

Introduction to Hearing Test Procedures (Pretest and Main Study)

[Instructions will be delivered as a group orientation, following the script below]

[STUDY STAFF: READ SCRIPT]:

Thank you for agreeing to take part in this study. We'd like to start by explaining what your participation will involve. The first step will be to take part in a hearing test which involves three parts:

- filling out a brief written questionnaire about your hearing,
- a visual exam of the ear canal and eardrum using an otoscope, a specialized flashlight
- a hearing test in which you will listen for soft beeps presented through foam earphones placed in your ear canals. You will raise your hand briefly when you hear even a soft sound. Each ear will be tested separately.

We will have you fill out the questionnaire in this room. Once you are done, we will escort you to the test room where it is necessary to be very quiet. First you will be seated. Then if you wear hearing aids, you will remove them. Please place them in your purse or pocket. Your ear canals and eardrums will be then examined using an otoscope, a specialized ear flashlight, to make sure that there is nothing that could affect testing or prohibit you from participating further.

You may have had your hearing tested previously with headphones. Today we will be using small foam earphones that work just like headphones but are more comfortable (show insert earphone). After the earphones are placed in your ear canals, you will listen for sounds like beeps that start out loud and then become very soft. Raise your hand briefly every time you hear the beeps even when they are very soft. Sometimes you may become aware of the beeps when they turn on or end—that counts as hearing the beeps so raise your hand. After testing, you will be provided with a brief summary of the hearing test which may include recommendations for follow up, if appropriate.

The hearing assessment will take approximately **20 minutes**. Do you have any questions?

[STUDY STAFF: AFTER QUESTIONS HAVE BEEN ANSWERED, CONTINUE WITH THE SCRIPT BELOW].

Please fill out this brief questionnaire about your hearing now [STUDY STAFF: HAND OUT QUESTIONNAIRE ON CLIPBOARD]. You will take the clipboard with you into the test room and give it to the audiology staff.

The hearing test you will have today will be conducted by audiologists from the UNC Hearing and Communication Center. This hearing test is part of a research study and is not a medical appointment. It is important that the room where the hearing tests are being done stays quiet (i.e. no conversation). If you would you like to schedule a clinical appointment to talk about your hearing, you are welcome to contact the UNC Hearing and Communication Center directly or contact the NC Speech, Hearing and Language Association of North Carolina to find an audiologist near you:

UNC Hearing and Communication Center
6015 Farrington Road Suite #103 • Chapel Hill, NC
27517-8822
(919) 493-7980 • UNC-HCC@med.unc.edu

The North Carolina Speech, Hearing & Language Association
530 North Person Street, Raleigh, NC 27604
Tel: 919-833-3984 • Fax: 919-832-0445

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Hearing Self-Report Questionnaire and Results Report

Name: _____

Date: _____

HEARING HISTORY

- | | | |
|--|-----|----|
| • Do you feel that you have hearing loss? | YES | NO |
| • Have you seen an Ear Nose and Throat physician or an audiologist in the past year? | YES | NO |
| • Do you have pain in your ears? | YES | NO |
| • Has your hearing changed in the past 6 months? | YES | NO |
| • In the past 6 months, have you developed ringing in your ears (tinnitus)? | YES | NO |
| • In the past 6 months, have you developed dizziness or vertigo? | YES | NO |

Explain: _____

The hearing test today was conducted to detect whether or not you have any hearing loss, and if so, the degree of the hearing loss. This test was not a comprehensive diagnostic hearing evaluation. In other words, today's test did not examine why you may have hearing loss or other medical factors associated with hearing loss. Therefore, this test should be considered a preliminary step in checking your hearing to see if further evaluation is required.

