

Preparation

- 1. The clinical evaluator will conduct the examination and the research assistant/RC will assist with data collection (a chaperone is required [per CRC policy] for the clinical evaluator regardless of evaluator's gender).
- 2. Will be performed uniformly on all participants regardless of age. Estimated time is 10 minutes in total.
- 3. Examiner responsible for completion of CRF 8 Pelvic examination
- 4. Detailed instructions for performing the Pelvic Examination are found on CRF 8A.
- 5. Performed in an examination room with a gynecologic examination table with extendable footrests or supine without stirrups in participants who cannot place feet in stirrups (e.g. older women).
- 6. If unable to perform ("not done") any part of the pelvic examination, note reason.
- 7. If <u>participant</u> declined, note one of the following:
 - a. Unable to understand instructions
 - b. Fear of pain exacerbation
 - c. Increased pain/discomfort at attempt of examination
 - d. Felt unsafe

e. Other

(e.g. refused)

- 8. If evaluator decides inability to complete ("not done"), note one of the following:
 - f. At heightened physical risk due to participant's circumstances/abilities
 - At heightened psychological/emotional risk to due to participant's circumstances and/or trauma history
 - Participant unable to understand instructions
- 9. Other:
- 10. The participant will be instructed by the RC to prepare for the examination by: a) removing clothing from the waist down; b) wrapping an examination sheet around their waist or putting on a gown (upper clothes can stay on); and c) having a seat on the end of the exam table with feet resting on the floor.
- 11. Position is the dorsal lithotomy position with head at a 45-degree angle.
- 12. Ensure adequate lighting of the perineum
- 13. Hand hygiene

Preempting a request from the participant to know their results, say to the participant:

"Hello [participant's name], I am (examiner's name and profession [MD, NP etc]. I am an investigator [or principal investigator] at/with the [CRC]. Thank you so much for being a participant in this study. Now I am going to do a pelvic examination. I do not use a speculum for this exam. First, I will be looking at the outside of your vagina and asking you to cough. Then, I will insert one finger into your vagina to test the strength of your muscles. I will put pressure on different areas in your vagina to determine the muscle tone and if you have any discomfort. At any time during the exam you can ask to stop. Please also let me know if there is any pain or discomfort during the exam. You are in control of the process. Is it OK if I begin the exam?".

1. Assessment of Pelvic Organ Prolapse (POP)

Objective: To determine presence of POP protruding beyond the hymen at rest and with Valsalva.

Prior to starting the prolapse assessment, say to the participant:

"First, please let your knees fall to the side. I am going to start with looking at the opening of the vagina, and then while you strain, push or bear down like you are moving your bowels."



Procedure:

- 1. For this part of the exam, evaluator should be positioned directly facing the participant's perineum.
- 2. With participant at rest and in dorsal lithotomy, view the perineum and vagina for presence of prolapse protruding beyond the introitus.
- 3. Ask participant to strain, push or bear down to note presence of prolapse beyond the introitus with Valsalva.
- 4. In some women, leakage of urine and/or stool may occur with Valsalva. If this occurs, it should be noted.
- 5. If prolapse is present beyond the hymen/introitus, should be manually reduced for the remainder of the pelvic examination.

<u>Data Collected:</u> Record a "No" or "Yes" for prolapse present at rest or prolapse present with Valsalva. Record "No", "Urine" or "Stool" for leakage.

Prolapse present at rest:	No	Yes	
Prolapse present with Valsalva:	🗌 No	Yes	
Leakage present:	🗌 No	Urine	Stool

2. Palpatory Assessment for Pubovisceral (PV) Muscle Integrity

Objective:

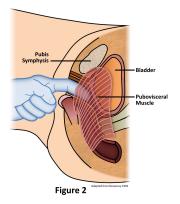
• To determine the extent of the PV muscle integrity where it passes the vaginal sidewall bilaterally by estimating felt presence using palpatory assessment.

Prior to assessing for PV muscle integrity, inform the participant that the **internal examination** will be performed next and say to the participant:

" I will be feeling the muscles inside the vagina. I will not use a speculum but will place 1 finger in your vagina. I will examine the muscles on each side of your vagina."

