.

For cases where national best practice is not available, a submission to the Research and Development Team will be required. If deemed inappropriate for Research approval then a further review will be undertaken by the Medical Director/Assistant Medical Director and the Clinical Effectiveness Group.
If agreed by the Clinical Effectiveness Group, the Medical Director will report the case to NICE as part of the NICE Interventional Procedures Programme for ongoing monitoring and future issuance of guidance where appropriate.

There may be instances during a clinical emergency where no other recommended treatment options are available and to not perform a new procedure may place a patient at risk of serious harm. If this occurs you must notify the Medical Director/Assistant Medical Director of Quality within 72 hours. These cases will be reviewed by the Clinical Effectiveness Group to identify any learning and to establish if further use can be continued.

Consent forms for inclusion in the health record must be signed off by the Paper Records Transformation Group if it is going to be stored in the casenotes. This includes any interim consent forms used during an agreed testing period until a clinical practice, procedure, intervention or device has been agreed and considered routine.

For any procedure involving x-rays or other ionising radiations, the Radiation Protection Advisor must be consulted in respect of review of the radiation risk assessment.

The Equality and Diversity Lead for the Trust will be able to advise appropriately if additional consideration are required for staff and patients who may be disadvantaged from the introduction of a new clinical practice, procedure, intervention or device. If a group of staff or patients are likely to be disadvantaged then alternative arrangements must be agreed and recorded accurately.

It is essential that relevant clinical guidance is created or updated in line with all agreed introduction or change to procedure.

6 Training and Competency

All requests to implement a new device or practice must consider training and competency requirements.

Assurance is required by the Medical Director/Assistant Medical Director and Clinical Effectiveness Group that all relevant Staff have received adequate training and assessment of competency and that records of this are maintained.

For clinicians or expert leads visiting the Trust to assist with mentoring responsibilities, it is essential that an honorary contract or equivalent documentation is completed for the duration of their visit. They are also required to provide:

- GMC Number
- Proof of indemnity
- Hepatitis B immunity confirmation
- Disclosure check if working with children
- Agreed mentoring process documentation

The Radiation Protection Advisor (RPA) must be notified for any procedures involving x-rays or other ionising radiations.

7 Financial Considerations

In most cases the financial implications of introducing a new device or procedure will be considered prior to submission to the Clinical Effectiveness Group.

The Director of Finance is responsible for approving revenue cost pressures up to £100k. For revenue cost pressures exceeding this amount the case will need to be referred to the Trust Management Executive (TME) for approval.

The Capital Steering Group is responsible for the approval of capital costs up to the amount of £25k. If there are capital costs exceeding this amount the case will need to be referred to the Investment Panel.

Where revenue cost pressures or capital requirements have been identified, Care Group Management Teams are responsible for submitting the Business Justification Template for financial approval prior to submitting a proposal to the Clinical Effectiveness Group.

It is therefore advisable to request advice from the Procurement Team in relation to costs associated with new devices and procedures at the early stages of an application.

8 Regulated Activity

Under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 the Trust must ensure that its services are registered with the Care Quality Commission. The advice of the Deputy Head of Quality Governance must be sought prior to implementation of a new device or procedure to determine whether its introduction will require a change to the Trust's registration.

9 Ongoing monitoring

All approvals are subject to ongoing monitoring through clinical audit. For each approved proposal the Clinical Effectiveness Group will agree a suitable timeframe and the number of cases to be audited and submitted to the group for review.
If there is an increased risk to; or the risk of infection is unclear it is essential that a surveillance period is undertaken prospectively to monitor the infection rate associated with the introduction of new devices and procedures.

10 Error and Incident Reporting

If the newly implemented clinical technology or practice goes wrong during the testing phase you must immediately adhere to the following:

- Cease use of the new device or procedure immediately
- Raise an incident on Datix
- Investigate the incident, taking advice where required from the Risk and Incident Team

- Inform the Medical Director or the Assistant Medical Director for Quality and agree the most appropriate course of action regarding continuance of the trial

The details of the incident or noted error will be reported to the next available Service Line and Care Group Governance meeting and reported to Clinical Effectiveness Group for review.

11 Overall Responsibility for the Document

This policy will be overseen by the Medical Director with delegated authority to the Assistant Medical Director. The successful implementation of this policy will be evident at the Clinical Effectiveness Group during the presentation of new clinical practice, procedures and devices.

12 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of three 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 procedures described.
This document will be approved by the Clinical Effectiveness Group and ratified by the Medical Director.

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the approving Clinical Effectiveness Group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes

13 Dissemination and Implementation

Following approval and ratification, this policy 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.
Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.
The document author(s) will be responsible for the dissemination of the newly ratified document.

