



FORM 1: VIEW Participant Screening

Participant ID: _____ - _____

Date: ____ / ____ / ____
MM DD YYYY

Check here if participant completed online screening Online Screening ID: _____

If participant completed online screening, skip to Screening Level 2 Summary Table

Part 1: Introduction

Caller: "Hello. My name is _____. I am calling from _____,

May I speak with (*State Respondent's Name*)?

You recently expressed interest in a research study about women's health. This is a study called VIEW funded by the National Institute of Health. Thank you for taking my call (*or sending us your contact information*).

START HERE IF SCREENING IN PERSON

I would like to describe the study and go over screening questions to see if you are eligible to be a part of it. If you are eligible to be in the study, I will go into more detail about it." **Is it okay to continue?**

YES: "Okay, let's get started" Continue with script Part 2.

NO: Ask: "Is there a better time to call back?"

YES: Ask: Can you tell me some better times to call-back?

OPTIONS for CALL BACK APPOINTMENT: _____

NO: Ask: "May I add your name and contact information to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and our other studies?"

YES: Go to Contact information Section

NO: Respond: "Okay, please feel free to call back if you are interested in any of our studies in the future. Thank you very much for your time today."

Part 2: Study Information

Caller: "Okay, let's begin with how you heard about our study. Can you tell me where you learned about our study?"

<input type="checkbox"/> Flyer	<input type="checkbox"/> Women's group	<input type="checkbox"/> Urology practice
<input type="checkbox"/> Pediatric primary care	<input type="checkbox"/> Day care center	<input type="checkbox"/> Church
<input type="checkbox"/> Adult primary care	<input type="checkbox"/> Health club	<input type="checkbox"/> Senior Center
<input type="checkbox"/> Adolescent health service	<input type="checkbox"/> College/University announcements	<input type="checkbox"/> Friend/Word of Mouth
<input type="checkbox"/> OB/Gyn Office	<input type="checkbox"/> Federally Qualified Health Centers	<input type="checkbox"/> Social Media
<input type="checkbox"/> Sexual health clinic	<input type="checkbox"/> Community Recruitment	<input type="checkbox"/> Website
<input type="checkbox"/> Women's health center	<input type="checkbox"/> Area Agencies on Aging	<input type="checkbox"/> _____
		<input type="checkbox"/> _____



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Screener: “Great, thank you. Now let me tell you a little about the study:”

The Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium is studying bladder health in different communities across the United States. There are many parts of the body involved in urination or “peeing” and the purpose of this study is to find the connections between the body and other influences to help keep bladder problems from happening.

We developed a survey to measure women’s bladder health. The purpose of the VIEW study is to make sure this survey works for all different women so that we can use the survey in future studies. If you are eligible to participate in the VIEW study, we will ask you to complete three different study activities. First, we will ask you to complete a 30-45 minute electronic or hardcopy survey about your bladder. Second, we will mail you records to keep at home, for example, we will ask you to record your bladder symptoms for two days and how much you pee every time you go to the bathroom for 24 hours. Lastly, we will schedule you to come to <insert practice name> for an in-person evaluation that will last up to 2 hours for some simple tests. These tests will not cost you anything, they will not hurt, and there are no shots, X-rays, or anything uncomfortable with these tests. After we go through these eligibility questions I will describe the study activities in detail and answer any questions you may have.

Time involved

SCREENER: For your participation in the different activities in this study, the survey, the home records and the office visit, you will be compensated for your time. If you are interested in learning more about this study, this phone call will last about 15 minutes.

Is it okay to continue?

YES: “Okay, let’s get started” *Continue with script Part 3.*

NO: Ask: “Is there a better time to call back?”

YES: Ask: Can you tell me some better times to call-back?

OPTIONS for CALL BACK APPOINTMENT: _____

NO: Ask: "May I add your name and contact information to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and our other studies?"



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- YES:** Go to Contact information Section
- NO:** Respond: "Okay, please feel free to call back if you are interested in any of our studies in the future. Thank you very much for your time today."

During this screening call, we wish to be respectful. To make sure we are not making assumptions about the personal characteristics or life events of anyone who participates in our study, we are asking everyone the same questions. If you feel uncomfortable answering any of these questions, please say, "I do not want to answer." To see if you qualify for this study, I will ask you some standard screening questions. **Is it okay to continue?**

- YES:** Go to Part 3: DEMOGRAPHIC and SCREENING questions on the next page:
- NO: SCREENER** Ask: "Can you share the reason for not wanting to continue?"

