

START: Are you proposing a change of practice? This includes:

- New device
- New intervention/ Technique
- New to the person performing procedure

Is there a sufficient body of evidence supporting the use of this practice nationally or internationally in recognised centres?

Is this a new device or practice?

Is there a similar procedure or device already in use in the Trust?

The following items are required:

- Business Justification Template
- Service Line approval
- Clinical Governance arrangements – eg Audit and training
- No of cases required for approval
- Supporting Literature
- Legal/Indemnity arrangements
- Education/ Mentorship
- Patient information including consent
- Timeframe
- Compliance with NICE guidance

Change to existing practice (individual or group)
N.B. If the change in practice results in a revenue cost pressure or requirement for capital investment, DoF, TME, CSG or IP prior approval should be sought as appropriate (see New Device pathway)

Submit request to Research and Development

Have you submitted request to Research and Development?

Has this been agreed?

To be reviewed by the Medical Director, Assistant Medical Director and CEG

This application will be supported by the Research and Development Team and submitted to a Health Research Authority (HRA).

Is there significant risk involved?

To be approved by Service Line Management Teams and reviewed at Clinical Governance Meeting.
 The following must be agreed:

- Clinical Governance arrangements – eg Audit and training and competency (This should include timeframe of monitoring period and sample size)
- The decision must be reported onwards to Care Group Clinical Governance meeting to enable reporting to Clinical Effectiveness Group on annual basis.

To be approved by CEG:
 The following items are required:

- Business Justification Template
- Service Line approval
- Clinical Governance arrangements – eg Audit and training
- No of cases approved
- Supporting Literature
- Legal/Indemnity arrangements
- Education/ Mentorship
- Patient information
- Timeframe
- Compliance with NICE guidance

No revenue cost pressure → Submit to CEG for approval

<100K → Director of Finance → Submit to CEG for approval

>100K → Trust Leadership Group → Submit to CEG for approval

No capital requirements → Submit to CEG for approval

<100K → Capital Steering Group → Submit to CEG for approval

>100K → Investment Panel → Submit to CEG for approval

Submit to CEG for approval