

ID: _____

- | | Yes | No | Comments |
|---|----------------------------|----------------------------|-------------------------------|
| 6. In the last 2 years, have you been hospitalized for psychological or emotional problems?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |
| 7 On average, how many drinks of alcohol do you have in a week? (1 drink=1 can of beer or 1 glass of wine or 1 shot of liquor. If you don't drink alcohol, enter 0.)..... | | | _____ . _____ drinks per week |

7a. **If you drink alcohol**, how often do you have six or more drinks on one occasion?

Never	<input type="checkbox"/>	1
Less than monthly	<input type="checkbox"/>	2
Monthly	<input type="checkbox"/>	3
Weekly	<input type="checkbox"/>	4
2-3 days/week	<input type="checkbox"/>	5
4-7 days/week	<input type="checkbox"/>	6

- | | Yes | No | Comments |
|--|----------------------------|----------------------------|----------|
| 8. Has your weight changed by more than 15 pounds within the last 3 months? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |
| 9. Are you currently participating in any other research studies or clinical trials? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |
| 10. Are you planning to move out of the area in the next two years?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |
| 11. Do you live in the same household with a PREMIER staff member or a PREMIER participant?..... | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |
| 12. Do you live in the same household with someone who is trying out for PREMIER? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | _____ |

Office Use: *If Yes:* Enter the ID number of the household member..... _____

For women only

13. Are you pregnant, planning to become pregnant in the next 24 months, or breast feeding?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
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Office Use:

Outcome:	Eligible <input type="checkbox"/> 1	Reviewed by (staff ID): _____
	Ineligible <input type="checkbox"/> 2	Entered by (staff ID): _____

Weight-loss Drugs (Question 4)

This list includes some but not all the prescription and over the counter weight loss products. Please respond “Yes” if you have used any of these products for weight loss within the past 3 months.

<u>Generic name</u>	<u>Brand name</u>
Benzphetamine.....	Didrex
dexfenfluramine	Redux
diethylpropion	Tenuate, Tepanil
fenfluramine	Pondimin
phentermine.....	Adipex, Fastin, Ionamin, Obenix, Oby-Cap, Oby-Trim, Pro-Fast, Zantril
fenfluramine/phentermine	Fen/Phen
mazindol.....	Sanorex, Mazanor
phendimetrazine	Plegine, X-trozine, Bontril, Prelu-2
phenmetrazine	Preludin
phenylpropanolamine	Dexatrim, Accutrim
d-amphetamine.....	Dexadrine, Dextrostat
methamphetamine	Desoxyn
orlistat	Xenical
sibutramine.....	Meridia

Eligibility Questionnaire

Overview

This Eligibility Questionnaire will typically be completed by the participant at the SV1 visit, but can also be completed at the participants home prior to the SV1 visit.

This questionnaire will begin the process of screening applicants for a variety of medical conditions and personal habits that would make participants ineligible. Some of these conditions/habits could interfere with the study by obscuring the effects of the study diet. Others might make it harmful or unwise for an individual to participate.

Administration Instructions

Using a blue or black pen, fill out the visit date on page 1. Be sure to use a four digit year.

Place ID labels on pages 1 and 2. If an ID# has not yet been assigned, leave blank and fill in later.

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

The following information is intended to help you assist participants in providing accurate answers to these questions. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire so that further review may be undertaken by a study clinician. **Ultimately, all responses must be resolved and coded either “Yes” or “No”.**

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	name	This field is used for sites that do a combined PSV/SV1 and will not be able to print labels prior to the time the participant fills out this form. It is not a required field. Once labels have been added, this field should be blacked out to avoid any breach of confidentiality when forms are faxed. For sites that do not do combined PSV/SV1 visits, this field can be masked off on the master when you make copies for participants, and then there will be no need to black out participant names later.
	1a-e	These questions are intended to screen for cardiovascular disease <u>other than</u> hypertension. An individual with <u>only</u> hypertension should answer NO to each question. If any question is answered YES, participant is ineligible for the study. Note: question 1a does not include heat stroke.
	2	Enter YES if the participant has ever had a diagnosis of cancer. If there is no history of cancer or participant has only had skin cancer, enter NO.
	2a	For <u>Inactive</u> cancers, those which have (1) been in remission for over two years <u>or</u> were removed over two years ago AND (2) have not resulted in any further treatment within the past two years, ENTER NO . For <u>Active</u> cancers, those present within the past two years OR which required treatment within the past two years, ENTER YES . If Yes, then participant is ineligible.
	3	If YES, participant is ineligible.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
	4	If YES, the participant is ineligible for this cohort, but may be screened for a subsequent cohort if they go off the medication. Participants must be off diet pills/weight loss medications 3 months prior to SV1. If No, double check if participant reviewed the list of Weight Loss Drugs on page 3.
1	5	If YES to any of the items (a, b, c, or d), the participant is ineligible. Note: the 5+ days per month do not have to be consecutive.
2	6	If YES, participant is ineligible.
	7	If answer is >21 drinks per week, the participant is ineligible. Participants who do not drink alcohol should enter zero. If the participant asks, a drink is defined as 12 oz. of beer, 5 oz. of wine, or a 1 oz. shot of liquor. If participant gives a range use the mid-range or higher number. For example, code "5-6" as "5.5", code "0.5 to 1" as 1, and code "4 to 6" as "5".
	7a	If 2-3 days/week or 4-7 days/week are checked, the participant is ineligible. Participants who do not drink alcohol should skip this question.
	8	If YES, the participant is ineligible.
	9	Q9 is not necessarily exclusionary. If YES, the clinician can decide if the two trials are in conflict and recode this answer to NO if there is no conflict.
	10	Q10 is not necessarily exclusionary. If YES, then find out exactly when the participant plans to leave the area. If it is after the last follow up date for the current cohort, then recode the answer to NO.
	11	If YES, participant is ineligible.
	12	Two household members may be screened for PREMIER, but only one can eventually be randomized. The other can be invited to participate in the assigned intervention. Screening may continue on both members until one is randomized.
	13	This question should be completed only by women. If YES, Participant is ineligible.
	Office Use:	If you have gotten to this point and the participant is still eligible, and all comments have been resolved, then enter "eligible".

Coding Instructions

Follow up on any blank items, or any items where participant wrote in the comments field. Code or recode the answers as appropriate following clinician/interventionist review. Add an explanation of the decision, and initial and date the correction.

When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is INELIGIBLE (at least ONE question = Yes on page 1 or 2, except Q2-1st part, or Q7 >21 drinks per week), mark as ineligible on the SV1 Visit Form (#03) for the SV1 Eligibility Questionnaire outcome.

If the participant is ELIGIBLE (Office use box is marked eligible), check the following items:

- ? Page 1 should be dated, pages 1-2 should have correct ID# labels. (See Additional Instructions below)
- ? Page 1: items 1a-e, 2a,3, 4, 5a-c should be coded (or recoded) NO;
- ? Pages 2-3: items 6, 8-11, 13 should be coded (or recoded) NO, item 7 should be less than or equal to 21; item 7a should be coded no higher than “weekly”. If item 12 is “Yes”, be sure to enter the PREMIER ID of the other household member being screened.

If all of the above items look acceptable, enter your Staff ID in the “reviewed by” section at the bottom of page 3, and enter “eligible” on the SV1 Visit Form (#03) for the SV1 Eligibility Questionnaire outcome.

Additional Instructions

If form was filled out prior to labels being printed, make sure to attach labels prior to data entry. Once the labels are attached, black out the participant’s name on page 1.