RESULTS:

Your hearing could not be tested today due to: ___ excessive wax ___ other

RIGHT EAR				LEFT EAR			
SPEECH FREQUENCIES				SPEECH FREQUENCIES			
<i>NORMAL</i>				<i>NORMAL</i>			
<i>MILD</i>	<i>MODERATE</i>	<i>SEVERE</i>	<i>PROFOUND</i>	<i>MILD</i>	<i>MODERATE</i>	<i>SEVERE</i>	<i>PROFOUND</i>
HIGH FREQUENCIES				HIGH FREQUENCIES			
<i>NORMAL</i>				<i>NORMAL</i>			
<i>MILD</i>	<i>MODERATE</i>	<i>SEVERE</i>	<i>PROFOUND</i>	<i>MILD</i>	<i>MODERATE</i>	<i>SEVERE</i>	<i>PROFOUND</i>

RECOMMENDATIONS:

You have normal hearing. Take care of your hearing by avoiding excessive noise exposure (even one exposure to loud noise may have delayed effects many years later), eat right and exercise. Good heart health is associated with maintaining good hearing.

Comprehensive hearing evaluation
 A comprehensive hearing test includes but is not limited to:

- Otoscopy: visual inspection of ear canal and ear drum
- Air conduction testing: evaluate ability to hear soft tones at various pitches
- Bone conduction testing: evaluate ability to hear soft tones at various pitches
- Speech Reception threshold testing: evaluate ability to hear soft speech
- Word Recognition testing: evaluate ability to understand speech

Medical consultation regarding:
 Wax removal: Right Left Both
 Ear Pain Vertigo/dizziness Tinnitus (ringing) Change in hearing
 Other _____

FDA Hearing Study Questionnaire

[PROGRAMMER: The OMB control number and expiration date should appear at the bottom of every screen. It should be as unobtrusive as possible.]

This study involves advertising for a new product. You will watch a television advertisement twice and then will be asked to answer the questions that follow.

To begin, please enter your participant ID in the following box.

Participant ID

[NEW SCREEN]

[PROGRAMMER: Begin playing audio recording of instructions as soon as the page opens. Play the instructions on a loop.]

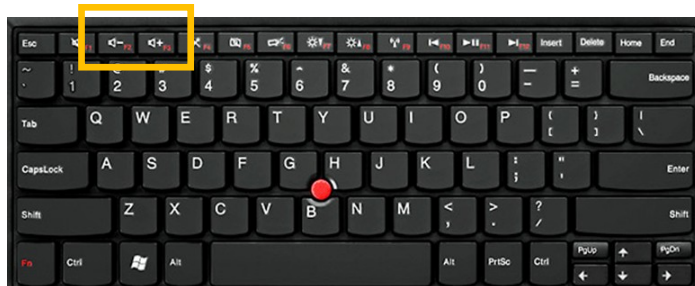
[AUDIO FILE]

Make sure you are comfortable and can read the screen from where you sit. Because the survey will include some audio, we first want to be sure the sound on your computer is active and you can hear the advertisement.

To adjust the volume, please use the laptop keyboard. There is an image of your laptop keyboard at the bottom of this page. You can scroll down to see it. The yellow box on the image of the keyboard shows where the volume keys are located.

To adjust the volume “up,” use the + key. To adjust the volume “down,” use the – key.

Please scroll down to the bottom of this screen and answer the volume question.





Q1. As you adjust the volume, you will see a number bar on your screen. When the volume is at a comfortable level, please record the volume number in the box below.

Volume number

I do not want to change the volume

[NEW SCREEN]

The study will take about 20 minutes to complete. We ask you to complete the study in one sitting (without taking any breaks) in order to avoid distractions.

On the next screen, you will see the television advertisement. The ad may take 15-30 seconds to start playing.

[SHOW THE AD ONCE]

[NEW SCREEN]

We would like you to watch the ad a second time. Please click the Next button to view the ad.

[SHOW THE AD A SECOND TIME]

[NEW SCREEN]

Q2. Did you change the volume after seeing the ad?

- Turned volume up
- Turned volume down
- Did not change volume

[MAIN MESSAGE RECALL – GIST MEMORY]

Q3. What was the main message of the ad you saw?

