



Pre-randomization
ID: _____
Date: ____ / ____ / _____

Eligibility Review Questionnaire

Please review and answer all of the questions on this form. Indicate your answers by placing an “x” in the appropriate box. Depending upon your answers, some of the questions may be skipped.

Thank you very much for your cooperation.

	Yes	No	Comments
1. Have you ever had any of the following?			
a. Stroke	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
b. Heart attack	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
c. Congestive heart failure	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
d. Coronary bypass surgery or angioplasty.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
e. Blood vessel surgery to open arteries in your neck or legs	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
2. Have you ever had cancer? (other than skin cancer)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
2a. <i>If yes</i> , was it: Active within the past 2 years or treated with radiation or chemotherapy in the past 2 years?			
	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
3. Have you taken any medications to control your blood pressure within the past 3 months?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
4. Have you taken any medications to control your weight within the past 3 months? (see attached list).....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
5. Do you regularly (more than 5 days per month) take any of the following medications?			
a. Steroid or corticosteroid pills? (e.g., prednisone).....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
b. Oral breathing medications other than inhalers?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
c. Insulin or pills for diabetes.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
d. Lithium?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____

ID: _____

Yes No Comments

6. In the last 2 years, have you been hospitalized for psychological or emotional problems? 1 2 _____

For women only

7. Are you pregnant, planning to become pregnant in the next 18 months, or breast feeding? 1 2 _____

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 Review Questionnaire

Overview

This Eligibility Review Questionnaire is completed in the 30 days prior to the randomization visit for all participants where more than 30 days will have elapsed between completing the Eligibility Questionnaire and randomization. It is likely that all participants will need to fill out this questionnaire.

Most of the questions are repeated from the Eligibility Questionnaire.

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.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	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.
	4	If YES, the participant is ineligible for this cohort, but may be screened for a subsequent cohort if they go off the medication. If No, double check if participant reviewed the list of Weight Loss Drugs on page 3.
	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.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
2	7	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 items left blank or 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, mark the outcome as ineligible on this form and on the Pre-Randomization Checklist for the Eligibility Review Questionnaire Outcome.

If the participant is ELIGIBLE, check the following items:

- Page 1 should be dated, pages 1-2 should have correct ID# labels.
- Page 1: items 1a-e, 2a, 3, 4, 5a-d should be coded (or recoded) NO;
- Page 2: item 6 should be coded (or recoded) NO, item 7 should be skipped or coded NO.

If all of the above items look acceptable, enter your Staff ID in the “reviewed by” section at the bottom of page 2, and enter “eligible” on the Pre-Randomization Checklist for the Eligibility Review Questionnaire outcome.