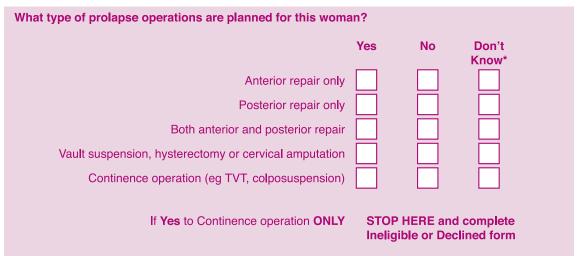




Recruitment Officer (RO) Information Case Report Form (CRF) (to be filled in at each site by RO or gynaecologist)

SCREENING QUESTIONS FOR RO TO ASSESS ELIGIBILITY FOR PROSPECT



* If planned operations are not known or pelvic floor repair type is unspecified, please check in notes, or ask the woman's consultant.

EXPLAIN STUDY AND SIGN CONSENT FORM Not recruited to PROSPECT STOP HERE and complete Ineligible or Declined form

Section A Contact information from woman and notes **PATIENT DETAILS (Sticker may be used below) A1** Title Mrs Miss Other Ms First name Surname Date of birth NHS/CHI number Record/Hospital number Address could use hospital label Mobile **Telephone No** Email Address **CONSULTANT DETAILS** A2 Title Dr Prof Ms Other Mr Initials Surname **A3 GP DETAILS** Initials Surname Address **A**4 **BEST CONTACT DETAILS** Ms Other Title Mr Mrs Miss First name Surname Address **Telephone No RELATIONSHIP OF BEST CONTACT TO PARTICIPANT A5** Please specify Have you asked the woman to tell this person that she has given us Yes these details?



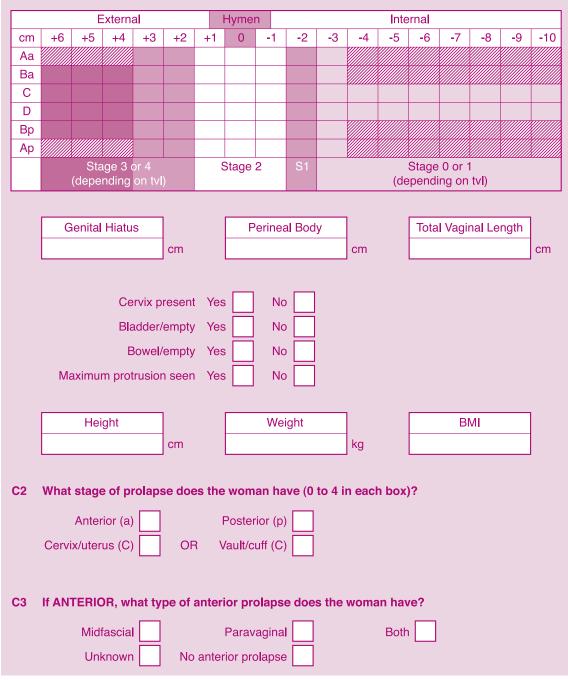
Sec	ction B	General	infor	mation fro	om woman				
B1	B1 Have you ever had any of the following operations or treatments in the past?								
							Yes	No	Don't Know
	A previous operation for prolapse (See D8)								
		Α	vaginal	hysterectomy	(from below)	(See D8)			
		An abdomi	nal hyst	terectomy (via	your tummy)	(See D8)			
				Vaginal pe	ssary or ring c	urrently?			
			l.	Physiotherapy	treatment for	prolapse			
		Phys	iothera	py treatment f	or urinary inco	ontinence			
				An operation f	or urinary inco	ontinence			
			Dr	ug treatment f	or urinary inco	ontinence			
B 2		ould you tel of deliveries	I me a l	little about the	e babies you s as two sepai				
B 3	Year last	child born	(year)	YYY	Υ				
B 4	Types of	delivery							
	Number o vaginal o	of normal deliveries			Caesareans our (elective)			Number of bi vaginal) de l iv	
	Number of deliveries	of forceps			Caesareans	cy)		Number of va extraction de	
B 5	Were an	y of these tw	/in deli	veries?					
	Yes	No			ter number of s	sets of twir	าร:		

Study Number						
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Section C Baseline (pre-operative) clinical patient information from notes or examination of woman

C1 Date of POP-Q

From last recorded POP-Q, without pessary. If not available, repeat before operation (if pessary currently in use, go to C3).



Section D Baseline information needed for randomisation from woman and notes					
D1 PROSPECT Study consent form signed:					
Yes No (If No , stop here and sign)					
D2 Surgery-specific leaflet received by woman:					
Yes No (If No , give Surgical Information S	sheet)				
D3 Centre (named, already known from Study ID no)					
D4 Date of birth D D M M Y Y					
D4a Age (Auto-calculated from DoB):					
<60 yrs ≥60 yrs					
D5 Type of prolapse for planned repair Yes	Νο				
Anterior					
Posterior					
D6 Concomitant upper vaginal prolapse surgery planned Yes	No				
Hysterectomy (vaginal)					
Hysterectomy (abdominal)					
Cervical amputation					
Vault repair <i>eg sacrospinous mesh suspension, sacrocolpopexy</i>					
(YES to any one of these is taken as a concomitant middle compa (If YES to a concomitant middle compartment procedure but NO to					
repair, then eligible for comprehensive cohort only)	o bolir amonor and poolonor				
D7 Concomitant incontinence surgery planned (e.g. TVT, colposus	spension)				
Yes No					
Study Number	Recruitment Officer CRF				
	Hoorditment Officer OnF				

