Directorate of Performance Assurance

INTRODUCING NEW SURGICAL OR OTHER PROCEDURES

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1.0 Purpose

The Trust is keen to support appropriate innovation and the introduction of developments in terms of medical technology and procedures. However, it is important that the introduction of such procedures is carried out in a recognised way and be subject to monitoring. This document outlines the approach to be followed within the Trust for introducing new surgical or other procedures. **This approach is not intended to stifle innovation or create an administrative or data burden but rather ensure that the introduction of such procedures is undertaken appropriately, is adequately funded and any issues to minimise risk to patients, the practitioner(s) involved and the Trust, have been addressed.**

2.0 Area

This document applies to the introduction of new surgical and other procedures to the Trust and to individual healthcare professionals. This includes new procedures arising from the results of clinical trials.

3.0 Duties

3.1 Personnel:

- Any health professional who wishes to introduce any new surgical or other procedure or development which goes beyond minor incremental changes or developments to his or her clinical practice
- Clinical Leads & Associate Chief Operating Officers
- Medical Director
- Associate Medical Directors
- Head of Quality Assurance
- Head of Risk and Clinical Audit

3.2 Details of the duties and responsibilities of the above are outlined in the following sections.

4.0 Actions

4.1 Any proposal for the introduction of a new surgical or other procedure should initially be considered within the relevant Clinical Directorate/Group and should have been considered by and have the support of the Clinical Lead and relevant Governance Group. The proposal should be supported by peer-reviewed, published evidence. It should include a risk assessment and there should be a realistic assessment of costs and benefits.

4.2 If the proposal is supported by the Clinical Lead and Directorate Governance Group, the Clinical Lead should present it to the Associate Medical Director and Associate Chief Operating Officer for their review and approval. The Associate Medical Director or Associate Chief Operating Officer should then refer the proposal to the Medical Director for consideration. The Associate Medical Director or Associate Chief Operating Officer, **as appropriate**, will provide the Medical Director with specific advice covering the following areas 4.2.1 to 4.2.12.

4.2.1 The potential benefits.

4.2.2 The cost implications.

4.2.3 The income implications and support from Commissioners if appropriate.

4.2.4 The potential risks and the controls in place or proposed for mitigating these (i.e. a risk assessment).

4.2.5 The training implications and the plan/timescales for addressing these. **N.B.** Any member of staff embarking upon techniques which are new to him or her and which are not part of an Ethics Committee approved research programme will be required to have completed a relevant training programme before he or she starts to perform the new technique/procedure.

4.2.6 Any possibility that the proposal may differently affect patients from diverse racial groups.

4.2.7 The implications for the Directorate/Group or speciality and supporting Directorates and services (including HSDU – see 6.0 below) of the introduction of the procedure and how this has/will be communicated.

4.2.8 The implications for other providers (e.g. GPs, District Nurses) and how this will be communicated (see also 4.2.9).

4.2.9 Whether the proposed procedure is covered by existing or proposed NICE interventional procedure guidance, the substance of any recommendations and the actions in place or proposed to ensure compliance – including the development of relevant policies/procedures or guidelines or an explanation of any proposed departure from those recommendations. Where the procedure is not covered by existing or proposed guidance, confirmation that the Head of Quality Assurance has been notified (see 4.4 below) and the means by which the special status of such procedures will be communicated to patients will be required.

4.2.10 Confirmation that, as part of routine sharing of information with Commissioners, the introduction of a new procedure has been notified/discussed (as appropriate) with Commissioning/GPCC colleagues.

4.2.11 The arrangements for auditing/monitoring the effectiveness of the proposed new arrangements (e.g. is there an agreed clinical audit programme in place/planned covering the procedure) and how any concerns will be escalated and addressed (e.g. via the Trust's Incident Reporting/governance arrangements).

4.2.12 The above requirements/advice should be backed by evidence wherever possible.

4.3 The Medical Director will notify the Trust Governance & Assurance Committee of the proposal and, will provide a recommendation to the committee in respect of the proposal. If the Trust Governance & Assurance Committee agrees with the proposal, it will recommend either that the procedure is instituted or developed as a pilot.

