Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

# Introducing New Clinical Procedures or Practices

**This procedural document supersedes: CORP/RISK 3 v.7 – Introducing New Clinical Procedures or Practices.**

**Did you print this document yourself?**
The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

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|---|---|
| Executive Sponsor(s): | Karen Jessop, Chief Nurse |
| Author/reviewer: (this version) | Juan Ballesteros - Associate Medical Director for Clinical Safety<br>Marie Hardacre – Head of Nursing, Corporate Services |
| Date written/revised: | March 2022 |
| Approved by: | Patient Safety Review Group |
| Date of approval: | October 2023 |
| Date issued: | March 2023 |
| Next review date: | March 2025 |
| Target audience: | Trust-wide |

# Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

| Version | Date Issued | Brief Summary of Changes | Author |
|---|---|---|---|
| Version 8 | January 2023 | • PSRG (Patient Safety Review Group) changed to PSC (Patient Safety Committee)<br>• Care Group changed to Specialty<br>• Medical Director changed to Executive Medical Director<br>• Director of Nursing and Midwifery changed to Chief Nurse | Juan Ballesteros Marie Hardacre |
| Version 7 | 11 December 2017 | • DBTH Trust log inserted and name throughout.<br>• Business support group (BSG) changed to Corporate Investment Group (CIG)<br>• Training section adjusted to reflect all clinical staff groups | Ray Cuschieri Lisette Caygill |
| Version 6 | 11 February 2015 | • Care Groups reflected throughout.<br>• Responsibility of PSRG to maintain a register of new procedures and to include in annual PSRG report.<br>• Equality Impact Assessment section and form included. | Deputy Medical Director and Head of Risk and Legal Services |
| Version 5 | 10 April 2014 | • Minor changes to job titles.<br>• Short review date given in light of proposed changes to the CSUs structure. | Deputy Director of Nursing, Midwifery and Quality |
| Version 4 | June 2011 | • Title change.<br>• Amend so applies to all 'clinicians', doctors, nurses, midwives and allied health professionals. | Deputy Medical Director<br>Deputy Director of Nursing |
| Version 3 | December 2008 | • New divisional structures and reporting mechanisms updated in line with organisational changes. | Medical Director and Risk Manager |

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## 1 INTRODUCTION

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 subject to monitoring in order to minimise clinical risk, from the patient's, practitioner's and Trust's point of view. This may also apply to procedures already done in the Trust but where a different group of clinicians is going to undertake them e.g. nurses doing endoscopies, radiographers doing x-ray interpretation.

For the purpose of this paper, the term clinician relates to all registered Health Professions including Medicine, Nursing, Midwifery, all Allied Health Professions and Scientists.

## 2 PURPOSE

The following outline protocol is suggested:

- Any health professional that wishes to introduce any new procedure, which goes beyond minor incremental changes or developments to their clinical practice, should raise it within their specialty initially. This should be raised for discussion within the relevant Specialty at their Clinical Governance meetings.

- Once agreed locally, it will be necessary to apply in writing to the Executive Medical Director (as the Clinical Governance Lead for the Trust) and the application must be submitted on the pro-forma attached at **Appendix 1**. Once the application is received he/she may seek appropriate professional advice about the advisability of such a change in practice. The application will also be forwarded to the Director of People and Organisational Development and Chief Nurse for their consideration and advice.

  The Executive Medical Director will wish to be assured that appropriate basic training has been undertaken prior to carrying out any new procedures in the Trust. The professional's competency for such new work would also need to be verified before the Executive Medical Director considered the request.

- Agreement to the introduction of a new technique would then be formally sought from the Patient Safety Committee (PSC). The clinician applying to introduce the new procedure will be invited to present his/her application to the group and provide evidence as appropriate in advance in support of their application. The applicant will need to assure the PSC, as a minimum, the following:

  - They are technically competent to carry out the procedure;
  - The new procedure is evidence based;
  - The training implications for other professions have been considered and accounted for e.g. nursing staff, theatre staff etc;
  - The provision of training for the introduction of new equipment;
  - The introduction of appropriate written 'Patient Information', which must

cover the risk and benefits of the procedure;
  - Training programmes for junior staff in the consenting of patients for the new procedure;
  - The outline plans for audit and review of practice by an MDT.

- In the case where a new group or clinician is going to undertake an established procedure, appropriate on-going supervision must be provided.

- Arrangements would be made to ensure that a review would be undertaken after a specified number of procedures had been performed.

- In the case of a professional who has been newly appointed to the Trust, the appropriate Specialty would require a list of any new procedures/skills the professional would be bringing to the Trust and evidence of competency for this work. The Division would then inform the Executive Medical Director for the same checking process to apply as above.

- New procedures approved by PSC will be entered on a central register by the PSC administrator and included in the annual PSC report.

Colleagues are asked to liaise with the Executive Medical Director at an early stage in considering the introduction of such procedures.

The foregoing is clearly in addition to any procedures required on the basis of ethical research approval, indemnification for alleged negligence as well as financial implications following the introduction of new procedures. A business case may have to be taken to the Clinical Investment Group (CIG) if the proposal has any increase or decrease in resources needed.

## 3 DUTIES AND RESPONSIBILITIES

Refer to Item 2 Purpose which outlines Roles and Responsibilities.

## 4 TRAINING/SUPPORT

Please note: The training requirements of staff will be identified through a learning needs analysis (LNA). Role specific education will be co-ordinated/delivered by the topic lead. Alternatively, training may be accessed via an approved e-learning platform where available.

