

Supplementary file 2. Preliminary data extraction form

DATA EXTRACTION DETAILS		
1	Who is extracting the data? (initials)	
	[][][]	
2	What is the name of the trust?	
3	What is the Trust ID?	
	[][][]	
4	Policy title:	
5	Current policy and/or version number:	
	[][][]	
SCOPE OF POLICY		
1	What procedures/devices does the policy apply to?	
a)	Invasive procedures	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<input type="checkbox"/> N/A	
	<i>If yes, answer i) - ii). If no or not stated go to question b).</i>	
	i) What term is used to describe these procedures?	
	ii) Does the policy define invasive procedures (or similar term used)?	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If yes -	
	• Copy and paste definition:	
b)	Invasive devices	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<input type="checkbox"/> N/A	
	<i>If yes answer i)-iv). If no or not stated go to c).</i>	
	i) What term is used to describe invasive devices?	
	ii) Does the policy define invasive devices (or similar term used)?	
	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	If yes -	
	• Copy and paste definition:	

2	When should the policy be implemented?		
a)	When procedures/devices are new (or a similar term that implies this)?		
	<input type="checkbox"/> Yes (explicitly states that the policy should be implemented in this instance)		
	<input type="checkbox"/> No (explicitly states that the policy should <u>not</u> be implemented in this instance)		
	<input type="checkbox"/> Unclear		
	<input type="checkbox"/> Not stated (does not state whether or not policy should be implemented in this instance)		
	<i>If yes, no or unclear answer i)-iii). If not stated go to b).</i>		
	i) Does the policy define 'new' (or similar term)?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
b)	When procedures/devices are modified (to include references to 'changes in clinical practice') (or a similar term that implies this)?		
	<input type="checkbox"/> Yes (explicitly states that the policy should be implemented in this instance)		
	<input type="checkbox"/> No (explicitly states that the policy should <u>not</u> be implemented in this instance)		
	<input type="checkbox"/> Unclear		
	<input type="checkbox"/> Not stated (does not state whether or not policy should be implemented in this instance)		
	<i>If yes, no or unclear answer i)-iii). If not stated go to c).</i>		
	i) Does the policy define 'modification' (or similar term)?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
c)	When a procedure/device is used within a research study		
	<input type="checkbox"/> Yes (explicitly states that the policy should be implemented in this instance)		
	<input type="checkbox"/> No (explicitly states that the policy should <u>not</u> be implemented in this instance)		
	<input type="checkbox"/> Unclear		
	<input type="checkbox"/> Not stated (does not state whether or not policy should be implemented in this instance)		
	i) Copy and paste all text: (if none, type N/A) [QUALITATIVE DATA]		
d)	When procedures/devices approved by research ethics are used outside of the specified protocol		
	<input type="checkbox"/> Yes (explicitly states that the policy should be implemented in this instance)		
	<input type="checkbox"/> No (explicitly states that the policy should <u>not</u> be implemented in this instance)		

	<input type="checkbox"/> Unclear		
	<input type="checkbox"/> Not stated (does not state whether or not policy should be implemented in this instance)		
	i) Copy and paste all text: (if none, type N/A) [QUALITATIVE DATA]		
e)	Other. Please state any other instances in which the policy should be implemented (if none, type N/A):		
PATIENT INFORMATION AND CONSENT			
1	Does the policy state that patients should receive information and/or complete a consent form that is specific to the new procedure/device delivered?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
	<i>If yes or unclear answer a)-c). If no go to section I.</i>		
a)	Is the applicant required to submit the patient information leaflet and/or consent form with the application?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
b)	Does the policy provide guidance on what details should be included in the patient information leaflet and/or consent form?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
	<i>If yes, answer i). If no or unclear go to section I.</i>		
	i) Does this include informing patients that the procedure/device is new/modified?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
c)	Does the policy state that specific PIL information should be provided for all approved procedures/devices?		
	Yes - specific PIL information should be provided for all new procedures/devices.		
	No - specific PIL information is only required in a subset of new procedures/devices (i.e. if there is no NICE Guidance in place).		
	Not stated		
AUDIT AND OUTCOME MONITORING			
1	Does the policy state that the use of new procedures/devices should be monitored/reviewed in any way?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
	<i>If yes, go to question 2. If no or not stated go to section H.</i>		
2	Does the policy require applicants to submit outcome data, including adverse events, clinical complications etc?		

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
<i>If yes, answer a)-d). If no or unclear go to question 4.</i>		
a) Who is responsible for submitting monitoring/outcome data? (tick all that apply)		
<input type="checkbox"/> Individual clinician		
<input type="checkbox"/> Head of department		
<input type="checkbox"/> Other. Please state:		
<input type="checkbox"/> Not stated		
b) Who is the monitoring/outcome data submitted too? (tick all that apply)		
<input type="checkbox"/> Trust committee responsible for the introduction of new procedures/devices		
<input type="checkbox"/> NICE		
<input type="checkbox"/> Audit & Effectiveness Dept/Group		
<input type="checkbox"/> Clinical effectiveness/safety group		
<input type="checkbox"/> Clinical audit group		
<input type="checkbox"/> Medical and/or Nursing Director		
<input type="checkbox"/> Clinical governance group		
<input type="checkbox"/> Other. Please state:		
<input type="checkbox"/> Not stated		
c) Does the policy specify the type of monitoring/outcome data to be submitted?		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	
<i>If yes, answer i)-ii). If no go to question d).</i>		
i) Which of the following outcomes are specified? (tick all that apply)		
<input type="checkbox"/> Adverse events		
<input type="checkbox"/> Safety		
<input type="checkbox"/> Effectiveness		
<input type="checkbox"/> Cost related outcomes		
<input type="checkbox"/> Near misses		
<input type="checkbox"/> Patient Experience/PROMS		
<input type="checkbox"/> Other. Please state:		
3 When does the policy state that the procedure should be reviewed/outcome data submitted?		
<input type="checkbox"/> After a certain length of time. <i>If selected answer a).</i>		
<input type="checkbox"/> After a certain number of cases. <i>If selected answer b).</i>		
<input type="checkbox"/> This is decided on a case by case basis or according to level of approval/recommendation given by the committee/group.		
<input type="checkbox"/> Unclear. <i>If selected answer c)</i>		
a) How many months?		
[] [] [] [] []		
<i>Go to question 6</i>		
b) How many cases?		

	[] [] [] []		
	<i>Go to question 6</i>		
	c) Copy and paste text:		
4	Does the policy outline when the procedure/device may be used in clinical practice without continuing review via this policy? (ie. when the procedure/device can be adopted in to routine clinical practice)		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
	<i>If yes or unclear, answer a). If no go to question 8.</i>		
	a) Copy and paste text:		
5	Does the policy outline when or why the use of a new procedure may be stopped/abandoned/immediately reported to MD?		
	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
	<i>If yes or unclear, answer a). If no go to section H.</i>		
	a) Copy and paste text:		
ADDITIONAL NOTES			
1	Please record any additional comments here. These may relate to data extraction or may be reflections on the policy.		