



ID: \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_

### Prescreen Eligibility Form

Thank you for your interest in the PREMIER study! Your answers to the following questions will help us to determine if you can become part of this important study. All of the information you provide will be kept strictly confidential.

1. Name: \_\_\_\_\_  
(first) (middle) (last)

2. Address: \_\_\_\_\_  
(number) (street) (apt. number)  
\_\_\_\_\_  
(city) (state) (zip code)

3. Daytime phone number: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

4. Evening phone number: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_



ID: \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

### Prescreen Eligibility Form

	Yes	No
1. Are you 25 years old or older?	<input type="checkbox"/>	<input type="checkbox"/>
2. Do you take insulin or pills for diabetes?	<input type="checkbox"/>	<input type="checkbox"/>
3. <b>For women only:</b> Are you pregnant, planning to become pregnant within the next two years, or breastfeeding?	<input type="checkbox"/>	<input type="checkbox"/>
4. Are you currently taking any medications to control your blood pressure?	<input type="checkbox"/>	<input type="checkbox"/>
5. Are you currently taking diet pills or any medications to control your weight?	<input type="checkbox"/>	<input type="checkbox"/>
6. Have you ever had a stroke, heart attack, or heart bypass surgery?	<input type="checkbox"/>	<input type="checkbox"/>
7. Do you have any other heart problems? <i>If yes, what?</i> _____	<input type="checkbox"/>	<input type="checkbox"/>
8. Are you currently being treated for a serious illness such as cancer, HIV, or liver or kidney disease? <i>If yes, what disease?</i> _____	<input type="checkbox"/>	<input type="checkbox"/>
9. Are you planning to leave the area within the next 2 years?	<input type="checkbox"/>	<input type="checkbox"/>
10. On the average, how many drinks of alcohol do you have in a week? <i>If you don't drink alcohol, enter 0.</i> <i>(one drink = 1 can of beer <u>or</u> 1 glass of wine <u>or</u> 1 shot of liquor)</i>		_____ drinks/wk
11. How tall are you? _____ ft. _____ in		
12. How much do you weigh? _____ pounds		
	Yes	No
13. Do you have any physical limitations that would make moderate intensity physical activity (like a brisk walk) difficult? <i>If yes, specify limitations:</i> _____	<input type="checkbox"/>	<input type="checkbox"/>
14. Has a physician or health care professional ever told you to limit the amount of physical activity that you do? <i>If yes, why?</i> _____ <i>is this an ongoing limitation?</i> _____	<input type="checkbox"/>	<input type="checkbox"/>

15. What is your **primary** race? American Indian or Alaskan Native <sup>1</sup>  
*( check one answer only)* Asian/Pacific Islander <sup>2</sup>  
Black/African American <sup>3</sup>  
White <sup>4</sup>  
Other (specify): \_\_\_\_\_ <sup>5</sup>

16. Do you consider yourself to be Hispanic? Yes <sup>1</sup>  
No <sup>2</sup>

17. What is your sex? Male <sup>1</sup>  
Female <sup>2</sup>

18. How did you hear about PREMIER? Mailed letter/brochure/flier <sup>01</sup>  
*(check one answer only)* Coupon pack <sup>02</sup>  
Other mass distribution <sup>03</sup>  
Article/story/print advertisement <sup>04</sup>  
Radio story/advertisement <sup>05</sup>  
TV story/advertisement <sup>06</sup>  
E-mail/web site <sup>07</sup>  
Screening event/presentation <sup>08</sup>  
Word of mouth <sup>09</sup>  
Other \_\_\_\_\_  \_ \_

19. What is your date of birth? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
mm dd yyyy

20. What are the last 4 digits of your social security number? \_\_\_\_\_

**For Office Use Only**

21. BMI checked:  eligible  ineligible

22. Optional SBP \_\_\_\_\_ Optional DBP \_\_\_\_\_

23. Interested? (use script) Yes <sub>1</sub> <sub>2</sub> No <sub>1</sub> <sub>2</sub>

24. Eligible for SV1 <sub>1</sub> <sub>2</sub>

25. What cohort is participant being screened for? \_\_\_\_\_

Reviewed by (staff ID): \_\_\_\_\_

Entered by (staff ID): \_\_\_\_\_

## PSV Script

This script can be administered over the phone or in person.

