




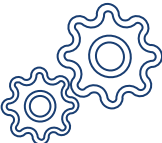



# CORE INFORMATION SET for surgical innovation



## 7 Information themes

*A guide for consultation discussions with patients offered new surgical procedures/devices*

New procedure details		<div>▷ Statement that the procedure/device is new</div> <div>▷ Details about what makes the procedure/device new</div>				
Conflict of interest		<div>▷ Statement of any relevant conflict of interests</div>				
Reasons for the innovation		<table><tr><th>Before surgery</th><th>After surgery</th></tr><tr><td><div>▷ Expected benefits, risks and/or consequences of the new procedure/device</div><div>▷ Reasons why the new procedure/device is believed to be appropriate for the patient</div></td><td><div>▷ Actual benefits, harms and/or consequences experienced</div><div>▷ Changes to which types of future patients the new procedure/device is suitable resulting from the benefits, harms and/or consequences experienced</div></td></tr></table>	Before surgery	After surgery	<div>▷ Expected benefits, risks and/or consequences of the new procedure/device</div> <div>▷ Reasons why the new procedure/device is believed to be appropriate for the patient</div>	<div>▷ Actual benefits, harms and/or consequences experienced</div> <div>▷ Changes to which types of future patients the new procedure/device is suitable resulting from the benefits, harms and/or consequences experienced</div>
Before surgery	After surgery					
<div>▷ Expected benefits, risks and/or consequences of the new procedure/device</div> <div>▷ Reasons why the new procedure/device is believed to be appropriate for the patient</div>	<div>▷ Actual benefits, harms and/or consequences experienced</div> <div>▷ Changes to which types of future patients the new procedure/device is suitable resulting from the benefits, harms and/or consequences experienced</div>					
Choice of treatment alternatives		<div>▷ Existence/availability of alternatives</div> <div>▷ Freedom to choose the new procedure/device or alternative care</div>				
Unknowns		<table><tr><th>Before surgery</th><th>After surgery</th></tr><tr><td><div>▷ Statement that there are unknowns about the new procedure/device in the context of relevant evidence</div><div>▷ Possibility that the new procedure/device may be modified, stopped or changed to an alternative</div></td><td><div>▷ Actual modifications to the new procedure/device, or explanation of why it was stopped or changed to an alternative</div><div>▷ Unexpected benefits, harms and/or consequences</div></td></tr></table>	Before surgery	After surgery	<div>▷ Statement that there are unknowns about the new procedure/device in the context of relevant evidence</div> <div>▷ Possibility that the new procedure/device may be modified, stopped or changed to an alternative</div>	<div>▷ Actual modifications to the new procedure/device, or explanation of why it was stopped or changed to an alternative</div> <div>▷ Unexpected benefits, harms and/or consequences</div>
Before surgery	After surgery					
<div>▷ Statement that there are unknowns about the new procedure/device in the context of relevant evidence</div> <div>▷ Possibility that the new procedure/device may be modified, stopped or changed to an alternative</div>	<div>▷ Actual modifications to the new procedure/device, or explanation of why it was stopped or changed to an alternative</div> <div>▷ Unexpected benefits, harms and/or consequences</div>					
Expertise with the innovation		<div>▷ Statement that the surgeons' level of skill in the new procedure may not be the same as standard care</div> <div>▷ Description of surgeons' level of skill in the new procedure/device</div>				
Governance, oversight & accountability		<div>▷ Relevant approvals in place for the introduction of the new procedure/device in the context of national and/or international regulatory guidance</div> <div>▷ Details of how patient safety is monitored</div> <div>▷ Relevant processes in place if anything goes wrong</div>				