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

NHS University Hospitals Plymouth NHS Trust

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

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.**

NUMBER	ASSESSMENT QUESTIONS	YES	NO	N/A	If Yes please add detail here
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.		