## 5 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

The Patient Safety Committee (PSC) will review the Annual register in April of each year and ensure each new procedure has been reviewed as detailed in **Appendix 1**.

| What is being Monitored | Who will carry out the Monitoring | How often | How Reviewed/ Where Reported to |
|---|---|---|---|
| All new procedures have been through Patient Safety Committee (PSC) | Patient Safety Committee (PSC) | Monthly | Patient Safety Committee (PSC) |
| Correct approval of Clinical Practice | Head of Clinical Audit<br>Associate Medical Director | | Patient Safety Committee (PSC) |
| People are technically competent to carry out the procedure | Health Professional introducing Procedure | | Patient Safety Committee (PSC) |
| The introduction of appropriate written Patient Information which must cover the risk and benefits of the procedure. | Patient Information Group | | Patient Safety Committee (PSC) |

## 6 DEFINITIONS

Patient Safety Committee (PSC)
Patient Safety Review Group (PSRG)

## 7 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment for All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 2).

## 8 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Equality Analysis Policy (CORP/EMP 27)
Fair Treatment for All Policy (CORP/EMP 4)

## 9 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

# APPENDIX 1 – PROTOCOL FOR INTRODUCING NEW CLINICAL PROCEDURES OR PRACTICES

Clinician Name …… Clinical Grade……

Details of New Procedure ……

……(continue on separate sheet if required)

Date approved by Divisional Clinical Governance Group ……..

**Verification of Competence (to undertake procedure)**

Details of Training or Qualifications attained ……

……

……

Please attach details of training courses, copies of certificates of achievement in support of verification of competency

**Evidence Based Practice**

Please state briefly details of evidence based practice/research in support of application (eg. NICE

Guidelines) ……

……

…… (please attach additional documents as required)

**Training Implications**

Have the training requirements for all staff groups supporting the introduction of the procedure been considered and where necessary training has/will be undertaken (Please attach details of training where appropriate)

| | Training required | Lead Manager |
|---|---|---|
| Nursing staff | Yes/No | |
| Midwifery staff | Yes/No | |
| AHP's (Allied Healthcare Professionals) | Yes/No | |
| Medical staff | Yes/No | |

**Medical Equipment**

Please give details of any equipment for which the user will need training to ensure that they are competent to use it, which may be utilised as part of the new procedure outlined above. (Please attach additional information as required)

| Equipment Name | Training required | Staff Group | Training Package Developed | Lead Person for training |
|---|---|---|---|---|
| | Yes/No | | Yes/No | |
| | Yes/No | | Yes/No | |
| | Yes/No | | Yes/No | |

**Consent and Patient Information**

Details of training packages and verification of all grades of clinical staff authorised to take consent
(Please attach additional information as required)

| Grades of Staff Authorised to take consent | Training package (Please attach) | Lead Trainer |
|---|---|---|
| | Yes/No | |
| | Yes/No | |
| | Yes/No | |

Attach a draft of the information, which will be provided to patients, this must include the risk and benefits of the procedure. **Attached Yes/No**

**Audit and Review**

Please provide details of any Audits which the procedure will be subject to either as a 'one-off' Audit or an annual process……..
……..
……..
……..
……..
……..
……..

The following process of review would will be undertaken after (insert number)……. of the procedures have been performed, or within 12 months of introduction and presented to PSC.
……..
……..
……..
……..
……..
……..

**Applicants Signature**

Applicants Signature…….

Date…….

**For Patient Safety Committee Use Only**

Date presented to PSC ……. Approved: Yes/No

Details of any further action required by applicant……..
……
……

Date entered on Data Base……..

Signed on Behalf of Patient Safety Committee

Signed…… Print Name……

Designation……

# APPENDIX 2 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

| Service/Function/Policy/Project/ Strategy | Division | Assessor (s) | New or Existing Service or Policy? | Date of Assessment |
|---|---|---|---|---|
| CORP/RISK 3 v.8 – Introducing New Clinical Procedures or Practices | Executive Medical Director | Marie Hardacre | Existing Policy | 26 January 2023 |

**1) Who is responsible for this policy?** Associate Medical Director for Clinical Safety

**2) Describe the purpose of the service / function / policy / project/ strategy?** To ensure new clinical procedures are introduced in a controlled and monitored way

**3) Are there any associated objectives?** Legislation, targets national expectation, standards:

**4) What factors contribute or detract from achieving intended outcomes?** – None

**5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief?** Details: [see Equality Impact Assessment Guidance] - No

- **If yes, please describe current or planned activities to address the impact** [e.g. Monitoring, consultation] – N/A

**6) Is there any scope for new measures which would promote equality?** [any actions to be taken] No

**7) Are any of the following groups adversely affected by the policy? No**

| Protected Characteristics | Affected? | Impact |
|---|---|---|
| a) Age | No | |
| b) Disability | No | |
| c) Gender | No | |
| d) Gender Reassignment | No | |
| e) Marriage/Civil Partnership | No | |
| f) Maternity/Pregnancy | No | |
| g) Race | No | |
| h) Religion/Belief | No | |
| i) Sexual Orientation | No | |

**8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box**

| Outcome 1 ✓ | Outcome 2 | Outcome 3 | Outcome 4 |
|---|---|---|---|

**If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27.**

**Date for next review: April 2025**

**Checked by: Juan Ballesteros** **Date: 26 January 2023**