

PSV			
ID#			
Visit Date _	/	/_	

Prescreen Eligibility Form

Thank you for your interest in the DASH2 study! Your answers to the following questions will help to determine if you can become part of this important study. Any information you provide will be kept strictly confidential.

Please print your name, address, and phone number.

First n	ame	MI	Last name		
Addres	ss	City	State	Zip	
Daytin	ne phone	Evening phone		V	NT.
1. 2	Are you 22 years old or older? Do you take insulin?			Yes	No
3.	For women only: Are you pregnan	t, planning to become pregna	ant, or breastfeeding?		
4	Have you taken any medications to months?	control your blood pressure	in the last three		
5.	Are you currently taking diet pills o	r any medications to control	your weight?		
6.	Do you currently chew tobacco or u	se snuff?			
7	On the average, how many drinks If you don't drink alcohol, enter (one drink = 1 can of beer or 1 g	0.		drinks p	er week
8.	Have you ever had a stroke or heart	attack?			
9	Do you have any other heart problem If yes, what?	ms?			
10.	Do you have any other serious illne. If yes, what disease?	ss such as cancer, HIV, or liv	ver or kidney disease?		
11.	Are you on a special diet or plannin If yes, what kind of diet?				
12.	Are there any foods that you cannot If yes, what and why?	or will not eat?			

13.	How tall are you?	ft	inches
14.	How much do you weigh?		pounds
15.	What is your primary race? (check one answer only)	American Indian or Alaskan Native Asian/Pacific Islander Black/African American White Other (specify)	□1 □2 □3 □4 □5
16.	Do you consider yourself to be Hispanic?	Yes No	□1 □2
17.	What is your sex?	Male Female	□1 □2
18.	How did you hear about DASH2? (check one answer only)	Mailed letter/brochure/flier Non-paid radio story Screening events/health fair Word of mouth/friends Non-paid print story/newspaper Non-paid TV story Presentations Other	1 2 3 4 5 6 7 7
19.	What is your date of birth?	mm dd	уууу
20.	What is your mothers maiden name?		
	For Office Use Only		
21. 22.	Optional SBP Optional DBP PSV eligible	—— Yes □1	No
23.	What cohort is participant being screened for?		
		Reviewed by (staff ID): Entered by (staff ID):	

Administration and Coding Instructions for Prescreen Eligibility Form

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** due to the detailed information that the recruitment committee is capturing for the "hear about study" question (Q18). If this form is given to the respondents to complete on their own, question 18 must be explained to the respondents.

Some of the questions on this form will 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 PSV eligible in the "office use only" section. The interview may then be concluded at this point or continued (at local discretion).

In addition to the questions asked on the form, the prescreening visit includes an optional blood pressure assessment. Space is included in the "office use only" section to record this information. The blood pressure assessment may be taken either before or after completing the questionnaire. If it is done before and the participant is not eligible, the remainder of the questionnaire need not be completed.

Record the visit date (be sure to write in a four digit year) in the upper right corner. If the participant is still eligible to continue at the end of the visit, the computer will assign a study ID number upon entry of the form and this should also be recorded on the form.

Record respondent's name, address, and phone number. Please print legibly to facilitate entry later.

General Coding Instructions

- 1) Use correct version of form. The correct version will always be on the file server.
- 2) Use either black or blue pen on all forms, not pencil.
- 3) Make sure that there is either a legible name or correct ID # or both, if needed, on each page of a form. It is strongly suggested that you use a printed label for ID numbers.
- 4) Make sure each question is answered. Be sure to resolve any questions before the respondent leaves and before entering data.
- 5) Check each question for ambiguous answers. Be sure to resolve these before the respondent leaves and before entering data.
- 6) Do not obliterate or erase any entry of the respondent.
- 7) All corrections are made by first making a slash through the incorrect entry and writing the correct entry next to it. Then, alongside the corrected entry, write your initials, the date of the correction and a note about why the correction was made (e.g., RL, 7/30/97, incorrect ID).
- 8) Flag any questions you are not sure of and give them to the clinic coordinator or dietitian for review.
- 9) Check all lead-in questions for correct skip patterns.
- 10) When filling out the "Reviewed by" and "Entered by" box, be sure to use the correct staff ID number. The "Entered by" staff ID # should not be written until the form is entered.

Questions 1-14 will NOT be entered:

- Q1. Only individuals aged 22 years or older as of PSV date are eligible to participate
- Q2. Respondents taking insulin are excluded from participation.
- Q3. Question 3 is asked only of women. Those who answer "yes" should be excluded. Inform the woman that, because of the effects of pregnancy on blood pressure, she is not eligible for the study at this time. Women who plan to deliver in the near future can be rescreened again after delivery, but cannot be checked as "no" based on an anticipated delivery date.