[OPEN-ENDED RESPONSE]

[CONFIDENCE IN MEMORY JUDGMENTS – MAIN MESSAGE RECALL]

Q4. How confident are you that you were able to correctly remember the main message of the ad?

- 0% confident
- 25% confident
- 50% confident
- 75% confident
- 100% confident

[BRAND RECOGNITION – VERBATIM MEMORY]

Q5. Which of the following drugs did you see advertised?

[PROGRAMMER: RANDOMIZE ORDER, BUT KEEP “NONE OF THE ABOVE” AT THE END OF THE LIST]

- GILARIX
- PEXACOR
- VOTREA
- None of the above

[RECALL OF RISKS – GIST MEMORY]

The ad you saw was about a prescription drug named VOTREA.

Q6. Based on the ad, what are the side effects of VOTREA? Please list as many side effects as you can remember.

[OPEN-ENDED RESPONSE]

[CONFIDENCE IN MEMORY JUDGMENTS – RISKS RECALL]

Q7a. How confident are you that you were able to correctly remember the side effects of VOTREA?

Not at all confident
Slightly confident
Moderately confident
Very confident
Extremely confident

Q7b. Using a different scale, how confident are you that you were able to correctly remember the side effects of VOTREA?

0% confident
25% confident
50% confident
75% confident
100% confident

[RECALL OF BENEFITS – GIST MEMORY]

Q8. Based on the ad, what are the benefits of VOTREA? Please list as many benefits as you can remember.

[OPEN-ENDED RESPONSE]

[CONFIDENCE IN MEMORY JUDGMENTS – BENEFITS RECALL]

Q9. How confident are you that you were able to correctly remember the benefits of VOTREA?

0% confident
25% confident
50% confident
75% confident
100% confident

[PERCEIVED RISK – LIKELIHOOD AND MAGNITUDE]

Please answer the following questions to the best of your ability, even if you have never taken the drug.

Q10. In your opinion, if 100 people take VOTREA, how many will have any side effects?

Please enter a number in the box below.

___ people

Q11. In your opinion, if VOTREA did cause you to have side effects, how serious would they be?

1	2	3	4	5	6
Not at all serious					Very serious

[BENEFIT RECALL]

Please answer the following questions to the best of your ability, even if you have never taken the drug.

Q12. In your opinion, if 100 people take VOTREA, for how many will the drug work? Please enter a number in the box below.

__ people

[PERCEIVED EFFICACY – MAGNITUDE]

Q13. In your opinion, if you took VOTREA, how effective do you think VOTREA would be in helping to lower your cholesterol?

1	2	3	4	5	6
Not at all effective					Very effective

[CLAIM RECOGNITION – VERBATIM MEMORY]

[PROGRAMMER: IF COMPLEXITY CONDITION = SIMPLE, SHOW Q14A ONLY. IF COMPLEXITY CONDITION = COMPLEX, SHOW Q14B ONLY]

The next few questions ask about information that may or may not have been in the advertising. Please answer each question, even if you do not remember the information.

[SIMPLE]

Q14a. Which of the following claims, if any, were in the ad you saw? Check all that apply.

[PROGRAMMER: RANDOMIZE ORDER, BUT KEEP “NONE OF THE ABOVE” AT THE END OF THE LIST]

- **[CORRECT]** VOTREA reduces bad cholesterol for people with several common risk factors for heart disease.
- **[CORRECT]** Women who could become pregnant should not take VOTREA.
- **[CORRECT]** TTP can occur within two weeks of taking VOTREA.
- **[CORRECT]** Muscle pain is a rare but serious side effect of taking VOTREA.
- **[FOIL]** Blurry vision is a side effect of taking VOTREA.
- **[FOIL]** People with kidney problems should not take VOTREA.
- **[FOIL]** A side effect of Votrea is nausea.
- **[FOIL]** None of the above

[COMPLEX]

Q14b. Which of the following claims, if any, were in the ad that you saw? Check all that apply.