14 Monitoring Compliance and Effectiveness

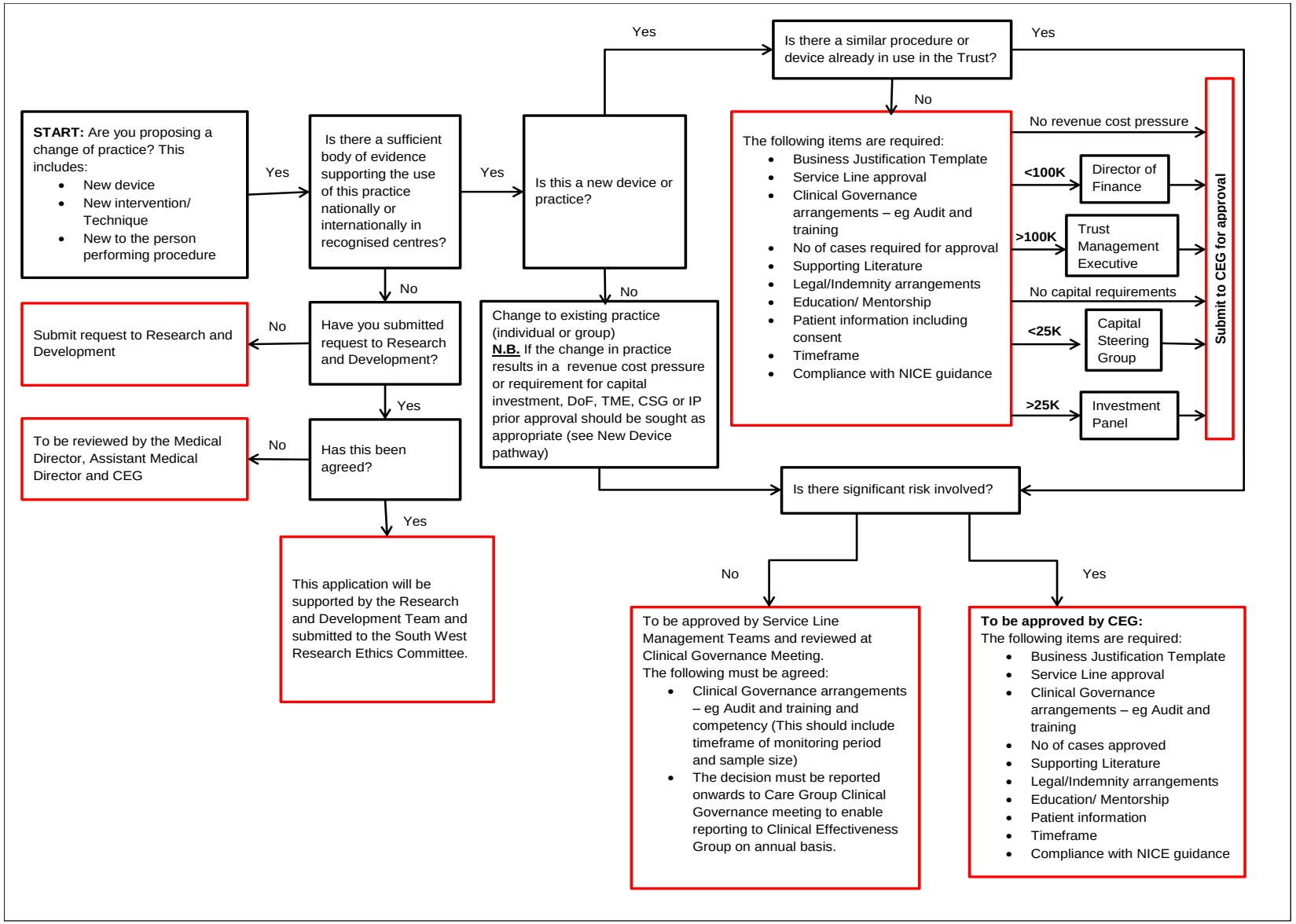
This policy will be monitored by the Medical Director/Assistant Medical Director for Quality through the Clinical Effectiveness Group (CEG).

The introduction of new devices or procedures will be included in the routine CEG report that is presented to the Safety and Quality Committee on a bi-monthly basis as well as in the annual report from CEG to the Safety and Quality Committee.

