

Form Approved:
OMB No. 0920-XXXX
Expiration Date: 00/00/2014

HIV Prevention among Latino MSM: Evaluation of a locally developed intervention

Attachment 3

Participant Screening Form

(NOTE: The Spanish version of the form will be used in the proposed study; the English version is included solely for purposes of review.)

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Screening

Thank you for calling the Chatham Social Health Council. _____ [The recruiter provides his full name] speaking.

¿Are you calling about the HOLA en Grupos research study for men?

[If the caller says that he is not calling about the research study, the recruiter should provide the information that caller may need, thanks the caller for calling, and finish the call politely.]

Good, you are calling about the HOLA en Grupos research study for men.

I have a few questions for you.

[The recruiter asks the following questions and documents the answers provided. Read only the questions outlined in Column A and denote potential participant's response in Column B. Follow instructions in Column C to determine whether the potential participant is eligible for that criterion and select the correct response in Column D.]

A	B	C	D
Criterio de inclusión	Respuesta	Instrucciones	Elegibilidad?
1) Which of the following best describes your ethnicity?	<input type="checkbox"/> ₁ Hispanic origin <input type="checkbox"/> ₀ Not of Hispanic origin	[If "Hispanic origin", select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
2) How old are you?	_____ years	[If ≥18 years old, select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
3) In which language would you consider yourself to be fluent?	<input type="checkbox"/> ₁ Only Spanish <input type="checkbox"/> ₂ More Spanish than English <input type="checkbox"/> ₃ Both equally <input type="checkbox"/> ₄ More English than Spanish <input type="checkbox"/> ₅ Only English	[If "Only Spanish", "More Spanish than English", or "Both equally", then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
4) What is your gender?	<input type="checkbox"/> ₀ Female <input type="checkbox"/> ₁ Male <input type="checkbox"/> ₂ Male to female transgender <input type="checkbox"/> ₃ Female to male transgender <input type="checkbox"/> ₄ Other [please specify]: _____	[If "Male", "Male to female transgender", or some other specific category that indicates that they were born a biologic male, then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
5) Since turning 18 years old, have you had sex with at	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí	[This is not an inclusion criterion, do not select anything in Column D.]	

least 1 woman?			
6) Since turning 18 years old, have you had sex with at least 1 man?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	[If "Yes", then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
7) In the past 12 months, have you participated in <u>HOLA</u> , <u>HOLA en Grupos</u> , <u>HoMBReS</u> or the <u>Latino Partnership</u> programs sponsored by Chatham Social Health Council or Wake Forest University?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes	[If "Yes", then select "No" in the following Column... If "No" in Column B, select "Yes".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes

[Now there are 2 options:]

- 1) [If there is a "NO" for any question in Column D, the recruiter says:]

Thanks for your help. I really appreciate your interesting in this study but the information that you have shared with us indicates that you are not eligible.

[The recruiter and the caller hang up.]

- 2) [If there are zero "NO" answers and 6 "YES" answers in Column D, the recruiter says:]

It looks like you are eligible to participate in this research study. It is a study that includes answering questions about your health and sexual behavior two times over a 6-7 month period. It also includes participating in 1 of 2 sets of educational sessions. One set of 4 educational sessions is about how to prevent HIV, the virus that causes AIDS. The other set of 4 educational sessions is about how to improve your general health. You will receive \$40.00 for answering questions the first time and \$50.00 for answering the second time. You also will receive \$40.00 for each of the 4 educational sessions you attend.

I would like to schedule a time to meet with you and tell you more about the study.

[The recruiter and caller set up a time and place that is convenient for the caller to meet and review the consent form and complete the baseline assessment if the caller chooses to participate.]

Also, give me your name and number. Hold on to my number as well in case you need to change appointment time and place. [The recruiter completes questions on the next pages and separates pages 1 and 2 from page 3.]

Date of call:	
Time of call:	
Name of potential participant:	
Telephone number of potential participant:	
Can we leave a message at this number?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
Date of appointment:	
Time of appointment:	
Place of appointment:	
How did you hear about this study?	

Screening

Gracias por llamar a Chatham Social Health Council. Habla _____ [The recruiter provides his full name]

¿Está llamando sobre el estudio de investigación para hombres que se llama HOLA en Grupos?