 If respondent is breastfeeding, inform the woman that she is not eligible for the study because of the effects of breastfeeding on blood pressure. Those women who are excluded only on the basis of this question can be invited back for rescreening if they plan on stopping breastfeeding prior to completion of the study. This question may not be checked "no" however, based on the anticipation that this will happen in the near future.
- Q4. If respondents have taken blood pressure medications in the past three months, they are excluded.
- Q5. Respondents taking any diet pills or medication to control weight are excluded.
- Q6 Respondents using chewing tobacco or using snuff are excluded.
- Q7 Probe to get a specific number of drinks per week. If more than 14 drinks in a week, the person is ineligible.
- Q8 Respondents who have had a stroke or a heart attack are excluded.
- Respondents having any heart problems may be excluded. Record the problem and then consult your clinician for those respondents answering "yes". The clinician will determine if the problem is cause for exclusion according to local protocol. If the clinician decides that the person is eligible, change the response to "no".
- Q10 Respondents having any other serious illness such as cancer, HIV, or liver or kidney disease may be excluded. Record the problem and then consult your clinician for those respondents answering "yes". The clinician will determine if the problem is cause for exclusion. If the clinician decides that the person is eligible, change the response to "no".
- Respondents who are planning to go on or are on a special diet may be excluded. Record the problem and then consult your dietitian for those respondents answering "yes". The dietitian will determine if the problem is cause for exclusion. If the dietitian decides that the person is eligible, change the response to "no".
- Q12 Respondents who can not eat certain foods may be excluded. Record the problem and then consult your dietitian for those respondents answering "yes".

The dietitian will determine if the problem is cause for exclusion. If the dietitian decides that the person is eligible, change the response to "no".

- Q13. Record height in feet and inches.
- Q14. Record weight in pounds.

<u>Body mass index</u> - To determine if the participant is BMI eligible, first locate the participant's height (from Q13) on the PSV reference chart (attached) and note the accompanying weight threshold. If the participants weight (from Q14) equals or exceeds this threshold, the participant is ineligible based on BMI.

The following questions CANNOT be left blank. Questions 15-20 and 22-23 will be entered if eligible. Entry is optional if respondent is ineligible.

- This question is intended for demographic purposes. Record the primary race. This should be the one the participant identifies with the most. Check only one answer. If the respondent enters "Hispanic" under "other", code Q16 as "yes", ask participant if they consider themselves to be white Hispanic, black Hispanic, or other Hispanic. Code Q15 as appropriate based on the answer. The "other" category should not be checked simply because the participant lists Hispanic.
 - 1=American Indian, Alaskan Native
 - 2=Asian/Pacific Islander
 - 3=Black/African American, Ethiopian, Mulatto
 - 4=White, Spanish, Capeverdian, Lebanese, Spanish, Persian, Jewish, Brazilian, Portuguese, Milano, Russian, German-Arab, Arab
 - 5=Other, (anything coded as "other" will not be classified as a minority by NIH. Contact the CC for "other" races that you are unable to recode into the above categories.)
- Q16. Although often used as a racial category, "Hispanic" actually relates more closely to ethnicity and is thus complementary to Q15. If Hispanic is written in above or Q16 is "yes", probe for primary race code.
- Q17. Self-explanatory.
- Q18 Check only one answer. The item that prompted the respondent to call or come in should be used. The respondent can write in other responses if they want. If a response is written in "other" it will need to be coded. Use the following definitions and categories as a guideline to determine which code you will use. This is a two digit field, you will need to write in leading 0's.
 - **01=Mailed letter/brochure/flier**: any mass mailing of DASH2 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 stores, malls). These should be coded as **(09)**.
 - **02=Non-paid radio story**: any free radio announcement, ad, interview or program that gives information about DASH2

- **03=Screening events/health fair**: any gathering or event that occurs outside a DASH2 clinic. It may last one or more days. Screening could include, churches, shopping malls, special events, etc.
- **04=Word of mouth/friends:** any referral or recommendation to DASH2 by friend or family that cannot be linked by the caller to target mailing. This would also include referral from a physician or health care provider or public clinic.
- **05=Non-paid print story:** any free local or national newspaper or magazine article or public service announcement or newsletter (church, worksite, hospital, HMO, MCO, and professional organization) that gives information about DASH2. This would also include payroll stuffers that are placed without a fee.
- **06=Non-paid TV story:** any free TV announcement, ad, interviews, or program that gives information about DASH2.
- **07=Presentations:** any presentations other than screening done outside a DASH2 center.

Additional codes:

- **08=Valpack:** any mass mailing through companies which include DASH2 brochure or special coupons with other coupons.
- **09=Brochure/flier distributed other than mailing:** this includes brochures left on display at sites, libraries, grocery stores, and pharmacies. These should be coded to distinguish them from other brochures. Be sure staff answering phones are aware of posting of information or distribution of fliers and brochures
- **10=Paid print advertisement**: any print (newspaper, circular, magazine, etc.) ad that is paid for by a DASH2 site. This could include inserts in newspapers or utility bills (if it was paid to be inserted).
- **11=Paid radio advertisement**: any radio ad or announcement that is paid for by a DASH2 site.
- **12=Paid TV advertisement**: any TV ad or announcement that is paid for by a DASH2 site.
- **13=Email**: any information obtained through e-mail.
- **14=Person was in prior study**: anyone who has been in a prior research study at the clinical center, including prior DASH participants. Later, we will specifically identify prior DASH1 participants.
- **15=Web page**: any information obtained from the internet or DASH web page
- Q19 Self-explanatory. Use a four digit year(e.g. 12/10/1960).
- Q20. Record the participant's mothers maiden name. This field is used to help distinguish multiple people with the same name.