[PROGRAMMER: RANDOMIZE ORDER, BUT KEEP “NONE OF THE ABOVE” AT THE END OF THE LIST]

- **[CORRECT]** VOTREA reduces bad cholesterol for people with several common risk factors for heart disease.
- **[CORRECT]** VOTREA is not for people who could become pregnant.
- **[CORRECT]** TTP can occur within two weeks of taking VOTREA.
- **[CORRECT]** A rare but serious side effect of taking VOTREA is muscle pain.
- **[FOIL]** Blurry vision is a side effect of taking VOTREA.
- **[FOIL]** People with kidney problems should not take VOTREA.
- **[FOIL]** A side effect of Votrea is nausea.
- **[FOIL]** None of the above

[CONFIDENCE IN MEMORY JUDGMENTS – CLAIM RECOGNITION]

Q15. How confident are you that you were able to correctly remember the claims in the ad?

- 0% confident
- 25% confident
- 50% confident
- 75% confident
- 100% confident

[CONFIDENCE IN COMPREHENSION JUDGMENTS – CLAIM RECOGNITION]

Q16. How confident are you that you understood the claims in the ad?

- 0% confident
- 25% confident
- 50% confident
- 75% confident
- 100% confident

[OVERALL AD COMPREHENSION]

Q17. Which of the following choices best summarizes the information from the ad?

[PROGRAMMER: RANDOMIZE RESPONSE OPTIONS]

- **[CORRECT]** VOTREA is a treatment for bad cholesterol, but not all people with bad cholesterol should take VOTREA. VOTREA has both common and uncommon side effects.
- **[FOIL]** VOTREA is a treatment for bad cholesterol, but serious side effects from taking VOTREA are common. If you are taking VOTREA, it is necessary to see your doctor regularly to monitor the serious side effects.
- **[FOIL]** VOTREA is a treatment for bad cholesterol, but if you have liver disease, you should get blood tests to check your liver while taking VOTREA.
- **[FOIL]** VOTREA is a treatment for bad cholesterol. VOTREA has some side effects, but none of the side effects are life threatening.

[CONFIDENCE IN COMPREHENSION JUDGMENTS – CLAIM COMPREHENSION]

[will ask one of the following, pending cognitive interviewing]

Q18a. How confident are you that you understood the information in the ad?

- 0% confident
- 25% confident
- 50% confident
- 75% confident
- 100% confident

Q18b. On a scale from 1 to 5, how confident are you that you understood the information in the ad?

- | | | | | |
|-------------------------|---|---|---|------------------------|
| 1 | 2 | 3 | 4 | 5 |
| Not at all
confident | | | | Extremely
confident |

[INTENTION FOR DRUG USE]

Q19. Based on the ads, please rate how likely or unlikely you are to do the following behaviors.

	1 Not at all likely	2	3	4	5	6 Extremely Likely
b. Ask your doctor to prescribe VOTREA						
e. Take VOTREA if your doctor prescribed it						

[ATTITUDE TOWARD USING DRUG]

Q20. Please tell us how you feel about using VOTREA. Mark the number that most closely indicates your response.

Using VOTREA would be...

		1	2	3	4	5	6	
A	Bad							Good
B	Not useful							Useful

[PERCEIVED ATTENTION TO AD]

Q21. How much attention did you pay to the ad you saw about VOTREA?

- None
- Very little
- Some
- Quite a bit
- A great deal

[COGNITIVE ABILITY – SELF-REPORTED]

Q22. How would you rate your ability to think quickly at the present time? Would you say your ability is...

- excellent
- very good
- good
- fair
- poor

Q23. How would you rate your memory at the present time? Would you say your memory is...

- excellent
- very good
- good
- fair
- poor

[NEW SCREEN]

Next you will see instructions for a new task.

[NEW SCREEN]

[COGNITIVE ABILITY LETTER DIGIT SUBSTITUTION TASK]

Please look at the key below. This key includes pairs of letters and numbers. For example “W” and “1” are a pair, “B” and “2” are a pair, and so on.

