

MICHIGAN STATE UNIVERSITY

Initial Study APPROVAL

June 18, 2018

To: [REDACTED]

Re: **MSU Study ID:** STUDY00000832
IRB: Soc. Sci./Edu./Behav. Inst Review Board (SIRB)
Principal Investigator: [REDACTED]
Category: Expedited 5, 6, 7
Submission: Initial Study STUDY00000832
Submission Approval Date: 6/18/2018
Effective Date: 6/18/2018
Project Expiration Date: 6/17/2019

Title: Optimizing OTC labels for older adults: Empirical evaluation of labels designed to provide older users the information they need to to minimize adverse drug events



**Office of
Regulatory
Affairs
Human Research
Protection Program**

4000 Collins Road
Suite 136
Lansing, MI 48910

517-355-2180
Fax: 517-432-4503
Email: irb@msu.edu
www.hrpp.msu.edu

This submission has been approved by the Michigan State University (MSU) SIRB. The submission was reviewed by the Institutional Review Board (IRB) through the Non-Committee Review procedure. The IRB has found that this research project protects the rights and welfare of human subjects and meets the requirements of MSU's Federal Wide Assurance (FWA00004556) and the federal regulations for the protection of human subjects in research (e.g., 45 CFR 46, 21 CFR 50, 56, other applicable regulations).

This project is approved as funding pending. A modification must be submitted to the MSU IRB if the grant is awarded to change the status from pending to received, along with any revised documents, such as the protocol or consent forms, or any other changes that might result from change in funding status.

Documents Included:

- DataSafetyMonitoringPlan.docx, Category: Other;
- Study 6 Eye tracking commercial Minimal Risk Consent.pdf, Category: Consent Form;
- Study 6 - Eye tracking commercial recruitment.docx, Category: Recruitment Materials;
- Study 4 and 5 - Info and Eye tracking recruitment.docx, Category: Recruitment Materials;
- Study 3a and B - Absolute and Xproduct judgements recruit.docx, Category: Recruitment Materials;
- Questionnaires- Health history_vision_Realm-R.docx, Category: Other;
- Study 2 - Change Detection Recruitment.docx, Category: Recruitment Materials;
- summary page.pdf, Category: Other;
- Study 3a Minimal Risk Consent Document.pdf, Category: Consent Form;

- Study 3a and B - Absolute and Xproduct judgements recruit.docx, Category: Recruitment Materials;
- r01 grant application.pdf, Category: IRB Protocol;
- Study 4 and 5 - Minimal Risk Consent Document.pdf, Category: Consent Form;
- Study 4 and 5 - Info and Eye tracking recruitment.docx, Category: Recruitment Materials;
- Explanation of MSU workers outside the control of the PIs.docx, Category: Other;
- Study 2 Minimal Risk Consent Document.pdf, Category: Consent Form;
- Study 2 - Change Detection Recruitment.docx, Category: Recruitment Materials;
- short-blessed-test.pdf, Category: Other;
- Study 3b- forced choice Minimal Risk Consent Document.pdf, Category: Consent Form;
- NIH Project IRB Template.docx, Category: IRB Protocol;

Continuing Review: IRB approval is valid until the expiration date listed above. If the research continues to involve human subjects, you must submit a Continuing Review request at least one month before expiration.

Modifications: Any proposed change or modification with certain limited exceptions discussed below must be reviewed and approved by the IRB prior to implementation of the change. Please submit a Modification request to have the changes reviewed. If changes are made at the time of continuing review, please submit a Modification and Continuing Review request.

Immediate Change to Eliminate a Hazard: When an immediate change in a research protocol is necessary to eliminate a hazard to subjects, the proposed change need not be reviewed by the IRB prior to its implementation. In such situations, however, investigators must report the change in protocol to the IRB immediately thereafter.

Reportable Events: Certain events require reporting to the IRB. These include:

- Potential unanticipated problems that may involve risks to subjects or others
- Potential noncompliance
- Subject complaints
- Protocol deviations or violations
- Unapproved change in protocol to eliminate a hazard to subjects
- Premature suspension or termination of research
- Audit or inspection by a federal or state agency
- New potential conflict of interest of a study team member
- Written reports of study monitors
- Emergency use of investigational drugs or devices
- Any activities or circumstances that affect the rights and welfare of research subjects
- Any information that could increase the risk to subjects

Please report new information through the project's workspace and contact the IRB office with any urgent events. Please visit the Human Research Protection Program (HRPP) website to obtain more information, including reporting timelines.

Prisoner Research: If a human subject involved in ongoing research becomes a prisoner during the course of the study and the relevant research proposal was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners under subpart C of 45 CFR part 46, the investigator must promptly notify the IRB.

Site Visits: The MSU HRPP Compliance office conducts post approval site visits for certain IRB approved projects. If the project is selected for a site visit, you will be contacted by the HRPP Compliance office to schedule the site visit.

For Projects that Involve Consent, Parental Permission, or Assent Form(s):

Use of IRB Approved Form: Investigators must use the form(s) approved by the IRB and must typically use the form with the IRB watermark.

Copy Provided to Subjects: A copy of the form(s) must be provided to the individual signing the form. In some instances, that individual must be provided with a copy of the signed form (e.g. projects following ICH-GCP E6 requirements). Assent forms should be provided as required by the IRB.

Record Retention: All records relating to the research must be appropriately managed and retained. This includes records under the investigator's control, such as the informed consent document. Investigators must retain copies of signed forms or oral consent records (e.g., logs). Investigators must retain all pages of the form, not just the signature page. Investigators may not attempt to de-identify the form; it must be retained with all original information. The PI must maintain these records for a minimum of three years after the IRB has closed the research and a longer retention period may be required by law, contract, funding agency, university requirement or other requirements for certain projects, such as those that are sponsored or FDA regulated research. See HRPP Manual Section 4-7-A, Recordkeeping for Investigators, for more information.

