Serious Adverse Event/Death Report Form

To be completed for any Serious Adverse Event (SAE) that is:

- **related (resulted from administration of any of the research procedures) and**
- **expected or unexpected (expected events are listed in section 8.4.2 of the protocol)**

ALL deaths must be recorded using this Report Form

PROSPECT Study No

Report Date Day / Month / Year

		/			/				

Patient Details:

Patient's Name

Date of Birth Day / Month / Year

		/			/				

Hospital Number

Q1 Type of event *(cross all appropriate to adverse event – if any boxes are crossed the adverse event is "serious")*

Patient died	
Hospitalisation	
Prolongation of existing hospitalisation	
Persistent or significant disability or incapacity	
Life threatening	
Considered medically significant by the investigator	

Q2 If the Serious Adverse Event was expected, please cross all that apply

Intraoperative occurrences associated with surgery

Injury to organs	
Excess blood loss	
Blood transfusion	
Anaesthetic complications	
Death	

Postoperative occurrences associated with surgery

Thrombosis	
Infection (UTI, sepsis, abscess)	
Pain	
Urinary retention	
Bowel obstruction	

Constipation	
Mesh erosion	
Excess blood loss	
Vaginal adhesions	
Haematoma	
Skin tag	
Granulation tissue	
New or persistent urinary tract symptoms	
Death	

Q3 Date of event

Day / Month / Year

Q4 Location

Q5 Describe the circumstances of the event

Q6 Details of any intervention required

Assessment of whether the event was caused by trial participation:

Q7 Is it reasonably likely that the adverse event was caused by taking part in PROSPECT?

Yes ☐ No ☐

Q7a Why?

Q8 If event likely to have been caused by taking part in PROSPECT, describe any implications for the safety of study participants and how will these be addressed?

Q9a Name and position of person making this judgment

Q9b Date of assessment

Day ☐☐ / Month ☐☐ / Year ☐☐☐☐