KEY

W	B	T	P	V	D	G	C	J
1	2	3	4	5	6	7	8	9

Use the key as a guide to fill in each blank square with the number that pairs with the letter above it. Try a practice round:

T	W	C	G	J	V	B	D	P	V

[NEW SCREEN]

KEY

W	B	T	P	V	D	G	C	J
1	2	3	4	5	6	7	8	9

Over the next few screens you will see the same key and more blank squares. Continue to use the key as a guide to fill in each blank square with the number that pairs with the letter above it. You will be timed. Fill in as many squares as you can in 30 seconds.

When you are ready, click “Next” and the timer will begin.

[CLICK TO NEXT SCREEN]

[PROGRAMMER: This page should have a 30 second timer (that the participant cannot see). At the end of 30 seconds, advance to the next screen automatically.]

KEY

W	B	T	P	V	D	G	C	J
1	2	3	4	5	6	7	8	9

Q24. Fill in the blank squares using the key.

P	D	V	B	T	D	P	W	B	J	D	T	C	V	G

J	P	W	C	B	V	J	D	P	C	G	W	T	B	V

T	G	V	B	P	W	C	V	D	J	W	J	G	D	C

G	T	J	C	W	C	G	D	J	P	B	V	T	C	B

[AUTOMATICALLY MOVE TO NEXT SCREEN]

Time is up. On the next screen, you will have 30 seconds to do a similar task.

When you are ready, click “Next” and the timer will begin.

[CLICK TO NEXT SCREEN]

[PROGRAMMER: This page should have a 30 second timer (that the participant cannot see). At the end of 30 seconds, advance to the next screen automatically.]

KEY

W	B	T	P	V	D	G	C	J
1	2	3	4	5	6	7	8	9

Q25. Fill in the blank squares using the key.

W	P	G	V	B	J	C	P	T	C	G	W	J	D	V

J	P	G	D	G	B	J	C	W	V	T	B	D	T	W

T	V	G	W	D	P	V	D	B	J	G	T	J	P	B

W	C	T	V	P	B	J	G	W	D	V	C	T	P	G

P	T	D	C	B

[AUTOMATICALLY MOVE TO NEXT SCREEN]

Time is up. Click next to continue with the rest of the survey.

[SUBJECTIVE HEALTH LITERACY]

Q26. How often do you have problems learning about any of your medical conditions because of difficulty understanding written information?

- Never
- Rarely
- Sometimes
- Often
- Always

[ILLNESS DIAGNOSIS]

Q27. Have you ever been diagnosed with high cholesterol by a physician or other qualified medical professional?

- Yes
- No
- Don't know

[PROGRAMMER NOTE: IF Q27=YES, ASK Q28. OTHERWISE, SKIP TO Q31]

[TIME SINCE TARGETED CONDITION DIAGNOSIS]

Q28. When did a healthcare professional first tell you that you had high cholesterol?

- Six months ago or less
- More than six months ago but less than a year ago
- A year ago or more but less than 5 years
- Five years ago or longer

[REPORTED IMPACT OF HIGH CHOLESTEROL]

Q29. How much does having high cholesterol affect your daily activities?

- | | | | | | |
|------------|---|---|---|---|--------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Not at all | | | | | A great deal |

[CURRENT PRESCRIPTION STATUS]

Q30. Are you currently taking, or have you ever taken, any prescription drugs to lower your cholesterol?

- Currently taking
- Have taken in the past, but not currently taking
- Have never taken

[FALSE AD RECOGNITION TENDENCY]

Q31. Have you ever seen any advertising for VOTREA before today?

- Yes
- No
- Not sure

[GENERAL PERCEPTION OF DRUG ADVERTISING]

Q32. In general, how do you feel about ads on television for prescription drugs? Would you say the ads are...

