APPENDIX A

Salisbury NHS Foundation Trust

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

ESTABLISHING THE CLINICAL CASE

This form is available electronically from Eolas here:

1.	Name of applicant – *should be Health Professional intending to carry out new procedure/technique*	
1.1	Name of Department / Division	
1.2	Extension numbers	
2.	Title of new procedure/technique	
2.1	Brief description of what is involved in the procedure/technique	
2.2	Is this procedure for children	☐ Yes ☐ 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 for consent, 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 • https://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 -
4.	Has this proposed new procedure/technique previously been performed:	☐ Yes ☐ No
4.1	At Salisbury Foundation NHS Trust	☐ Yes ☐ No If yes, by whom?
4.2	Has this proposed new procedure/technique previously been observed and performed by the applicant?	☐ Yes ☐ No If yes, where? How many times observed? ☐ How many times performed? ☐ Records available ☐ Yes ☐ No

5.	Is research evidence available regarding the effectiveness/safety of this new procedure/technique?	☐ Yes ☐ No If yes, please complete 5.1
5.1	Please state if appropriate: A. Research paper reference(s)	
	B. NHS Evidence	
	C. NICE Guidance *(title and number)*	

6.	Has the proposed procedure/technique/drug been discussed with:	Medical Devices Committee: ☐ Yes (attach Minutes) ☐ No Procurement Department ☐ Yes (attach Minutes) ☐ No Drugs and Therapeutics Committee ☐ Yes (attach Minutes) ☐ No All appropriate Clinical Directors – especially in the case of multi-professional working: ☐ Yes ☐ No If yes, please list: Other relevant colleagues – internal and external to Trust: e.g. Diagnostics, CCG ☐ Yes ☐ No If 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?	
10.	Has the practitioner undertaking the procedure met externally set standards of training, if available?	☐ Yes ☐ No
	Details of external training:	
11.	What are the additional competencies required and for whom?	
	How will these be met?	

12.	Are there any workforce implications for the team involved? e.g. grading issues, skill mix changes, number of staff required?	☐ Yes ☐ No If 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 Divisional service plan? 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: …….. Divisional Manager Approved: ☐ Yes ☐ No …….. Date: …….. Divisional Finance Manager approved: ☐ Yes ☐ No …….. Date: …….. Chief Medical Officer 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 Executive Services Manager for agenda item on Trust Management Committee.

For Office Use only:

- Audit data due: …… (date) Audit Dept aware ☐
- Patient information checked (must include risks, benefits and alternatives) ☐
- Patient information available on Eolas ☐
- Local protocols / guidelines written, approved and on Eolas ☐
- Competency of practitioner agreed ☐

  Evidence kept: ……

- To Trust Management Committee for approval ☐

  Date: …….

- Divisional Manager and Lead Clinician to include in Service Plan ☐
- TMC Approved procedure added to New Procedures database

  Date: …….

- Director of Corporate Development aware ☐