

Respondent ID: _____

OMB Control # _____

OMB Expiration Date _____

CURRENT LABEL

US Public Health Service

Condom Label Study

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing, and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH/OCER/DDUPSA (HFZ-230)
1350 Piccard Drive
Rockville, MD 20850

“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.”

Recruitment Script/Instrument

Hello, I am _____ from (Research Company) and I am doing a study for the US Public Health Service about a sensitive subject. The study takes about 20 minutes if you are eligible and you will be paid \$XX.XX for your participation.

I should tell you the study is confidential and your name will not be shared with anyone. The study is not for any manufacturer and is about the information located on and inside condom packages. We will ask questions about condoms but none of the questions are about your sexual behavior. ***(Do not ask if they remain interested but assume they are unless they state they are not interested)***

Label Test**Condom Label Comprehension Study****Survey steps:**

1. **Intercept – ask if he/she would like to participate in a study about information located on and inside condom packages.**

Refer to interviewer training guide for wording when approaching potential participants.
2. **Administer screening instrument to determine eligibility (terminate if not eligible) (Refer to interviewer training guide)**
3. **Informed consent**
4. **Administer REALM**
5. **Provide condom package information for study subject to read**
6. **Administer questionnaire -> Tell subject they may refer back to condom package information to answer questions (Refer to interviewer training guide)**

Screening and Eligibility Instrument

I would like to ask you a few questions to determine whether or not you are eligible to participate. The study is about condom package information, and includes questions about sexually transmitted diseases and condom use, so some of the questions may be a little sensitive. However, your answers will be anonymous and kept confidential. Please remember, the study is NOT about your sexual behavior. It is ONLY about what you understand from reading the package information.

The study is **not** being done for any company or organization that sells condoms. Again, this study is for the US Public Health Service.

It will take about 5 minutes to see if you are eligible. If you are eligible, and you still wish to participate, the entire survey will take about 20 minutes.

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Your name will not be on the questionnaire and your responses will remain anonymous and completely confidential. The information collected from you is for research only.

If you are eligible to participate, you will be paid \$XX.XX to participate.

Now, I am going to ask you some questions to see if you qualify to participate in the research study.

1. Which of the following age categories applies to you? Are you: **(Read List. Check only one answer.)**

Under 18 -> **Not eligible to participate and terminate interview**

18-24

25-34

35-44

45-54

55 or older -> **Not eligible to participate and terminate interview**

Refuse to answer -> **Not eligible to participate and terminate interview**

2. When reading printed materials, can you read English?

YES

NO ---> **Not eligible to participate and terminate interview**

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3. Have you ever used or would you consider using male latex condoms with a past, current or future partner?

YES

NO -> **Not eligible to participate and terminate the interview**

4. Do you or does anyone in your household work in any of the following?
(Household is defined as all relatives living in the home of the potential respondent)

Medical or health care field (For example as a doctor, physician's assistant, nurse, pharmacist, medical researcher, health educator, medical assistant)	YES	NO
Food and Drug Administration (FDA)	YES	NO
National Institute of Health (NIH)	YES	NO
Centers For Disease Control and Prevention (CDC)	YES	NO
Drug or medical device company	YES	NO
Research company (For example market research, health research)	YES	NO
Company or organization that is involved with condom use, HIV, sexually transmitted diseases, and/or birth control	YES	NO

If any of the boxes are checked "yes", the individual is not eligible and terminate the interview.

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5. Have you participated in any research studies in the past two months?

YES → ***Not eligible to participate and terminate interview***

NO → ***Continue***

6. Have you personally ever read the information on or inside a condom package?
(Check only one answer)

Yes

No

Do not read below but check if mentioned.

Do not know/Cannot remember

Great, based on your answers you can participate in this study.

Your opinions are very important and we appreciate your time.

Before we can begin we need you to read a document and sign that you understand the study and agree to participate. ***(Please read consent form to respondent before handing it to them.)***

Here is the consent form for you to review and sign. Please take as much time as you need.

If you have any questions feel free to ask me.

Check here that consent has been signed

Now that you have agreed to participate, the first set of questions we have for you are regarding medical words.

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REALM TEST

Instructions for scoring the test (adapted from the REALM manual):

1. Record the results using the scoring sheet on the following page.
2. Place a check mark (✓) in the box next to each word the participant pronounces correctly.
3. Place an "O" in the box next to each word the participant does not attempt or mispronounces.

**Read Instructions and
Record the Responses on the Next Page**

We'd like to get an idea of what medical words you are familiar with. Please look at this list of words and beginning here <point to the first word on the purple laminated list> say all of the words you know. If you come to a word you don't know, you can sound it out or just skip it and go on.

**RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE
(REALM)©**

Terry Davis, PhD Michael Crouch, MD Sandy Long, PhD

	List 1			List 2			List 3	
	Correct	Not Correct		Correct	Not Correct		Correct	Not Correct
fat			fatigue			allergic		
flu			pelvic			menstrual		
pill			jaundice			testicle		
dose			infection			colitis		
eye			exercise			emergency		
stress			behavior			medication		
smear			prescription			occupation		
nerves			notify			sexually		
germs			gallbladder			alcoholism		
meals			calories			irritation		
disease			depression			constipation		
cancer			miscarriage			gonorrhea		
caffeine			pregnancy			inflammatory		
attack			arthritis			diabetes		
kidney			nutrition			hepatitis		
hormones			menopause			antibiotics		
herpes			appendix			diagnosis		
seizure			abnormal			potassium		
bowel			syphilis			anemia		
asthma			hemorrhoids			obesity		
rectal			nausea			osteoporosis		
incest			directed			impetigo		

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Read:

I will be showing you the package information for male latex condoms. In order to test the package information, please read this, and take all the time you need. When you are done reading I will ask you some questions about what you have read.