- “The purpose of the PREMIER Study is to find out how changes in exercise, diet, alcohol use, and weight affect blood pressure.”
- “This is not a drug study.”
- “If you join the study, you will be randomly assigned, as in the flip of a coin, to one of three intervention programs to help you lower your blood pressure and improve your overall health.”
- “The study will last 18 months.”
- “To be eligible to participate, you’ll first have to come to \_\_\_\_\_ for approximately 3 screening visits to make sure that you have higher than optimal blood pressure or mild high blood pressure and are free from any health conditions that would make participation unsafe.”
- “Once enrolled in the study, you will be asked to come to \_\_\_\_\_ on numerous occasions over the next 18 months, both to learn about lifestyle change, and to collect study measurements. “
- “The number of visits depends on the group to which your are assigned.”
- “Study measurements include blood pressure, weight, blood and urine specimens, a fitness test, and questions about your diet and physical activity levels.”
- “In addition to participation at no charge in the lifestyle programs and regular blood pressure monitoring, you will receive \$\_\_\_\_\_ at the end of the study as our way of saying thanks for your involvement.”

# Prescreen Eligibility Form Training Manual and Coding Instructions

## Overview

The Prescreen Eligibility Form may be completed in one of three contexts:

- over the phone,
- during a community screening activity, or
- in the clinic.

It is recommended that this form be administered in an **interview format**. If this form is given to the participants to complete on their own, question 18 (on how the participant heard about PREMIER) needs to have the definitions of recruitment sources explained to the participant (see attached definitions).

Some of the questions on this form result in immediate exclusion from the study, others are intended to gather demographic information, to aid in recruitment monitoring, and some are used as a flag to be reviewed by a clinician or dietitian.

As soon as a participant is determined to be ineligible, the staff person should check the “No” box under Question 24 and terminate the interview.

ID labels will be affixed to pages 1-3 of this form after it has been entered. At that time, the first page should be detached and filed separately.

## Administration Instructions

Using a blue or black pen, fill out the visit date on pages 1 and 2.

The remaining items can be completed by the participant or by the interviewer.

<b><u>Page</u></b>	<b><u>Question</u></b>	<b><u>Special Administration Instructions (if any)</u></b>
1	1	self-explanatory
	2	self-explanatory
	3	self-explanatory
	4	self-explanatory
2	1	If NO, then enter NO for Q24 and terminate interview. If participant will soon have a birthday, you may bring them back after they turn 25 and repeat the prescreen.
	2	If YES, then enter NO for Q24 and terminate interview.
	3	Skip this question for males. If participant is female and answers YES, then enter NO for Q24 and terminate interview. Inform the woman that, because of the effects of pregnancy and/or breastfeeding on blood pressure, she is not eligible for the study at this time. The participant can be rescreened later after they deliver and/or stop breastfeeding. This question may not be checked NO based on the expectation that the participant will deliver and/or stop breastfeeding in the near future.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
2	4	If YES, then enter NO for Q24 and terminate interview.
	5	If YES, then enter NO for Q24 and terminate interview.
	6	If YES, then enter NO for Q24 and terminate interview.
	7	If YES, gather as much detail as possible, complete the remainder of the form, and refer the form to the clinician for review (assuming the participant is otherwise eligible). If the clinician decides that the person is eligible, recode the answer to Q7 to NO. Otherwise, enter NO for Q24.
	8	If YES, gather as much detail as possible, complete the remainder of the form, and refer the form to the clinician for review (assuming the participant is otherwise eligible). If the clinician decides that the person is eligible, recode the answer to Q8 to NO. Otherwise, enter NO for Q24.
	9	If YES, then find out exactly when the participant plans to leave the area. If it is after the last followup date for the current cohort, then recode the answer to NO. Otherwise, enter NO for Q24 and terminate interview.
	10	Probe to get a specific number of drinks. If >21, then enter NO for Q24 and terminate interview.
	11	Record height in feet and inches
	12	Record weight in pounds. To determine eligibility, first locate the participant's height (from Q11) on the attached BMI Reference Chart and note the accompanying weight limits. If the participant's weight is below the lower limit, or above the upper limit, check ineligible for Q21, enter NO for Q24 and terminate the interview. Otherwise, check eligible for Q21.
	13-14	If YES, gather as much detail as possible and then exclude the participant (enter NO for Q24) if any of the following limitations/reasons is specified: use of cane, walker, or other walking aid; severe arthritis, musculoskeletal injury, broken limb, or structural foot problems, which would make walking difficult; respiratory disease that causes difficulty in breathing with light exertion. Exclude by entering NO for Q24. If unable to decide, refer to PI or Intervention Director for decision.
3	15	If OTHER, gather as much detail as possible about the participant's self-described primary race and be sure to follow the coding instructions on page 6. If "Hispanic" is recorded, or Q16 is YES, probe for primary race code.
	16	Although often used as a racial category, "Hispanic" actually relates more closely to ethnicity and is thus complementary to Q15.
	17	self-explanatory