- | | | | | | |
|----------------------|---|---|---|---|-------------|
| 1 | 2 | 3 | 4 | 5 | 6 |
| Not at all
useful | | | | | Very useful |

[SELF-REPORTED HEARING LOSS]

Q33. Do you feel you have a hearing loss?

- Yes
- No
- Don't know

Q34. Do you need the television volume turned up loud when you are watching the television?

- Yes
- No

[SELF-REPORTED SPEECH RECOGNITION]

The following questions ask about your ability and experience hearing and listening in different situations. On a scale from 0 to 10, how well can you follow along in each situation?

	Not at all										Perfectly
	0	1	2	3	4	5	6	7	8	9	10
Q35a. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow that the person you're talking to says?											
Q35b. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation?											
Q35c. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying?											

Q35d. Do you frequently have to ask people to repeat themselves or misunderstand what they say?

- Yes
- No
- Not sure

Q35e. Do you have to concentrate hard when listening to a conversation or to the TV?

- Yes
- No
- Not sure

[HEARING LOSS DIAGNOSIS]

Q36. Before today, has a doctor or other health professional ever diagnosed you with a hearing loss?

- Yes
- No
- Don't know

[HEARING AID USE]

Q37. On an average day, do you use any of the following hearing devices? Check all that apply.

- One or more hearing aids
- Cochlear implant
- Personal FM System
- TV Ears (or a voice clarifying headset)
- Other
- None of the above

[PROGRAMMER: IF PARTICIPANT CHECKS ONLY "NONE OF THE ABOVE" IN Q37, SKIP Q38 – Q40.]

[FREQUENCY OF HEARING AID USE]

Q38. Think about how much you used any hearing device over the past two weeks. On an average day, how many hours did you use the hearing device?

- None
- Less than 1 hour a day
- 1 to 4 hours a day
- 4 to 8 hours a day
- More than 8 hours a day

[HEARING AIDS DURING STUDY]

[PROGRAMMER: IF PARTICIPANT CHECKS MORE THAN ONE HEARING DEVICE IN Q37, ASK Q39A AND SKIP Q39B. IF PARTICIPANT CHECKS ONLY ONE HEARING DEVICE IN Q37, SKIP Q39A AND ASK Q39B.]

Q39a. Are you using one of your hearing devices now (during this study)?

- Yes
- No

Q39b. Are you using your hearing device now (during this study)?

Yes

No

[PROGRAMMER: FOR COGNITIVE INTERVIEWS, SKIP Q40 FOR EVERYONE. PARTICIPANTS WILL NOT WEAR HEADPHONES DURING COGNITIVE INTERVIEWS.]

Q40. Did the headphones that you wore for this study interfere with your hearing device at any time?

Yes

No

[GENDER]

Q41. What is your sex?

Male

Female

[AGE]

Q42. Please tell us your age.

___ years old.

[EDUCATION]

Q43. What is the highest level of education you have completed?

- Less than high school
- High school graduate (high school diploma or GED)
- Some college, but no degree
- Associate's degree (2-year)
- Bachelor's degree (4-year) (example: BA, BS)
- Advanced or postgraduate degree (example: MA, MD, DDS, JD, PhD, EdD)

[RACE/ETHNICITY]

Q44. What is your race? (Select all that apply)

- American Indian or Alaska Native
- Asian
- Black or African-American
- Native Hawaiian or Other Pacific Islander
- White
- Some Other Race

Q45. Are you:

- Hispanic or Latino
- Not Hispanic or Latino

[DRUG INFORMATION SEARCH BEHAVIOR]

Q46. Would you like to see more information about VOTREA?

- Yes, look for more information now
- Yes, look for more information later
- No, do not look for more information

[DEBRIEFING]

Thank You!

The purpose of this research is to learn about how people feel about information provided in ads and to learn how they use this information to understand how well prescription drugs work. VOTREA is not a real product and is not for sale. Please see your healthcare professional for questions about your health and your medical conditions.

[You may exit the survey room to receive your reimbursement.](#)