[If the caller says that he is not calling about the research study, the recruiter should provide the information that caller may need, thanks the caller for calling, and finish the call politely.]

Bueno, está llamando por el estudio de investigación para hombres que se llama HOLA en Grupos.

Tengo unas cuantas preguntas para usted.

[The recruiter asks the following questions and documents the answers provided. Read only the questions outlined in Column A and denote potential participant's response in Column B. Follow instructions in Column C to determine whether the potential participant is eligible for that criterion and select the correct response in Column D.]

A	B	C	D
Criterio de inclusión	Respuesta	Instrucciones	Elegibilidad?
1) ¿Cuál de éstos describe mejor su grupo étnico?	<input type="checkbox"/> ₁ Origen hispano <input type="checkbox"/> ₀ No de origen hispano	[If "Hispanic origin", select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí
2) ¿Cuántos años tiene?	_____ años	[If ≥18 years old, select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí
3) ¿En qué idioma considera que es fluido?	<input type="checkbox"/> ₁ Solamente en español <input type="checkbox"/> ₂ Más en español que en inglés <input type="checkbox"/> ₃ En ambos igualmente <input type="checkbox"/> ₄ Mas en inglés que en español <input type="checkbox"/> ₅ Solamente en inglés	[If "Only Spanish", "More Spanish than English", or "Both equally", then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí
4) ¿Cuál es su género?	<input type="checkbox"/> ₁ Mujer <input type="checkbox"/> ₂ Hombre <input type="checkbox"/> ₃ Transgénero de masculino a femenino <input type="checkbox"/> ₄ Transgénero de femenino a masculino <input type="checkbox"/> ₅ Otro [por favor especifique]: _____	[If "Male", "Male to female transgender", or some other specific category that indicates that they were born a biologic male, then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí

5) Desde que cumplió 18 años, ¿ha tenido sexo con al menos una mujer?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí	[This is not an inclusion criterion, do not select anything in Column D.]	
6) Desde que cumplió 18 años, ¿ha tenido sexo con al menos un hombre?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí	[If "Yes", then select "Yes" in the following Column... Otherwise, select "No".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí
7) En los últimos 12 meses ha participado en <u>HOLA</u> , <u>HOLA</u> en <u>Grupos</u> , <u>HoMBReS</u> , o en el <u>programa Latino Partnership</u> patrocinados por Chatham Social Health Council o Wake Forest University?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí	[If "Yes", then select "No" in the following Column... If "No" in Column B, select "Yes".]	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Sí

[Now there are 2 options:]

- 1) [If there is a "NO" for any question in Column D, the recruiter says:]

Gracias por toda su ayuda. Realmente le agradezco su interés en nuestro estudio pero por la información que ha compartido con nosotros parece que no es elegible. Gracias.

[The recruiter and the caller hang up.]

- 2) [If there are zero "NO" answers and 6 "YES" answers in Column D, the recruiter says:]

Parece que usted es elegible para participar en este estudio de investigación. Es un estudio en el que tiene que responder preguntas sobre su salud y su comportamiento sexual dos veces, en un periodo de 6 a 7 meses. También participará en 1 de 2 grupos de sesiones educativas. Un grupo de 4 sesiones educativas trata sobre cómo prevenir el VIH, el virus que causa el SIDA. El otro grupo de 4 sesiones educativas trata sobre cómo mejorar su salud general. Usted recibirá una muestra de agradecimiento por el tiempo de su participación en este estudio. Usted recibirá \$40.00 por el primer grupo de preguntas. Recibirá \$50.00 por el segundo grupo de preguntas que se llevará a cabo 6 meses después que el programa finalice. También recibirá \$40.00 por cada una de las sesiones educativas que usted asista.

Quisiera hacer una cita para encontrarme con usted y decirle más acerca del estudio.

[The recruiter and caller set up a time and place that is convenient for the caller to meet and review the consent form and complete the baseline assessment if the caller chooses to participate.]

También, déme su nombre y su número de teléfono. Guarde mi número también, en caso necesite cambiar la hora de la cita y el lugar. [The recruiter completes questions on the next pages and separates pages 1 and 2 from page 3.]

Date of call:	
Time of call:	
Name of potential participant:	
Telephone number of potential participant:	
Can we leave a message at this number?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes
Date of appointment:	
Time of appointment:	
Place of appointment:	
How did you hear about this study?	