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
3	18	Check only one answer. The item that prompted the participant to call or come in should be used. The participant can write in other responses if they want, but it will need to be coded later. See attached table for definitions.
	19	Use a 4-digit year (e.g. 12/10/1999 or 1/15/2000)
	20	If asked, explain to participants that this is used to identify them in case some other participant has the same name.
	21	Fill out based on instructions for Q12
	22	This optional BP measured with a standard mercury sphygmomanometer, is optional. Guidelines for eligibility are SBP 118-179 and DBP 78-109. Clinical discretion may be used to further evaluate potential subjects if they indicate that the pre-screen BP determination was atypical. However, the pre-screening escape guidelines must be followed, and the participant referred to a physician within one week whenever the SBP exceeds 180 or the DBP exceeds 110. If the BP is outside the limits and the clinician does not decide to make an exception, then enter NO for Q24 and terminate the interview.
	23	Read the script describing the study and the nature of the interventions, and ask participant if he/she is still interested in participating. If NO, then enter NO for Q24 and terminate the interview.
	24	If you have gotten to this point and the participant is still eligible, and any necessary clinician review of Q7-8 and interventionist/clinician review of Q13-14 has been completed, then enter YES.
	25	self-explanatory

### **Coding Instructions**

Follow up on any YES answers to Q7, Q8, Q13, or Q14. Recode the answers as appropriate following clinician/interventionist review. Add an explanation of the decision, and initial and date the correction.

Make sure any OTHER answers to Q15 are recoded appropriately. The following table lists some common responses listed under OTHER and how to categorize them. Contact the CC for a decision if you have an answer which is not covered in the table.

Description from participant	Recode to:
Ethiopian, Mulatto, West Indian	3=Black/African American
Spanish, Cape Verdian, Lebanese, Persian, Jewish, Brazilian, Persian, Arab, Portuguese, Milano, Russian	4=White

Make sure any OTHER answers to Q18 are recoded appropriately. Contact the CC for a decision if needed.

## Review Instructions

If participant is INELIGIBLE (Q24=NO), confirm that there is at least one item on page 2 that makes them ineligible. This form does not need to be entered, so enter your Staff ID in the “reviewed by” section at the bottom of page 3, and put a large “X” in the “entered by” section.

If the participant is ELIGIBLE (Q24=YES), check the following items:

- Pages 1-2 should be dated.
- Participant’s name on page 1 should be complete, legible, and in the right order (first then last, not last then first).
- Page 2:
  - item 1 should be coded YES;
  - items 2,5,6,7,8,9,13 and 14 should be coded (or recoded) NO;
  - item 3 should be coded NO or skipped (males);
  - item 10 should be less than or equal to 21;
  - item 12 should be within the range allowed for the height shown in item 11.
- Page 3:
  - all items should be completed (except the optional Q22).
  - All items initially coded to OTHER on Q15 and Q18 should now be assigned to an appropriate code. If no code applies, contact the CC for a decision.
- All pages: all corrections should be explained, initialed, and dated. Corrections should be made in a different color pen than was used in filling out the form. It is suggested that you use red or green.
- If all of the above items look acceptable, enter your Staff ID in the “reviewed by” section at the bottom of page 3.
- If the participant remains ELIGIBLE at the end of the review process, then forward the form to the data entry person to be entered. Do not separate page 1 from pages 2-3 until after labels have been generated.

