The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Techniques and Medical Devices Group (TaMDg)
Application form for the Introduction of a New Technique or Medical Device
Please return completed forms to **TaMDg@rlbuht.nhs.uk**

To be completed by the applicant in conjunction with the Directorate Manager

Name of Clinical Lead:	**Internal Contact Number (& Mobile)**
Name of Directorate Manager:	**Internal Contact Number (& Mobile)**
Directorate:	
Name/Title of New Technique/Medical Device:	
Summary of clinical topic to be addressed by new Technique/Medical Device:	
Your application will need to be supported by the following documentation. Please cross the relevant box to indicate that the specific document/s has/have been attached to your application form:	

	Sufficient detail about the new technique or device with reference to the advantages and the risks to the patient.
	Current evidence available on research previously conducted – *to be reviewed by the applicant and attached* Questions for Evaluation of Studies .
	Possible technique/ device incidents and safety alerts have been researched using the following databases and resource tools. **Cochrane, MHRA, NICE, NPSA**. ***((Click on the respective title to access)***
	Please indicate if a (Patient Information Form) PIF is applicable to your application Yes/No Draft Patient Information Leaflet (**as per Trust template**). All information should include the risks (with percentages or likelihood of risks occurring) benefits, alternatives and effects of no treatment.
	Please liaise and obtain from the manufacturer any device or safety alerts related to the

	application.
	CE mark/product license. ***Please provide number*** [ ]
	Please provide NICE Interventional Procedure Guidance (IPG) no. …….. or tick to confirm NICE have been informed of this if an IPG has not been published (as per **New Techniques and Medical Devices policy** (see Appendix 3.)

Training method of applicant/team (Please cross relevant box(s):			
	Audio visual		Training demonstration/seminar
	Trained by expert/ Centre of Excellence		Mentored by expert

Declaration of Competing Interests[1]		
A competing interest exists when professional judgment concerning a primary interest (e.g. this application) may be influenced by a secondary interest (such as financial gain, involvement in trials or personal rivalry)		
This section should be filled in by both the applicant and the Clinical Director		
1. Have you, in the past five years, accepted the following from an organisation that may in any way gain or lose financially from the result of your application:		
	Applicant	**Clinical Director**
Reimbursement for attending a symposium?	Yes/No	Yes/No
A fee for speaking?	Yes/No	Yes/No
A fee for organising education?	Yes/No	Yes/No
Funds for research?	Yes/No	Yes/No
Funds for a member of staff?	Yes/No	Yes/No
Fees for consulting?	Yes/No	Yes/No
2. Have you, in the past five years, been employed by an organisation that may in any way gain or lose financially from the results of your application?		
	Yes/No	Yes/No
3. Do you hold any stocks or shares in an organisation that may, in any way, gain or lose financially from the results of your application?		
	Yes/No	Yes/No
4. Have you acted as an expert witness on the subject of your application?		
	Yes/No	Yes/No
5. Do you have any other competing financial interests?		
	Yes/No	Yes/No
If yes, to question 5 please specify here:		

If you have answered "yes" to any of the above 5 questions, we consider that you may have a competing interest, which, in the spirit of openness, should be declared. Please draft a statement to be submitted with your application below. It might, **for example**, read:

- *Competing interest: RS has been reimbursed by Shangri La Products, the manufacturer of Elysium, for attending several conferences; TD has been paid by*

[1] The declaration of interest section is taken from the International Committee of Medical Journal Editors' Unified Competing Interest form currently being trialed by the British Medical Journal.

Shangri La Products for running educational programmes and has her research registrar paid for by the company; JS has shares in the company.

We are restricting ourselves to asking directly about competing financial interests, but you may want to disclose another sort of competing interest that would embarrass you if it became generally known after consideration of your application. The following list gives some examples.

- A close relationship with, or a strong antipathy to, a person whose interests may be affected by your application.
- An academic link or rivalry with somebody whose interests may be affected by your application.
- Membership of a political party or special interest group whose interests may be affected by your application.

If you want to declare such a competing interest then please add it to your statement.
Statement of Declaration of Interest:

Name of Applicant.....……. Signature …… Date …….

Name of Clinical Director …… Signature …… Date …….

Directorate Support	
All signatures must be obtained before submission. (Signatories are encouraged to attach additional recommendations/comments)	
Directorate Accountant – Please cross appropriate box(s):	
	Funding has been fully identified for all additional costs
	Funding has been identified to cover expected additional costs
	No funding identified but additional costs expected
	No additional costs expected (e.g. cost neutral)
	Additional financial implications/recommendations attached
Procedure	
How many procedures and over what period of time are to be undertaken?	
How many procedures are currently carried out? [ ]	
Will the new technique/ device impact the Trust's activity volume? Yes/No – If yes, how?	
Please quote the current OPCS (Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures)/ ID Code [ ]	
Does the new technique or device change the coding? If yes, what is the impact on the Healthcare Resource Group (HRG) tariff?	
Capital Costs	

Please provide details of any items that will require sterilisation e.g. containers / trays.
Please provide details of capital costs of any new equipment.
What would the maintenance arrangements be? Are there any additional costs? Yes/No. If yes, please provide details.
Impact on Revenue Costs

Details of current consumables (price (£) and volume)	£: Volume:
Details of future consumables (price (£) and volume)	£: Volume:

Are additional consumables required? Yes/No If Yes – please specify.
Is there an additional impact on theatre time? Yes/No If Yes – please specify.
If additional theatre sessions are required please provide details.
Please detail any other impact on staff time or numbers.
Please provide details of any associated costs.
Summary of financial impact (To be completed by the Divisional or Directorate Accountant).
Signature of Directorate Accountant …… Date ……..
Clinical Lead (Applicant)
☐ Additional recommendations/comments attached. **Signature of Clinical Lead. …… Date ……**
Directorate Manager

	Additional recommendations/comments attached.

Signature of Directorate Manager…….. Date ……

Clinical Director	
	Additional recommendations/comments attached.
	Signature of Clinical Director …….. ……. Date …… ***(If the applicant is the Clinical Director the signature of the Divisional Associate Medical Director is required)***

New Technique/Device Evaluation Form	
Name of Lead Clinician:	
Designation:	**Directorate:**
Name/Title of New Technique/Medical Device:	
Feedback process ***to be agreed at TaMDg meeting*** Written report/presentation to TaMDg *delete as appropriate After [ ] number of procedures or After [ ] months Feedback to include: • Total number of procedures • Complications • Method of training • Financial analysis (cost benefit) Please also refer to the TaMDg Mandatory Update Form. TaMDg Mandatory Update Form	
Clinical Audit Required: Yes/No - If yes, please complete audit proforma	
Anticipated date initial evaluation findings to be reported to the Techniques and Medical Devices group. ***To be agreed in conjunction with TaMDg on approval of application.***	
Applicant Signature	

Signature: ……..…… Date ……..…..
Chair of T&MD group Signature
Signature: ……. …….….Date……..…
Department Reference no. (Leave blank)

Application Outcome					
	Approved		Not Approved		Approved subject to changes
Recommendations:					
Signed by Chair of T&MD group ……. …….Date……					