

Form 1 Participant Screening

Participant ID (participantid)

Date Screened (ps_date)

_____ (mm-dd-yyyy)

The content of this field is generated by the Shazam External Module (oscr_table)

Check here if participant completed online screening (1)

Online Screening ID: (scr_id)

Did you re-screen this participant (Questions 1-10)?
(oscr_rescreen)

Yes (1) No (0)

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." (ps_script)

Is it okay to continue? (ps_interest)

Yes: "Okay, let's get started" Continue with script Part 2 (1)
 No (0)

Ask: "Is there a better time to call back?" (ps_timetotalk)

Yes: Ask: Can you tell me some better times to call back? (1)
 No: Respond: "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?" (0)

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 our other studies?" (ps_futurestudies1)

Yes: go to Contact Information Section (1)
 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." (0)

Options for Call Back Appointment:
(ps_callbackoptions)

Participant was successfully called back (ps_callbacksuccess)

- Yes (1)
 No (0)

Part 2 Study Information

SCREENER: Ok, let's begin with how you heard about our study. Can you tell me where you learned about our study? (ps_plus_descr)

- Flyer (1)
 Pediatric primary care (2)
 Adult primary care (3)
 Adolescent health service (4)
 OB/Gyn Office (5)
 Sexual health clinic (6)
 Women's health center (7)
 Women's group (8)
 Day care center (9)
 Health club (10)
 College/University setting (11)
 Federally Qualified Health Centers (12)
 Community Recruitment (13)
 Area Agencies on Aging (14)
 Church (15)
 Senior Center (16)
 Friend/Word of Mouth (19)
 Social Media (20)
 Website (21)
 Clinical Practice (22)
 Other (17)
 Participant did not answer (18)

Other, specify: (ps_recruitother)

Screeener: "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 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. (ps_desc)

Is it okay to continue? (ps_interest2)

- Yes: "Okay, let's get started" Continue with script Part 3 (1)
 No (0)
-

Ask: "Is there a better time to call back?" (ps_timetotalk2)

- Yes: Ask: Can you tell me some better times to call back? (1)
 No: Respond: "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?" (0)
-

SCREENER:"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?" (ps_futurestudies2)

- Yes: go to Contact Information Section (1)
 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." (0)
-

Options for Call Back Appointment:
(ps_callbackoptions2) _____

Participant was successfully called back (ps_callbacksuccess2)

- Yes (1)
 No (0)
-

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? (ps_oktogoona)

- Yes Go to Part 3: DEMOGRAPHIC and SCREENING questions that follow on the next page (1)
 No: Ask: "Can you share the reason for not wanting to continue?" (0)
-

Reason for not continuing, if shared: (ps_reasonforno)

- Not interested (1)
 No time (2)
 Not what I thought it was about (3)
 Other (4)
 Declined to answer (5)
-

Other, specify: (ps_reasonfornoother) _____

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?" (ps_futurestudies3)

- Yes: go to Contact Information Section (1)
 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." (0)

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? (ps_othlangcomfort)

- Yes: Continue with script moving to question 2 (1)
 No: or (0)
 Declined to answer (2)

SCREENER: Okay, unfortunately all our interviews 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? (ps_futurestudies4)

- Yes: go to Contact Information Section (1)
 No: Respond: Thank you very much for your time today. Have a good day. (0)

2. SCREENER: Can you confirm that you are female? (ps_sex_birth)

- Yes: Continue with script moving to Question 3 (1)
 No: or (0)
 Declined to answer (2)

SCREENER: Okay. Thank you very much for your time and interest today, but our current studies focus on individuals with female anatomy to answer our 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? (ps_nonfem)

- Yes: go to Contact Information Section (1)
 No: Respond: Thank you very much for your time today. Have a good day. (0)

3. SCREENER: Are you 18 years old or older? (ps_age)

- Yes: Ask: "How old are you?" (1)
 No: or (0)
 Declined to answer (2)

How old are you? (ps_agen)

(yrs)

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? (ps_notagerange)

- Yes: Go to contact information Section (1)
 No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

4. SCREENER: Are you pregnant? (ps_preg)

- Yes: Ask: "When is your due date?" (1)
 No: or (0)
 Declined to answer (2)

4a. SCREENER: Are you currently pregnant? (ps_preg_v2)

- Yes: Ask: "When is your due date?" (1)
 No: or (0)
 Declined to answer (2)

When is your due date? (ps_pregdt)

_____ (mm-dd-yyyy)

4b. SCREENER: Have you had a baby recently? (ps_pp)

- Yes: Ask: "When was your delivery date?" (1)
 No: Continue with script moving to Question 5 (0)

When was your delivery date? (ps_ppdt)