## Additional Instructions

Do not enter forms where outcome is ineligible. Forms with outcome=“eligible” can be entered at any time (since it is the first form in the sequence).

The Data Entry application will assign a participant ID. **Write the ID number at the top of each page of the form.**

After the form has been entered, use the Data Management application to print labels and attach the labels over the top of the hand-written ID on each page of the form.

Once the form has been labeled, detach page 1 from the rest of the form. If you are ever asked to send the form to the CC for validation or to solve some data problem, send only pages 2 and 3 to avoid transmitting confidential information (name, address, phone).

**PSV BMI Reference Chart**

Participants weight must be greater than or equal to the minimum weight for their height in the table below, and less than or equal to the maximum weight.

Height in feet and inches	Weight in Pounds	
	Minimum Weight	Maximum Weight
4' 6"	74	188
4' 7"	77	196
4' 8"	80	203
4' 9"	83	210
4' 10"	86	217
4' 11"	89	225
5' 0"	92	233
5' 1"	95	240
5' 2"	98	248
5' 3"	101	257
5' 4"	105	265
5' 5"	108	273
5' 6"	111	282
5' 7"	115	290
5' 8"	118	299
5' 9"	122	308

Height in feet and inches	Weight in Pounds	
	Minimum Weight	Maximum Weight
5' 10"	125	317
5' 11"	129	326
6' 0"	132	335
6' 1"	136	344
6' 2"	140	354
6' 3"	144	364
6' 4"	147	373
6' 5"	151	383
6' 6"	155	393
6' 7"	159	403
6' 8"	163	414
6' 9"	168	424
6' 10"	172	435
6' 11"	176	445
7' 0"	180	456

## Definitions for items in Question 18 :

- 01: Mailed Letter/Brochure/Flier:** any mass mailing of PREMIER information that requests a mail or phone response. This does not include calls or cards returned as a result of distributing brochures by other means (I.e. hand distribution at malls). Those should be coded as “Other Mass Distribution.”
  - 02: Coupon Pack:** any mass mailing through companies which include PREMIER brochures or special coupons with other coupons.
  - 03: Other Mass Distribution:** this includes brochures distributed by hand or left on display at sites, libraries, grocery stores, and pharmacies.
  - 04: Article/story/print advertisement:** this includes any participant who heard about the study via a newspaper, newsletter or magazine, regardless of whether it was a story or a paid advertisement.
  - 05: Radio story/advertisement:** this includes any participant who heard about the study via the radio, regardless of whether it was a story or a paid advertisement.
  - 06: TV story/advertisement:** this includes any participant who heard about the study via a TV, regardless of whether it was a story or a paid advertisement.
  - 07: E-mail/web site:** this includes any participant who heard about the study via an e-mail message, electronic bulletin board, or the internet.
  - 08: Screening event/presentation:** this includes any participant who attended a gathering, event, or presentation that occurs outside a PREMIER clinic. It may last one or more days. This could include screenings at churches, shopping malls, etc.
  - 09: Word of mouth:** this includes any participant who was referred to PREMIER by a friend, family member, physician, health care provider, or public clinic. If the participant also heard of the study through one of the target mailings, code as appropriate for the mailing.
- Items listed under Other:** if the response can not be coded as 1-9 above, it should be coded as 10 or proceed with instructions under 11.
- 10: Person was in prior study:** anyone who was in a prior research study at the clinical center, including DASH and DASH2.
  - 11:** If the item does not fit any of the above categories, contact the CC for a decision.