Reason for not continuing, if shared:

- Not interested
- No time
- Not what I thought it was about
- Other: _____
- Declined to answer

Following response to giving reason for not participating, or if they decline to respond:

SCREENER Ask: "May I add your name and contact information to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

- YES:** Go to Contact information Section
- NO:** Respond: "Okay, please feel free to call back if you are interested in any of our studies in the future. Thank you very much for your time today."



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Part 3: Demographic and Screening Questions

1. **SCREENER:** "Are you able to read and follow instructions presented in English and complete surveys in English without assistance?"

YES: *Continue with script moving to Question 2*

NO: *or*

DECLINED TO ANSWER:

SCREENER: Okay, unfortunately all our surveys are in English, so this will not be a good option for you at this time. We appreciate your interest and thank you for your time. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

YES: *Go to Contact Information Section*

NO: SCREENER: Thank you very much for your time today. Have a good day.

2. **SCREENER:** "Can you confirm that you are female?"

YES: *Continue with script moving to Question 3*

NO: *or*

DECLINED TO ANSWER:

SCREENER: Okay. Thank you very much for your time and interest today, but our current studies focus on individuals with female anatomy and the surveys contain questions about women's bladder health. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

YES: *go to Contact Information Section*

NO: SCREENER: Thank you very much for your time today. Have a good day.

3. **SCREENER:** Are you 18 years old or older?

YES: Ask: "How old are you?" _____ yrs

→ *If age 18 – 50 go to Question 4*

→ *If 51+ skip to Question 5*

NO: *or*

DECLINED TO ANSWER:



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SCREENER: “I am sorry, but you are not within the age range for the current study. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?”

YES: go to *Contact Information Section*

NO: SCREENER: Thank you very much for your time today. Have a good day.

4a. SCREENER (If age 18 – 50): “Are you currently pregnant?”

YES: Ask: “When is your due date?” _____ (mm/dd/yyyy)

→ *If due date is within 1 month of screening call, flag as time sensitive postpartum but do not randomize until participant is 6 weeks postpartum*

→ *If due date > 4 months flag as postpartum thank participant for her interest (see below). Flag as screen failure and enter into REDCap.*

NO: Continue with script moving to Question 4b.

DECLINED TO ANSWER: Okay. Thank you very much for your time and interest today, We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and other studies?”

YES: go to *Contact Information Section*

NO: SCREENER: Thank you very much for your time today. Have a good day.

4b. SCREENER (If age 18 – 50): “Have you had a baby recently?”

YES Ask:” *When was your delivery date?* _____ (mm/dd/yyyy)

→ *If delivery date is within the past 8 weeks of screening date, flag as postpartum*

→ *If delivery date is between 8-12 weeks of screening date, research coordinators need to make her/his own judgement on flagging as postpartum or non-postpartum.*

NO: Continue with script moving to Question 5.

5. SCREENER: “Have you ever been diagnosed with or treated for bladder cancer, had a kidney transplant, pelvic radiation, or are currently getting dialysis?”

YES: or

DECLINED TO ANSWER: Okay. Thank you very much for your time and interest today, but our current studies focus on women who do not have a history of these bladder or kidney issues. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future



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opportunities for participating in our research and to receive other information on bladder health and other studies?”

- YES:** go to Contact Information Section
- NO: SCREENER:** Thank you very much for your time today. Have a good day.
- NO:** Continue with script moving to Question 6

6. **SCREENER:** “Are you able to stand up on your own for up to 3 minutes without help from another person?” (Note to RC: cane/walker okay)

- YES:** Continue with script moving to Question 7
- NO:** or
- DECLINED TO ANSWER:** Okay. Thank you very much for your time and interest today, but our current study requires participants to be able to stand up on their own for up to 3 minutes. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?”
 - YES:** go to Contact Information Section
 - NO: SCREENER:** Thank you very much for your time today. Have a good day.

7. **SCREENER:** “Are you able to get to the bathroom and to use the toilet on your own - without help from another person?” (Note to RC: cane/walker okay)

- YES:** Continue with script moving to Question 8
- NO:** or
- DECLINED TO ANSWER:** Okay. Thank you very much for your time and interest today, but our current study requires participants to use a toilet on their own. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?”
 - YES:** go to Contact Information Section
 - NO: SCREENER:** Thank you very much for your time today. Have a good day.

8. **SCREENER:** “Are you currently participating in any research study about the bladder?”