15 References and Associated Documentation

Health Service Circular (HSC) 2003/011

Appendix 1 Process Flow Chart



Appendix 2 New clinical devices and procedures Form

Proposal for change to clinical practice or introduction of new procedure or device

This form is not for Point of Care Testing (patient sampling devices) - please refer to Point of Care Testing Policy on StaffNET

NHS University Hospitals Plymouth NHS Trust

Clinician Lead:		**CEG Ref:**	To be assigned
Service Line		**Date:**	

Proposed change

Please detail

NUMBER	ASSESSMENT QUESTIONS	YES	NO	N/A	If Yes please add detail here
1	Does this proposal involve new medical devices or technology unused in the Trust?				
2	Are there evidence based advantages to the proposed change?				**Please provide references to literature**
3	Are there any known incidents or safety alerts?				**Please provide references to literature**
4	Are there any known disadvantages?				
5	Does the device or medical technology have a kitemark/licensing details?				
6	Is there national best practice? Please list				
7	Have you submitted a business justification template? If Yes please confirm the status				
8	Do you have commissioner approval/backing?				
9	Have you produced a patient information leaflet and GP correspondence?				
10	Do you have training/competency plans in place? (For Medical Devices please review the Medical Deviced Training Policy)				**Please indicate the number of cases required for approval, timescales and any additional education/mentoring requirements**
11	Have you reviewed the consent process and considered procedure specific consent?				**The Paper Records Transformation Group must be informed of all pilot consent forms that will be stored in the casenotes and the pilot time period.**
12	Have you outlined your audit plans?				**Please submit a copy of your audit plan.**

13	Has this been presented for Service Line/Care Group approval?				
14	Are there any known indeminity issues or concerns?				
15	Have you completed a research proposal and received ethics committee approval?				
16	Does the proposed change of practice, device, procedure implementation pose a disadvantage to staff members or patients? Please list				
17	Is there an increased risk of infection or the risk of infection is unclear? Risks include the requirement for additional controls to be used outside of standard practice such as a conventionally ventilated theatre.				
18	What are the estimated timescales for implementation?				
19	Does the introduction of the new medical device / procedure impact on the use of medicines?				**The Medicines Utilisation and Assurance Committee will need to be approached to approve the change in medicines use**
20	Have clinical guidelines or pathways been amended, or new documents created where they did not exist previously?				**Please submit revised or newly created documents**

DECLARATION		
STATEMENT	**NAME**	**DATE**
The information above has been completed to the best of my knowledge.		

Dissemination Plan and Review Checklist | Appendix 3

Dissemination Plan	
Document Title	The introduction of new clinical devices and procedures
Date Finalised	June 2018
Previous Documents	
Action to retrieve old copies	Remove from StaffNET. Previous version exceeding review date

Dissemination Plan

Recipient(s)	When	How	Responsibility
All staff	July 2018	Email/Vital Signs	Document Control
All staff	August 2018	Electronic Newsletter/Email	Quality Governance

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Yes
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Equalities and Human Rights Impact Assessment | Appendix 4

Core Information	
Date	June 2018
Title	The introduction of new clinical devices and procedures
What are the aims, objectives & projected outcomes?	To govern the safe introduction of new clinical devices and procedures within the Trust and to ensure that a period of ongoing monitoring is undertaken for all approved proposals

Scope of the assessment
The Equality Impact Assessment (EIA) has been undertaken ensure that the publication of this policy is compliant with the Equalities Act 2010.

Collecting data	
Race	This is mitigated as the policy can be made available in alternative languages.
Religion	Consideration should be given to the implications of implementing a change to clinical practice or new device to patients and staff.
Disability	Consideration should be given to the implications of implementing a change to clinical practice or new device to patients and staff.
Sex	Consideration should be given to the implications of transferring clinical practice to new staff group.
Gender Identity	The document has no impact in this area.
Sexual Orientation	The document has no impact in this area.
Age	The document has no impact in this area.
Socio-Economic	The document has no impact in this area.
Human Rights	Consideration should be given to the implication of implementing a change to clinical practice that does not disadvantage staff from being given the opportunity to participate.
What are the overall trends/patterns in the above data?	Additional considerations staff and patients in regards to the implementation of new clinical practice or devices
Specific issues and data gaps that may need to be addressed through consultation or further research	This assessment will highlight any areas of inequality with the implementation of this policy.

Involving and consulting stakeholders	
Internal involvement and consultation	Clinical Effectiveness Group – membership includes clinicians Equality and Diversity Lead for Trust Infection Control Lead Finance Department Medical Workforce Research and Development Team
External involvement and consultation	This policy did not involve external consultation

Impact Assessment	
Overall assessment and analysis of the evidence	This policy does not have a direct impact of equality and diversity however the new clinical devices and procedures approved may impact on staff on patients. An assessment tool has been created to ensure all the relevant considerations have been made during the application process.

Action Plan

Action	Owner	Risks	Completion Date	Progress update
To provide the E&D Team with access to information of relevant	CEG Secretary	Minimal	Indefinite	