_____ (mm-dd-yyyy)

Last date to schedule in-person visit: (pp_enddate)

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

- Yes or (1)
 Declined to answer (2)
 No: Continue with script moving to Question 6 (0)

SCREENER: 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 opportunities for participating in our research and to receive other information on bladder health and other studies?" (ps_medhxy)

- Yes: go to Contact Information Section (1)
 No: SCREENER: Thank you very much for your time today. Have a good day. (0)

6. SCREENER: "Are you able to stand up on your own for up to 3 minutes without help from another person?" (ps_stand)

- Yes: Continue with script moving to Question 7 (1)
 No: or (0)
 Declined to answer (2)

SCREENER: 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?" (ps_notstand)

- Yes: Go to contact information Section (1)
 No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

7. SCREENER: "Are you able to get to the bathroom and to use the toilet on your own - without help from another person?" (ps_toilet)

- Yes: Continue with script moving to Question 8 (1)
- No: or (0)
- Declined to answer (2)

SCREENER: 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?" (ps_notoilet)

- Yes: Go to contact information Section (1)
- No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

8. SCREENER: "Are you currently participating in any research study about the bladder?" (ps_othres)

- Yes: or (1)
- Declined to answer (2)
- No: Continue with script moving to Question 9 (0)

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? (ps_othresy)

- Yes: Go to contact information Section (1)
- No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

9. SCREENER: "Did you previously participate in a focus group or one-on-one interview about bladder health?" (ps_fg)

- Yes: or (1)
- Declined to answer (2)
- No: Continue with script moving to Question 10 (0)

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? (ps_fgy)

- Yes: Go to contact information Section (1)
- No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

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

- Yes: or (1)
- Declined to answer (2)
- No: Continue with script moving to Screening Level 1 (0)

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? (ps_livingy)

- Yes: Go to contact information Section (1)
- No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

Screening Level 1:

Q1. Which of the following statements best describes your bladder?
(ps_q1)

- Does not cause me any problems at all (1)
- Causes me some very minor problems (2)
- Causes me some minor problems (3)
- Causes me some moderate problems (4)
- Causes me severe problems (5)
- Causes me many severe problems (6)

Screening Level 2: Symptoms**FREQUENCY**

Ga1. In the past year, have you ever had times when you peed more often than usual? (ps_ga1)

- Yes (1)
- No (0)

INCONTINENCE

Gb1. In the past year, have you ever accidentally leaked urine, or lost control of pee, even just a drop or two?
(ps_gb1)

- Yes (1)
- No (0)

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? (ps_gc1)

- Yes (1)
- No (0)

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)? (ps_gd1)

- Yes (1)
- No (0)

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? (ps_ge1)

- Yes (1)
- No (0)

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? (ps_gf1)

- Yes (1)
- No (0)

SCREENING LEVEL 2 SUMMARY TABLE

For each section the person qualifies - mark the box in the appropriate column based on Level in Screening 1 (ps_scl2)

HEALTHY

HEALTHY (ps_healthy) Healthy (Qx=1) (1)

GA-FREQUENCY

	Mild (Qx=2 or 3) (1)	Moderate (Qx=4) (2)	Severe (Qx=5 or 6) (3)
Row 1 GA (ps_gapy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Row 2 GB (ps_gbpy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Row 3 GC (ps_gcpy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Row 4 GD (ps_gdpy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Row 5 GE (ps_gepy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Row 6 GF (ps_gfpy)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

AGE GROUP

- 18-25 years old (1)
- 26-44 years old (2)
- 45-64 years old (3)
- 65+ years old (4)

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? (ps_rccheck)

- NO: Continue with Eligibility Script (0)
- YES (1)

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? (ps_rccheckn)

- Yes: Go to contact information Section (1)
- No: SCREENER: "Thank you very much for your time today. Have a good day." (0)

The individual DOES qualify:

SCREENER: Are you still interested in participating in the study?" (ps_stillinterest)

- Yes (1)
- No (0)

May I know the reason why? (ps_no_reason)

- Not interested (1)
- No time (2)
- Not what I thought it was about (3)
- Other (4)
- Declined to answer (5)

Other reason: (ps_no_reason_other)

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?" (ps_responsetono)

- Yes: Go to Contact Information Section (1)
- No: Okay, thank you again for your time today and for your responses to the questions. Have a great day. (0)

CHOOSE ONE: (participant_status)

- PARTICIPANT IS READY TO BE RANDOMIZED (1)
- Participant not currently needed (due to sx severity, LUTS, or age) (2)

Confirm that participant is ready to be randomized:
(ps_randconfirm)

- Participant is ready to be randomized (1)

Notes (ps_notes)

Study Personnel Initials (ps_init)

Date data entered (ps_rcdate)

(mm-dd-yyyy)