When they have finished reading the package information, read:

Please answer the following questions based on your understanding of what you read in the package information. **Please feel free to refer to the package information to answer the questions.** The questions are about the package information and not a test of you.

1. According to the package information, will properly using a male latex condom help reduce the risk of transmission of sexually transmitted diseases?

Read list and check only one answer.

Yes

No

Maybe If answer choice, ask respondent to please explain.

(Do not read answers below. Check one that applies.)

Not clear

Not addressed

2. According to the package information, how often should a man use a latex condom when engaging in sex to reduce the risk of transmission of sexually transmitted diseases? PLEASE WAIT UNTIL I READ ALL CHOICES BEFORE YOU ANSWER. **(Read list/check only one answer.)**

Every time

Most of the time

Some of the time

Rarely

Never

Do not read below but check if mentioned.

Not clear

Not addressed

3. According to the package information, when should a condom be put on to most effectively reduce the risk of transmission of sexually transmitted diseases? PLEASE WAIT UNTIL I READ ALL CHOICES BEFORE YOU ANSWER. **(Read list/check only one answer.)**

Before **any** intimate contact

Just before vaginal, oral or anal penetration

Just before ejaculation

Does not matter when it is put on

Do not read below but check if mentioned.

Not clear

Not addressed

4. According to the package information, how should the penis be withdrawn after sex? **PLEASE WAIT UNTIL I READ ALL CHOICES BEFORE YOU ANSWER. (READ LIST.)**

Hold on to the rim of the condom when withdrawing the penis

It doesn't matter when or how the penis is withdrawn

Wait until the penis is no longer erect before withdrawing the penis

Do not read below but check if mentioned.

Not Clear

Not Address

5. According to the package information, does properly using a male latex condom help reduce the risk of:

(Read the sentence above for each disease. After each disease, read the 3 answer choices, circle the answer that best matches the respondent's answer, and repeat for each of the diseases on the list.)

Read Answer Choices Below

Do Not Read Answers Below But, circle if mentioned.

	Yes	No	Maybe		Not Clear	Not Addressed
Genital Herpes	1	2	3		4	5
Chlamydia	1	2	3		4	5
Genital Warts	1	2	3		4	5
Gonorrhea	1	2	3		4	5
Hepatitis B	1	2	3		4	5
Syphilis	1	2	3		4	5
Influenza	1	2	3		4	5
HIV/AIDS	1	2	3		4	5

6. According to the package information, does a condom with the spermicide (pronounced SPER-ma-side) nonoxynol-9 (pronounced non-OX-e-nol-9) (N-9) provide additional pregnancy protection?

(Read list and check only one answer).

Yes

No

Maybe

Do not read below but check if mentioned.

Not clear

Not Addressed

Ask after checking the answer above:

Can you add more explanation to your answer?

7. According to the package information, what does the spermicide (pronounced "SPER-ma-side") nonoxynol-9 (pronounced "non-OX-e-nol-9") (N-9) on a condom do?

(Read list and check only one answer.)

Protects against pregnancy better than a condom without N-9

Reduces the number of active sperm

Reduces the risk of getting HIV/AIDS from an infected partner

Do not read below but check if mentioned.

Other (PLEASE SPECIFY): _____

Not clear

Not Addressed

8. We want to have the best **package information** possible. To help us, as you read the package information did you find any words or phrases that you did not fully understand or thought were a little confusing?

(Check only one answer – yes or no.)

Yes -> Which ones? **(Write in answers, when they have finished, probe asking "anything else?")**

No

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To help with our analysis of the data we would like to ask some questions about you such as your race, education, and income.

9. Which of the following best describes you? PLEASE WAIT UNTIL I READ ALL CHOICES BEFORE YOU ANSWER. Are you: **(Read list/check only one answer.)**

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

Do not read below but check if mentioned.

- Other (Please Specify): _____
- Refused

10. Which of the following best describes you? Are you: **(Read list/check only one answer.)**

- Hispanic or Latino
- Not Hispanic or Latino

Do not read below but check if mentioned.

- Other (Please Specify): _____
- Refused

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11. What is the highest level of education you have completed? **(Read list/check only one answer.)**

- Did not complete high school
- Completed high school / GED
- Some college or technical school
- Graduated from college / technical school
- Post-graduate degree

Do not read below but check if mentioned.

- Other (Please Specify): _____
- Refused

12. Which of the following best describes your household income last year? **(Read list and check only one answer.)**

(Household income is defined as the income of the individual, or the individual and their spouse/significant other.)

- Under \$15,000
- \$15,000 to \$24,999
- \$25,000 to \$34,999
- \$35,000 to \$49,999
- \$50,000 to \$74,999
- \$75,000 or over

Do not read below but check if mentioned.

- Refused

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13. Which of the following best describes the area where you live today? PLEASE WAIT UNTIL I READ ALL CHOICES BEFORE YOU ANSWER. (**Read list/check only one answer.**)

Rural

Suburbs

Urban area

14. **Do not read.** Check the appropriate box that fits the respondent.

Female

Male

Read:

Thank you very much for your time today. Here is your payment for your participation today.