Procedure:

- Will be performed and recorded on the right and left side of the participant.
- The index finger is placed at the expected anatomical location of the midmuscle of the PV as felt about 2 cm inside the vaginal sidewall (typically to 1st and no more than 2nd knuckle), with the finger curled to the right or left (Figure 2).
- Start palpating by lightly pressing against the vaginal sidewall (see Figure 2).
- Then sweep slightly up and down using the finger pad to palpate for fullness of the PV muscle at rest.
- If the PV muscle cannot be clearly felt, the above procedure can be repeated while the woman attempts a pelvic muscle contraction (a Kegel maneuver or squeeze or tightening of the PFMs).
- During the upward sweep, assess for continuous soft tissue resistance interposed between the lateral vaginal wall and the bony pubic rami.
- Absence of muscle will be felt as a bony area at the inferior pubic ramus, and there will be





pronounced thinness of the PV muscle more dorsally.

- Repeat on the opposite side.
- Note if participant experiences pain during assessment.

<u>Data Collected</u>: To score the muscle and record findings on the woman's right and left side, choose between three categories:

PV Muscle Present: the muscle is definitely felt

Equivocal: if <u>cannot</u> clearly and confidently ascertain that the PV muscle is either "present" or "absent"

Not palpable/Absent: if the muscle is <u>not felt</u>, and instead there is a sense of indentation and/or feeling of hardness of the pubic ramus

Right PV Muscle	Left PV Muscle		
2 Present	2 Present		
🗌 1 Equivocal	🗌 1 Equivocal		
0 Not Palpable/absent	0 Not Palpable/absent		
Indicate relevant muscle body bulk by each side			
Both sides equal			
Right side muscle bulk more than Left side			
Left side muscle bulk more than Right side			

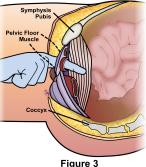
3. Pelvic Floor Muscle (PFM) Evaluation of Functional Strength

Objectives:

To perform a digital internal vaginal examination to evaluate the functional strength of the participant's PFMs.

Procedure:

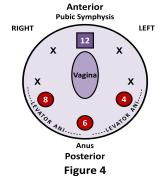
- Will be performed and recorded on the right and left side.
- Say to the participant: *"Next, I examine the muscles around your vagina. I will ask you to squeeze these muscles around my finger. You may know this as a Kegel contraction."*
- Position the GYN footrests appropriately for the participant and have them place a foot in each footrest. Ask them to lie back on the exam table and slide down to the end. Keep the participant adequately draped with the examination sheet.



Insert one-gloved lubricated index finger a few (4-6) centimeters (approx. 2
Figure 3
inches) into the vagina. As a pronated finger is inserted into the vagina (finger pad down) in a posterior direction, you will eventually encounter the edge of the LA (if finger is advanced more posteriorly, it will drop off the edge) (see Figure 3). The PFM can be palpated just inside to the hymeneal ring.



- Place your finger so that it rests on the midline (centrally) of the muscle belly of the levator ani (LA).
- The muscle is tested at the midline (6 o'clock position) and bilaterally (right and left side) at the 4 o'clock and 8 o'clock position (see Figure 4).
- Ask the participant to contract (squeeze, tighten) the PFM firmly around your finger. Specifically, say to the participant: *"I am going to count to 3 and when I say 3, I want you to tighten or squeeze your pelvic floor muscle and hold it as I count to 5. I am going to have you do this 3 times."*



- Instruct them to "pull in" or "lift up" the floor of their vagina or to imagine that she is trying to control passing gas or pinching off a stool.
- If unable to contract the PFM, "tactile feedback" can be used to help a participant: 1) identify the correct muscle to contract, 2) understand how to contract the PFMs, and/or 3) improve the contraction in the case of very weak PFMs.
 - To provide tactile feedback, tap or provide a quick, but very slight stretch to the muscle by pressing down towards the perineal body between the vagina and rectum. This may activate PFM stretch receptors, causing a heightened response to the participant's voluntary effort to contract the muscle, or may result in a reflexive muscle resistance response, which will be brief.
- Note if participant experienced pain during PV assessment: Did the PV muscle assessment provoke pain? Yes No

Data Collected: Adapted Oxford Grading System used to measure PFM strength as shown in this table.

		Right PFM Strength Score (choose one number)	Left PFM Strength Score (choose one number)	Midline PFM Strength Score (choose one number)
No contraction	No discernable muscular contraction	0	0	0
Flicker	Very slight muscular contraction	1	1	1
Weak	An increase in tension is detected, without any discernible lift	2	2	2
Moderate	Lifting of the muscle belly with elevation of the posterior vaginal wall	3	3	3
Good with lift	Increased tension, good contraction elevating the posterior vaginal wall	4	4	4
Strong	Finger is squeezed and drawn into the vagina	5	5	5

4. Myofascial Pain Screening Examination

Objective: To determine presence of obturator internus and levator ani myofascial pain with palpation.