"For Office Use Only" section

<u>SBP</u> - If a blood pressure measurement is taken, record the SBP and mark either eligible or ineligible to indicate whether the participant was excluded on the basis of this measurement. No eligibility limits are established for PSV blood pressure measurement. It is recommended however, that individuals with a SBP less than 116 be excluded. In addition individual clinics should establish their own upper eligibility limits, and participants whose blood pressure exceeds these limits should be excluded and referred to a physician for further follow-up.

<u>DBP</u> - If a blood pressure measurement is taken, record the DBP and mark either eligible or ineligible to indicate whether the participant was excluded on the basis of this measurement. No eligibility limits are established for the PSV blood pressure measurement. It is recommended however, that individuals with a DBP less than 76 mm Hg be excluded. In addition individual clinics should establish their own upper eligibility limits, and participants whose blood pressure exceeds these limits should be excluded and referred to a physician for further follow-up.

PSV Eligible:

This section should be filled out after reviewing all the participant responses on the form. Only one outcome status should be checked.

PSV eligible - The Eligible box should be checked "yes" if <u>all</u> of the following are true:

Question 1 is answered "yes";

Questions 2, 3, 4, 5, 6, 8, are answered "no";

Question 7 indicates the person drinks < 14 drinks per week.

Question 9, 10, 11, 12 are answered "no" or if answered "yes" the clinician or dietitian DID NOT determine the problem to be a reason for exclusion.

SBP and DBP are within the eligible range; (if measured)

"Body mass index" is within the eligible range (Questions 13,14);

If any of the above are NOT true, code PSV eligible as "no".

<u>What cohort is participant being screened for</u> - Write the number of the cohort that the participant will be placed in. In most cases the participant will be placed in the current cohort. However, in some cases the participant may be screened for the following cohort.

<u>Reviewed by:</u> - Record the staff ID of the person reviewing the form for completeness and eligibility. This can not be left blank.

<u>Entered by</u> - At data entry time record the staff ID of the person entering the form. This can not be left blank.

PSV Reference Chart

Body Mass Index Table (for use with Prescreen Eligibility Form)

Locate participants height (from Q13) on the table below and note the accompanying threshold weight. If participants weight (from Q14) equals or exceeds this threshold, the participant is ineligible based on BMI.

threshold		threshold		threshold	
height	weight (lbs.)	height	weight (lbs.)	height	weight (lbs.)
46"	165.9	55"	240.4	64"	328.6
47"	172.1	56"	247.8	65"	337.3
48"	178.4	57"	255.4	66"	346.1
49"	184.8	58"	263.1	67"	355.1
410"	191.4	59"	270.9	68"	364.1
411"	198.0	510"	278.8	69"	373.3
5	204.8	511"	286.8	610"	382.5
51"	211.7	6	294.9	611"	391.9
52"	218.7	61"	303.2	7	401.4
53"	225.8	62"	311.5		
54"	233.0	63"	320.0		
5 51" 52" 53"	204.8 211.7 218.7 225.8	511" 6 61" 62"	286.8 294.9 303.2 311.5	610" 611"	382.5 391.9

CHEATSHEET: CODES FOR Q18 OF PSV

Brochures

- **01=Mailed letter/brochure/flier**: any mass mailing of DASH2 information that requests a mail or phone response.
- **08=Valpack:** any mass mailing through companies which include DASH2 brochure or special coupons with other coupons.
- **09=Brochure/flier distributed other than mailing:** this includes brochures left on display at sites, libraries, grocery stores, and pharmacies.

Radio

- **02=Non-paid radio story**: any free radio announcement, ad, interview or program that gives information about DASH2
- **11=Paid radio advertisement**: any radio ad or announcement that is paid for by a DASH2 site.

Print

- **05=Non-paid print story:** any free local or national newspaper or magazine article or public service announcement or newsletter (church, worksite, hospital, HMO, MCO, and professional organization) that gives information about DASH2. This would also include payroll stuffers that are placed without a fee.
- **10=Paid print advertisement**: any print (newspaper, circular, magazine, etc.) ad that is paid for by a DASH2 site. This could include inserts in newspapers or utility bills (if it was paid to be inserted).

Television

- **06=Non-paid TV story:** any free TV announcement, ad, interviews, or program that gives information about DASH2.
- **12=Paid TV advertisement**: any TV ad or announcement that is paid for by a DASH2 site.

Events

- **03=Screening events/health fair**: any gathering or event that occurs outside a DASH2 clinic. It may last one or more days. Screening could include, churches, shopping malls, special events, etc.
- **07=Presentations:** any presentations other than screening done outside a DASH2 center.

Other

- **04=Word of mouth/friends:** any referral or recommendation to DASH2 by friend or family that cannot be linked by the caller to target mailing. This would also include referral from a physician or health care provider or public clinic.
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