D8	Has the woman had a previous prolapse repair?							
	Yes No If no, go to D9							
	What was the previous repair compartment?							
D8a	Anterior only: Number of repairs Mesh used: Yes No							
D8b	Posterior only: Number of repairs Mesh used: Yes No							
D8c	Compartment unknown (assume that the woman is having a primary repair)							
D8d	Previous hysterectomy Yes No (<i>if without A or P, we assume that the</i>							
D8e	Previous cervical amputation Yes No woman is having a primary repair)							
D8f	Previous vault procedure Yes No (<i>if without A or P, we assume that the woman is having a primary repair</i>)							
D9	(calculated by database from response to D5 and D8)							
	Therefore, type of prolapse surgery planned is: Primary Secondary							
D10	Is we man aligible for rendemination AND is concept to rendemination signed?							
DIU	Is woman eligible for randomisation AND is consent to randomisation signed?							
	(If No to either, woman is eligible for Comprehensive Cohort only)							
D11	1 If No, reason for not randomising:							
	Patient declined Reason							
	Gynaecologist declined Reason							
D12	12 Types of mesh available for randomisation: Yes							
	Synthetic non-absorbable							
	Biological							
	Mesh kit							
D13	(After entry of above details to Prospect DB) Randomised allocation is:							
	Primary: Standard midline Secondary: Standard midline							
	Synthetic mesh inlay Synthetic mesh inlay							
	Biological mesh inlay Mesh Kit							
	(or if not randomised) COMPREHENSIVE COHORT							
D14	Theatre informed / arrangements made to implement allocated procedure							
	Yes No							

Sec	Section E Intra-operative (theatre) information from notes or gynaecologist						
E1 E2		admission D D M M Y Y operation D D M M Y Y					
E3	Grade of	Operating Gynaecologist					
	Consulta	nt Specialty doctor					
	Registrar	/junior Supervised by consultant Yes No					
E4	Grade of	Anaesthetist					
	Consulta	nt Specialty doctor					
	Registrar	/junior Supervised by consultant Yes No					
E5	Operatio Please s	on time Decify time of (<i>using 24 hour clock</i>):					
	Entry into	anaesthetic room:					
	Time of le	eaving operating room: H H : M M					
E 6	Which ty	pe of anaesthetic was used? (Tick all relevant boxes)					
	General	Spinal / epidural					
	Local	Other (please give details)					
	If Other a	naesthetic, please give details:					
E7	Was a pi	rophylactic antibiotic used for the operation? Yes No					
E8	Type of v	vaginal prolapse surgery carried out:					
	Anterior	Type of mesh used: No mesh					
		Synthetic non-absorbable inlay					
		Biological inlay					
	Posterio	r Type of mesh used: No mesh					
	FUSIEIIO	Synthetic non-absorbable inlay					
		Biological inlay					
		Mesh kit					

E9 Did the woman receive the randomised allocation? Yes No Comprehensive Cohort (N/A)						
(If No, go to E9a)						
E9a If NO - Please give reason:						
E10 Concomitant upper compartment prolaps	e surgery:					
VAGINAL						
Cervical amputation	Abdominal hysterectomy					
Vaginal hysterectomy	*Abdominal vault fixation					
* Vaginal vault suspension / fixation	*Abdominal uterine suspension					
* Vaginal uterine suspension						
* E10a If Vault or Uterine Suspension procedure	, please give details of mesh used:					
No mesh	Biological					
Synthetic non-absorbable	Mesh kit					
If any other prolapse surgery, enter details	in E12					
E11 Concomitant incontinence surgery:						
Continence procedure (vaginal)	Continence procedure (abdominal)					
E11a Please give details of mesh used for continence surgery:						
No mesh						
Synthetic non-absorbable						
Biological						
E12 If any other surgery, please give details:						
E13 What was the estimated blood loss?	mls (add to E17)					
E14 Was a catheter inserted in theatre?	Yes No Don't know					
E15 If Yes, what type of catheter was used?	. 🗖					
Suprapubi	oth					
Urethral	None					
	Don't know					

E17 Intra-or post operative	e complic	ations befo	re discharge (If none tick:)
Ureteric injury	Yes	No	If YES, complete Adverse Events Form
Bladder injury	Yes	No	If YES, complete Adverse Events Form
Bowel injury	Yes	No	If YES, complete Adverse Events Form
Vascular injury	Yes	No	If YES, complete Adverse Events Form
Neurological injury	Yes	No	If YES, complete Adverse Events Form
Blood loss > 500 ml	Yes	No	If YES, complete Adverse Events Form
Peri or postoperative blood transfusion	Yes	No	If YES, complete Adverse Events Form
Peri or post-operative thromboembolism	Yes	No	If YES, complete Adverse Events Form
Death	Yes	No	If YES, complete Adverse Events Form

Section F Postoperative information from notes or nursing cardex

POS	TOPERATIVE DATA					
F1	Return to theatre for prelated event within 7		Yes	No	Details	
F2	Catheterisation require more than 10 days po		Yes	No	Details	
F3	Pain relief Or Pa		Yes	No No		
F4	Laxatives		Yes	No		
F5	Infection		Yes	No		
	If Yes: F5a UTI		Yes	No		
	F5b Wound	Infection	Yes	No		
	F5c Pelvic s abscess septicae	s/	Yes	No	If Yes , complete Adverse Events Form	
F6	Treatment for infectio	n				
	Antibiotio	CS	Yes	No		
F7	Haematoma		Yes	No		
F8	Other adverse events postoperatively		Yes	No		
	If YES, give details and contact study office					
F9	Date of discharge D D M M Y Y					