- YES:** or
- DECLINED TO ANSWER:**



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SCREENER: Thank you very much for your time and interest today, but our current study cannot include women enrolled in other bladder or urinary research.-We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

- YES:** go to Contact Information Section
- NO: SCREENER:** Thank you very much for your time today. Have a good day.
- NO:** Continue with script moving to Question 9

9. **SCREENER:** "Did you previously participate in a focus group or one-on-one interview about bladder health? (Note to RC: If yes, follow up with participant to see if they participated in SHARE or CLEAR BHI. If so, mark "yes" below. If they did not participate in SHARE or CLEAR BHI, mark "no".)

- YES:** or
- DECLINED TO ANSWER:**

SCREENER: Thank you very much for your time and interest today, but our current study cannot include women enrolled in other bladder or urinary research.-We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

- YES:** go to Contact Information Section
- NO: SCREENER:** Thank you very much for your time today. Have a good day.
- NO:** Continue with script moving to Question 10

10. **SCREENER:** "Are you currently living in a skilled nursing home, long term care or rehabilitation center?"

- YES:** or
- DECLINED TO ANSWER:**

SCREENER: Thank you very much for your time and interest today, but our current study requires participants to be living outside of a skilled nursing home, longer term care, or rehabilitation center. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

- YES:** go to Contact Information Section
- NO: SCREENER:** Thank you very much for your time today. Have a good day.
- NO:** Continue with script moving to Screening Level 1



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Screening Level 1:

Q1. Which of the following statements best describes your bladder? My bladder...

- 1 Does not cause me any problems at all. → *Qualifies for Tracking Log "Healthy" column*
- 2 Causes me some very minor problems. → *Qualifies for Tracking Log "Mild" column*
- 3 Causes me some minor problems. → *Qualifies for Tracking Log "Mild" column*
- 4 Causes me some moderate problems. → *Qualifies for Tracking Log "Moderate" column*
- 5 Causes me severe problems. → *Qualifies for Tracking Log "Severe" column*
- 6 Causes me many severe problems. → *Qualifies for Tracking Log "Severe" column*

Tracking Log column Group 1: Healthy, answered above item Q1 with a 1

Tracking Log column Group 2: Mild Symptoms, answered above item Q1 with 2 or a 3

Tracking Log column Group 3: Moderate Symptoms, answered above item Q1 with a 4

Tracking Log column Group 4: Severe Symptoms, answered above item Q1 with 5 or 6

Screening Level 2: Symptoms

FREQUENCY

Ga1. In the past year, have you ever had times when you peed more often than usual?

- 1 Yes → Qualifies for Tracking Log row 1 (**Frequency**). Go to Gb1.
- 2 No → Go to Gb1.

INCONTINENCE

Gb1. In the past year, have you ever accidentally leaked urine, or lost control of pee, even just a drop or two?

- 1 Yes → Qualifies for Tracking Log row 2 (**Incontinence**). Go to Gc1.
- 2 No → Go to Gc1.

URGENCY

Gc1. In the past year, have you ever had a sudden and urgent need to pee, that “gotta go” feeling you just had to go right away?

- 1 Yes → Qualifies for Tracking Log row 3 (**Urgency**). Go to Gd1.
- 2 No → Go to Gd1.



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PAIN/DISCOMFORT

Gd1. In the past year, have you ever felt discomfort, pressure or pain in your bladder or when peeing (i.e. a burning sensation when you pee)?

- 1 Yes → Qualifies for Tracking Log row 4 (**Pain/Discomfort**). Go to Ge1.
- 2 No → Go to Ge1.

PEEING

Ge1. In the past year, have you had any problems such as trouble starting to pee, or completely emptying your bladder, or dribbling a few drops after you finish peeing?

- 1 Yes → Qualifies for Tracking Log row 5 (**Peeing**). Go to Gf1.
- 2 No → Go to Gf1.

UTI

Gf1. In the past year, have you had three or more UTIs or bladder infections, or 2 or more UTIs or bladder infections in the past 6 months?

- 1 Yes → Qualifies for Tracking log row 6 (**UTI**). Go to Screening Level 2 Summary Tables.
- 2 No → Go to Screening Level 2 Summary Tables.



