**APPLICATION TO INTRODUCE A NEW PROCEDURE, TECHNIQUE OR MAJOR CHANGE IN CLINICAL PRACTICE WITHIN SALISBURY NHS FOUNDATION TRUST**

**ESTABLISHING THE CLINICAL CASE**

*To receive this form electronically email claire.gorzanski@salisbury.nhs.uk*

*or telephone on extension 2033 or 4046*

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| --- | --- | --- |
| 1. 1.11.2 | Name of applicant – *should be Health Professional intending to carry out new procedure/technique*Name of Department / DirectorateExtension numbers |  |
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| 2.2.12.2  | Title of new procedure/technique Brief description of what is involved in the procedure/techniqueIs this procedure for children |  |
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|  Yes NoYes / No |
| 3. | NICE status - please tick: see www.nice.org.uk/guidance*Refer to page 5 and Appendix 2 of policy* | **A:** **NICE approved guidance issued –** safety and efficacy appears adequate for use with the normal arrangements forconsent, audit and clinical governance**B:** **Part of an approved research** **programme** – requires approval by the R&D Dept and HRA (please visit <http://www.salisbury.nhs.uk/InformationForPatients/Departments/Research/Pages/IndexPage.aspx> and [www.hra.nhs.uk](http://www.hra.nhs.uk)or **C: Requires special arrangements** for audit/evaluation in accordance with NICE requirements**D: No guidance issued** **E:** **If none of the above** please state -  |

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| --- | --- | --- |
| 4.4.14.2 | Has this proposed new procedure/technique previously been performed:At Salisbury Foundation NHS Trust Has this proposed new procedure/technique previously been observed and performed by the applicant? |  Yes No Yes NoIf yes, by whom? Yes NoIf yes, where?How many times performed? performed?How many times observed? Records available  Yes No |
| 5.5.1 | Is research evidence available regarding the effectiveness/safety of this new procedure/technique?Please state if appropriate:1. Research paper reference(s)
2. NHS Evidence
3. NICE Guidance*(title and number)*
 |  Yes NoIf yes, please complete 5.1 |
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| 6. | Has the proposed procedure/technique/drug been discussed with: | Medical Devices Committee:  Yes (attach Minutes) NoProcurement Department  Yes (attach Minutes) NoDrugs and Therapeutics Committee Yes (attach Minutes) NoAll appropriate Clinical Directors – especially in the case of multi-professional working: Yes NoIf yes, please list:  Other relevant colleagues – internal and external to Trust: e.g. Diagnostics, CCG Yes NoIf yes, please list:   |
| 7.  | Please describe the benefits to the patient:  |  |
| 8.  | Please describe any risks to the patient:  |  |
| 9. | What are the additional training requirements and for whom?How will these be met?How will these be met? |  |
|  |
| 10. | Has the practitioner undertaking the procedure met externally set standards of training, if available?Details of external training:  |  Yes No |
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| 11. | What are the additional competencies required and for whom?How will these be met? |  |
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| 12. | Are there any workforce implications for the team involved? e.g. grading issues, skill mix changes, number of staff required? |  Yes NoIf yes, please state: |
| 13.  | Please describe the proposed informed consent process to be put in place:  |   |
| 14. | Please describe the proposed audit/evaluation plan, including measures and frequency of reporting: **NB. The Trust will monitor the completion of these and expect an audit within a year of the introduction of the practice** |  |
| 15. | Is this new procedure/technique included in the Trust or Directorate serviceplan?If yes, is a business case required to progress this new procedure (see appendix 2 on how to write a business case) |  Yes No Yes (attach) No |
| 16. | Signatures required to validate the Clinical Case:Lead Clinician Approved: Yes No ……………………………………………………………………….. Date :…………………………………..Clinical Director Approved: Yes No ……………………………………………………………………….. Date :…………………………………..Directorate Manager Approved: Yes No ……………………………………………………………………….. Date :…………………………………..Senior Finance Manager approved: Yes No ……………………………………………………………………….. Date :…………………………………..Medical Director Approved: Yes No ……………………………………………………………………….. Date :………………………………….. |

KEEP MASTER COPY

Return COPY to Head of Clinical Effectiveness, Block 24, Quality Directorate, SDH for inclusion on ‘New procedures’ database

Contact Head of Corporate Governance for agenda item on Trust Management Committee.

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| *For Office Use only:** Audit data due : ……………………………………(date) Audit Dept aware
* Patient information checked (must include risks, benefits and alternatives)
* Patient information available on ICID
* Local protocols / guidelines written, approved and on ICID
* Competency of practitioner agreed Evidence kept:…………………………………………
* To Trust Management Committee for approval Date:………………………………..
* Directorate Manager and Lead Clinician to include in Service Plan
* TMC Approved procedure added to New Procedures database

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* Director of Corporate Development aware
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