4.4 If the procedure is not covered by existing or proposed guidance then the Head of Quality Assurance will notify NICE using the electronic form published on its website. It is the responsibility of the relevant Clinical Directorate/Group to determine the means by which the special status of such procedures shall be communicated to patients (and for the Medical Director/Trust Governance & Assurance Committee to assure itself that this has been considered as part of the original proposal/request).

4.5 If the new procedure requires medicines that are not in the Trust Formulary, an application will need to be made to the Medicines & Therapeutics Committee to include the medicine in the Formulary.

4.6 In the case of a professional newly appointed to the Trust, who wishes to undertake a new procedure, the Associate Medical Director will require evidence of competency of the individual to undertake that procedure. If the procedure had not been agreed as part of the job description of the professional then the above process outlined in 4.1 to 4.4 will apply.

4.7 Where a new procedure has been used in a clinical emergency, the medical practitioner must inform their Associate Medical Director, who in turn should inform the Medical Director within 72 hours. The Medical Director will notify the Trust Governance & Assurance Committee, at its next scheduled meeting, who will consider approval of the procedure for future use.

4.8 The Trust Governance & Assurance Committee (via the Directorate of Performance Assurance) will maintain a register of such procedures recording the date of introduction, the verification of competency and the arrangements for clinical audit. It will also record the NICE status of the procedure including any agreed departure from NICE recommendations.

4.9 The Head of Risk & Clinical Audit will notify relevant others of additions to the register of new procedures e.g. Clinical Coders.

4.10 Colleagues should liaise informally with the Medical Director at an early stage in considering such new procedures. S/he will be able to advise on this policy and provide help in progressing the proposal through the process.

4.11 The foregoing is clearly in addition to any processes required as the basis of ethical research approval, indemnification for alleged negligence as well as a detailed business case where these are appropriate. Non-medical staff should also make reference to the Trust Policy for Adjusting the Scope of Professional Practice which details the systematic process by which they may develop their roles.

4.12 In some circumstances it may be appropriate to seek approval for the new procedure at the Executive Team or at the Trust Board.

5.0 Monitoring Compliance and Effectiveness

The Trust Governance & Assurance Committee will be responsible for monitoring compliance with this policy. The arrangements for monitoring the effectiveness of any new procedures/arrangements implemented in accordance with this policy are as outlined in 4.2.11 and 4.8 above.

6.0 Associated Documents

6.1 Policy for Adjusting the Scope of Professional Practice (DCP260).

6.2 *Schedule 7 of the DSA with Synergy in relation to HSDU (requirement to inform Synergy of major service changes requiring additional instrumentation/decontamination.

6.3 https://www.england.nhs.uk/wp-content/uploads/2015/09/natssips-safety-standards.pdf

7.0 References

None.

8.0 Definitions

NICE – National Institute for Health and Care Excellence.

9.0 Consultation & Approval

The Trust Governance & Assurance Committee will be responsible for the ratification of this policy/procedure.

10.0 Dissemination

A copy of this policy/procedure will be sent to all Clinical Directorates – including Directors, Associate Medical Directors, Associate Chief Operating Officer and Consultants and will also be posted on the Trust's Intranet. Amendments to the policy/procedure will be communicated to these staff as and when they occur.

11.0 Implementation

It will be the responsibility of the relevant Associate Medical Directors/ ACOOs to ensure implementation of and adherence to this policy within their respective areas.

12.0 Equality Act (2010)

12.1 In accordance with the Equality Act (2010), the Trust will make reasonable adjustments to the workplace so that an employee with a disability, as covered under the Act, should not be at any substantial disadvantage. The Trust will endeavour to develop an environment within which individuals feel able to disclose any disability or condition which may have a long term and substantial effect on their ability to carry out their normal day to day activities.

12.2 The Trust will wherever practical make adjustments as deemed reasonable in light of an employee's specific circumstances and the Trust's available resources paying particular attention to the Disability Discrimination requirements and the Equality Act (2010).