Prior to assessing for myofascial Pain, say to the participant:

"Now, I would like to move to the next step of the assessment. I will press on 4 muscles during a vaginal examination to assess your pelvic floor for any pain or discomfort. Is it ok to proceed?"



Procedure:

- Orient the participant to the internal examination by pressing on mid-thigh to provide a reference pressure that will be applied on the internal examination.
 - The **mid-thigh** (belly of quadriceps femoris) serves as a **reference point** for pressure to be applied and also to introduce that muscle palpation should feel like pressure and not be painful (unless muscle injury present).

Say to the participant:

"First, I will first press on your thigh to let you know how the pressure will feel when I press internally (inside you). Do you feel my finger on your thigh? (palpate mid-thigh) This is as firmly as I am going to be pressing on the muscles. Is there any pain or discomfort? If not, this will be a "0" on a scale of "0-10". Please let me know if you experience pain or discomfort and rate that pain or discomfort on a scale of 0 to 10. No pain or discomfort would be a 0 and severe pain or discomfort is a 10."

• Apply moderate to firm palpation (similar to pressure that would "blanch" the clinical evaluator's nail bed on a desk top) medial to at each site and ask the participant if this elicits pain or discomfort.

Say to the participant:

"I will begin the exam by inserting 1 finger into your vagina and begin with the muscles on your RIGHT side, then will test the muscles on your left side."

"When I press on this muscle, is it only pressure, a "0" or is there pain or discomfort? If there is pain or discomfort, please rate it on a scale of 1-10. "Mild" pain or discomfort would be a 1,2 or 3, "moderate" pain or discomfort a 4,5 or 6, and "severe" pain or discomfort a 7,8,9, or 10."

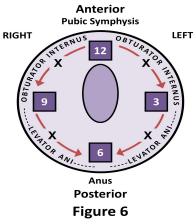
- Internal palpation is performed with the index finger of the dominant hand
- Once in the center of the muscle belly, then in a sweeping motion along the length of the muscle in the direction of the orientation of that muscle and proceeds counter-clockwise:
 - RIGHT obturator internus (OI)
 - RIGHT levator ani (LA)
 - LEFT LA
 - LEFT OI



Obturator Internus Figure 5

PROTOCOL

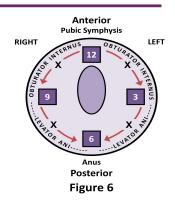
Obturator internus (see Figure 5) **Palpation of mid muscle belly** is typically 3-4 inches (8-10 cm) from the introitus (typically metacarpophalangeal joint of 1st finger, large joint in the hand where the finger bones meet the hand bones)– **this is the site of mid muscle belly measurement. (see Figure 5) Palpation along length of muscle belly** – Start near pubic symphysis (PS) and move along length of muscle to length that is possible for clinical evaluator and participant (see Figure 5)





If the introitus is visualized with a clock face overlying it, the RIGHT OI would be identified between 10-11 o'clock and the LEFT OI between 1-2 o'clock (see Figure 6).

- a. Medial to lateral movement of the ipsilateral knee by the clinical evaluator will activate the OI which can help identify the muscle during palpation of the muscle
- b. The OI is anterior to the arcus tendinous (fibrous band that spans from the ischial spine to the pubic symphysis; also where the levator ani originate) and palpation of the arcus can help differentiate between the OI and the LA





Levator Ani Figure 7

Levator ani (see Figure 7)

Palpation of mid muscle belly is typically 3-4 inches (8-10 cm) from the introitus (typically metacarpophalangeal joint of 1st finger, large joint in the hand where the finger bones meet the hand bones) between arcus tendinous and median raphe – **this is the site of mid muscle belly measurement. Palpation along length of muscle belly** – Start near arcus tendinous and move along length of muscles towards the midline

If the introitus is visualized with a clock face overlying it, the RIGHT LA would be identified between 7-8 o'clock and the LEFT LA between 4-5 o'clock (see Figure 6).

- a. Location of the ipsilateral OI and/or the arcus tendinous will help identify the LA.
- b. LA is typically palpated within 1-4 inches (8-10cm) from the introitus (typically metacarpophalangeal joint of 1st finger)

Data Scoring: A maximum score (0-10) obtained from palpation at mid muscle belly and along length of muscle is recorded.

	Numeric Rating Scale	0-10 scale	
RIGHT obturator internus	_/10	0= Pressure, no pain 1-3= Mild pain 4-6= Moderate pain 7-10= Severe pain	
RIGHT levator ani	/10		
LEFT levator ani	_/10		
LEFT obturator internus	/10		