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SCREENING LEVEL 2 SUMMARY TABLE

For each section the person qualifies - mark the box in the appropriate column based on Level in Screening 1

<i>Self-Report of Bladder Problems</i>					
Healthy Qx=1	<i>Self-Report of LUTS</i>		Mild Qx=2 or 3	Moderate Qx=4	Severe Qx= 5 or 6
<input type="checkbox"/>	Row 1 – GA	FREQUENCY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Row 2 – GB	INCONTINENCE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Row 3 – GC	URGENCY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Row 4 – GD	PAIN/DISCOMFORT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Row 5 – GE	PEEING	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Row 6 – GF	UTI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18-25 years old	26-44 years old	45-64 years old	65+ years old
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Screening In/ Out

- 1) Each cell in columns Mild, Moderate or Severe in the table should have at least two qualified participants; beyond each symptom being present in a minimum of 2 participants, it does not matter how many participants have that symptom. Each woman can fulfill more than one row/ box in a given column. The column for Healthy should have a total of twelve participants; it does not matter which, if any, row they fall in. If they are in the Healthy column and do not fall into any row that is fine.
- 2) Transfer the information from this form to the Master Tracking Log to identify completion of enrollments/completes for each section.



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Part 4: Eligibility

If the individual DOES qualify for the study eligibility, does the coordinator believe that the person, due to cognitive or linguistic issues, cannot participate in study?

NO: Continue with Eligibility Script

YES: SCREENER: Unfortunately, you do not qualify for our study at this time. We appreciate your interest and thank you for your time. We may be doing some studies at a later date which you may qualify for. May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

YES: Go to Contact Information Section

NO: SCREENER: Thank you very much for your time today. Have a good day.

SCREENER: "I'm happy to say you are eligible to potentially participate in the VIEW Women's Bladder Health Study. As we briefly mentioned at the beginning of this call, there are several activities in this study. This will include a survey questionnaire, a bladder diary, and a clinic visit.

Continue with the following paragraph for non-postpartum participant:

In the first part of this study, we will be sending you a survey, by either US mail or email. If it is sent via email, the email will be from me and contain a url link for you to complete the survey. If it is sent to your email, you cannot complete the survey on your smartphone, please access it using your desktop or laptop. If the survey is sent US mail, it will come from University of Minnesota, our coordinating center and include a stamped addressed envelope for you to mail the survey back to Minnesota. The survey will take approximately 45 minutes to complete and mail back.

Or

Continue with the following paragraph for postpartum participant:

All study activities will need to be completed by 12-week after your delivery date. In the first part of this study, we will be sending you a survey, by either US mail or email. Do you have a preference? (*or RC to decide, based on how far post-delivery the participant is. If participant is less than 6 weeks post-partum, let them know we need to wait until that date for them to complete the survey*). If it is sent via email, the email will come from me and contain a url link for you to complete the survey. You cannot complete the survey on your smartphone, please access it using your desktop or laptop. . If the survey is sent US mail, it will come from University of Minnesota, our coordinating center and include a stamped addressed envelope for you to mail the survey back to Minnesota. The survey will take approximately 45 minutes to complete and mail back.



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Continue with the following paragraph for all participants:

Once you have returned your survey, I will contact you to set up an appointment for the clinic visit. I will also send you a purple box that contains the material and instructions for the bladder diaries. There are two different diaries. One asks you to keep track of how often you pee for 2 days, and the other asks you to keep track and measure how much you pee for one day. We will include a container in the box that you can use to measure your pee, along with instructions for both diaries.

The clinic appointment at <insert practice site> will take up to 2 hours. This involves meeting with a health care practitioner who will ask you questions about your bladder. We will also do some simple tests of your bladder such as asking you to pee in a toilet that measures urine flow, and a bladder ultrasound scanner that is placed on your abdomen to check how much urine is in your bladder. There will be no physical examination or pelvic exam.

You will be compensated for each activity. *(If participant asks about total compensation: In total, you could receive up to \$100 for completing every activity in the study. (\$15 for completion of BHI, \$35 for completion of bladder diaries, \$50 for completion of in-person visit))*

SCREENER: Are you still interested in participating in the study? For postpartum participant: If so, will you be able to come to a clinic visit within 12 weeks of your delivery date?

YES

NO: SCREENER: "May I know the reason why?"

Not interested

No time

Not what I thought it was about

Other: _____

Declined to answer

Following response to giving reason for not participating, or if they decline to respond:

SCREENER: "May I add your name to the PLUS email and research mailing lists to receive information on future opportunities for participating in our research and to receive other information on bladder health and on our other studies?"

YES - go to Contact Information Section

NO - Okay, thank you again for your time today and for your responses to the questions. Have a great day.

SCREENER: "We appreciate your willingness to participate in our study. Now, we need to complete your contact information including your mailing address and email address so we can make sure you receive the study materials.

Complete the Contact information Section