PROSPECT
Prolapse Surgery: Pragmatic Evaluation and Randomised Controlled Trials

PROSPECT Study ID

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

What type of prolapse operations are planned for this woman?

	Yes	No	Don't Know*
Anterior repair only	☐	☐	☐
Posterior repair only	☐	☐	☐
Both anterior and posterior repair	☐	☐	☐
Vault suspension, hysterectomy or cervical amputation	☐	☐	☐
Continence operation (eg TVT, colposuspension)	☐	☐	☐

If **Yes** to Continence operation **ONLY** **STOP HERE and complete Ineligible or Declined form**

* 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

A1 PATIENT DETAILS (Sticker may be used below)

Title ☐ Mrs ☐ Miss ☐ Ms ☐ Other

First name

Surname

Date of birth D D M M Y Y

NHS/CHI number

Record/Hospital number

Address

could use hospital label

Telephone No

Mobile

Email Address

A2 CONSULTANT DETAILS

Title ☐ Mr ☐ Dr ☐ Prof ☐ Ms Other

Initials

Surname

A3 GP DETAILS

Initials

Surname

Address

A4 BEST CONTACT DETAILS

Title ☐ Mr ☐ Mrs ☐ Miss ☐ Ms Other

First name

Surname

Address

Telephone No

A5 RELATIONSHIP OF BEST CONTACT TO PARTICIPANT

Please specify

Have you asked the woman to tell this person that she has given us these details? Yes ☐

PROSPECT
Prolapse Surgery: Pragmatic Evaluation and Randomised Controlled Trials

Section B General information from woman

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)**	☐	☐	☐
A vaginal hysterectomy (from below) **(See D8)**	☐	☐	☐
An abdominal hysterectomy (via your tummy) **(See D8)**	☐	☐	☐
Vaginal pessary or ring currently?	☐	☐	☐
Physiotherapy treatment for prolapse	☐	☐	☐
Physiotherapy treatment for urinary incontinence	☐	☐	☐
An operation for urinary incontinence	☐	☐	☐
Drug treatment for urinary incontinence	☐	☐	☐

B2 Please could you tell me a little about the babies you have had?

Number of deliveries ☐☐ (count twins as two separate births)

B3 Year last child born **(year)** ☐Y☐Y☐Y☐Y

B4 Types of delivery

Number of **normal vaginal** deliveries ☐

Number of **Caesareans before** labour (elective) ☐

Number of **breech** (vaginal) deliveries ☐

Number of **forceps** deliveries ☐

Number of **Caesareans during** labour (emergency) ☐

Number of **vacuum** extraction deliveries ☐

B5 Were any of these twin deliveries?

Yes ☐ No ☐ (If **Yes**) Enter number of sets of twins: ☐

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

C1 Date of POP-Q D D M M Y Y

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

	External					Hymen		Internal									
cm	+6	+5	+4	+3	+2	+1	0	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
Aa																	
Ba																	
C																	
D																	
Bp																	
Ap																	
	Stage 3 or 4 (depending on tvl)					Stage 2			S1		Stage 0 or 1 (depending on tvl)						

Genital Hiatus		Perineal Body		Total Vaginal Length	
	cm		cm		cm

Cervix present Yes ☐ No ☐
Bladder/empty Yes ☐ No ☐
Bowel/empty Yes ☐ No ☐
Maximum protrusion seen Yes ☐ No ☐

Height		Weight		BMI
	cm		kg	

C2 What stage of prolapse does the woman have (0 to 4 in each box)?

Anterior (a) ☐ Posterior (p) ☐
Cervix/uterus (C) ☐ OR Vault/cuff (C) ☐

C3 If ANTERIOR, what type of anterior prolapse does the woman have?

Midfascial ☐ Paravaginal ☐ Both ☐
Unknown ☐ No anterior prolapse ☐

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 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	No
Anterior	☐	☐
Posterior	☐	☐

D6 Concomitant upper vaginal prolapse surgery planned

	Yes	No
Hysterectomy (vaginal)	☐	☐
Hysterectomy (abdominal)	☐	☐
Cervical amputation	☐	☐
Vault repair *eg sacrospinous mesh suspension, sacrocolpopexy*	☐	☐

(YES to any one of these is taken as a concomitant middle compartment procedure)

(If YES to a concomitant middle compartment procedure but NO to both anterior and posterior repair, then eligible for comprehensive cohort only)

D7 Concomitant incontinence surgery planned (e.g. TVT, colposuspension)

Yes ☐ No ☐

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 ☐

D8e Previous cervical amputation Yes ☐ No ☐ *(if without A or P, we assume that the woman is having a primary repair)*

D8f Previous vault procedure Yes ☐ No ☐ *(if without A or P, we assume that the woman is having a primary repair)*

D9 **(calculated by database from response to D5 and D8)**

Therefore, type of prolapse surgery planned is: Primary ☐ Secondary ☐

D10 **Is woman eligible for randomisation AND is consent to randomisation signed?**

(A) BY WOMAN Yes ☐ No ☐

(B) BY GYNAECOLOGIST Yes ☐ No ☐

(If No to either, woman is eligible for Comprehensive Cohort only)

D11 **If No, reason for not randomising:**

Patient declined ☐ Reason

Gynaecologist declined ☐ Reason

D12 **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:		**Secondary:**	
Standard midline	☐	**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 ☐

Section E | Intra-operative (theatre) information from notes or gynaecologist

E1 Date of admission D D M M Y Y

E2 Date of operation D D M M Y Y

E3 Grade of Operating Gynaecologist

Consultant ☐ Specialty doctor ☐

Registrar /junior ☐ Supervised by consultant Yes ☐ No ☐

E4 Grade of Anaesthetist

Consultant ☐ Specialty doctor ☐

Registrar /junior ☐ Supervised by consultant Yes ☐ No ☐

E5 Operation time

Please specify time of (*using 24 hour clock*):

Entry into anaesthetic room: H H : M M

Time of leaving operating room: H H : M M

E6 Which type of anaesthetic was used? *(Tick all relevant boxes)*

General ☐ Spinal / epidural ☐

Local ☐ Other (please give details) ☐

If Other anaesthetic, please give details:

E7 Was a prophylactic antibiotic used for the operation? Yes ☐ No ☐

E8 Type of vaginal prolapse surgery carried out:

Anterior ☐ **Type of mesh used:**

No mesh ☐

Synthetic non-absorbable inlay ☐

Biological inlay ☐

Mesh kit ☐

Posterior ☐ **Type of mesh used:**

No mesh ☐

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 prolapse surgery:

VAGINAL		**ABDOMINAL**	
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	☐

E16 Was a vaginal pack inserted in theatre? Yes ☐ No ☐ Don't know ☐

E17 Intra-or post operative complications before 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

POSTOPERATIVE DATA

F1 **Return to theatre for procedure related event within 72 hours** Yes ☐ No ☐ Details

F2 **Catheterisation required for more than 10 days post op** Yes ☐ No ☐ Details

F3 **Pain relief** Oral Yes ☐ No ☐

Parenteral Yes ☐ No ☐

F4 **Laxatives** Yes ☐ No ☐

F5 **Infection** Yes ☐ No ☐

If **Yes**:

F5a **UTI** Yes ☐ No ☐

F5b **Wound Infection** Yes ☐ No ☐

F5c **Pelvic sepsis/ abscess/ septicaemia** Yes ☐ No ☐ If **Yes**, complete Adverse Events Form

F6 **Treatment for infection**

Antibiotics 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