Closure: If the research activities no longer involve human subjects, please submit a Continuing Review request, through which project closure may be requested. Human subject research activities are complete if data collection is complete and there is no further interaction or intervention with human subjects, and analysis of identifiable private information is complete.

For More Information: See the HRPP Manual (available at <https://hrpp.msu.edu/msu-hrpp-manual-table-contents-expanded>).

Contact Information: If we can be of further assistance or if you have questions, please contact us at 517-355-2180 or via email at IRB@ora.msu.edu. Please visit hrpp.msu.edu to access the HRPP Manual, templates, etc.

Expedited Category. The project involves only procedures listed in Expedited Category(ies) 5, 6, 7. Please see the appropriate research category below for the full regulatory text.

Expedited 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Expedited 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited 3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Expedited 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the

subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Expedited 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expedited 8. Continuing review of research previously approved by the convened IRB as follows:

- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- (b) where no subjects have been enrolled and no additional risks have been identified; or
- (c) where the remaining research activities are limited to data analysis.

Expedited 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Research Participant Information and Consent Form

Study 2: Optimizing OTC labels for older adults: Empirical evaluation of labels designed to provide older adults the information they need to to minimize adverse drug reactions

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

1. PURPOSE OF RESEARCH

The purpose of this research study is to investigate how different labeling formats of Over-the-Counter (OTC) drugs affect the noticeability of critical information presented on the label.

You have been asked to participate in this study because you are:

- *65 or older*
- *Are a consumer of Over-the-Counter drugs*
- *Manage your own medication*
- *Legally Sighted (not legally blind)*
- **HAVE NO HISTORY OF SEIZURES**

Your participation in this study will take no longer than 1.5 hours.

2. WHAT YOU WILL DO

As part of this research, we will record your sex, ethnicity, educational background, and age.

We will also ask you to read several words aloud as a measure of your ability to read medical labels. We will ask you a series of basic questions; we will ask you to read a series of numbers made of colored dots; we will also ask you to read the smallest line of a card consisting of a series of lines of text as a measure of your visual acuity (20/20, 20/30, etc.).

Experiment Procedure

After the color blindness and visual acuity are tested, you will be asked to view several images of Over-the-Counter labels on a computer screen. A test image continuously alternates with the same image, slightly altered with a gray (blank) screen. This image-blank-test-blank will loop, providing a “flickering” at the place of alteration, until you press the space bar, indicating that you have found the change. You will then be asked to click on the place where you saw the flickering of the image. If you cannot find the change within 1 minute, the software will move testing to the next trial. This process will be repeated for a total of 64 trials. There will be a break after you complete 32 trials. The research team can help you with this if you have any questions.

3. POTENTIAL BENEFITS

You will not directly benefit from your participation in this study. However, the study does carry benefit to society. Using the data generated in this study, it is our hope that we can design Over-the-Counter labels that are easier to use and that will facilitate correct choices.

4. POTENTIAL RISKS

There are limited risks associated with participation in this study. We will ask you to read aloud a series of words. It is possible that you may not be familiar with these words and this will be embarrassing to you. In the event that you are uncomfortable with any of the tasks, you may elect to skip a portion of the study, or discontinue altogether.

There is a possible risk of seizure associated with viewing flashing images; as a result, if you have a history of seizure, you are not eligible to participate. If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research-related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility.

The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

5. PRIVACY AND CONFIDENTIALITY

The data for this project will be kept confidential. All information will be tied to a subject number; collected information will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information retrieved during this entire study will be protected on a password protected computer or in a locked file cabinet on the campus of Michigan State University for a minimum of three years after the close of the project.

Only the appointed researchers and the Institutional Review Board will have access to the research data. Within these restrictions, results of the study will be made available to you at your request.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

6. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

You have the right to say no to participate in the research. You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

You will receive \$50 in exchange for your participation in this study. Even if you do not complete some portions of the study or choose to withdraw from this study altogether, you will still receive the \$50

8. CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, [REDACTED] 448 Wilson Road East Lansing, MI 48824 [REDACTED]

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-

355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

9. DOCUMENTATION OF INFORMED CONSENT.

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

You will be given a copy of this form to keep.

Research Participant Information and Consent Form

Study 3a: Optimizing OTC labels for older adults: Empirical evaluation of labels designed to provide older users the information they need to to minimize adverse drug using an Absolute Judgement Task

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

1. PURPOSE OF RESEARCH

The purpose of this research study is to investigate how different labeling formats of Over-the-Counter (OTC) drugs influence information processing.

You have been asked to participate in this study because you are:

- *65 or older*
- *Are a consumer of Over-the-Counter drugs*
- *Manage your own medication*
- *Legally Sighted (not legally blind)*

Your participation in this study will take no longer than 1.5 hours of your time.

2. WHAT YOU WILL DO

As part of this research, we will record your gender, ethnicity, educational background, and age.

We will also ask you to read several words aloud as a measure of your ability to read medical labels. We will ask you a series of basic question; we will ask you to read a series of numbers made of colored dots; we will also ask you to read the smallest line of a card consisting of a series of lines of text as a measure of your visual acuity (20/20, 20/30, etc.).

Experiment Procedure

You will see a series of trials on a computer screen, which will consist of Over-the-Counter drug labels that are feature different aspects of the critical labeling information (e.g. an ingredient warning). You will be asked to answer Y/N questions about the products (e.g. does this product contain aspirin) as quickly as possible depressing the appropriate key on the keyboard. The labels of the products are organized in different ways so that we can learn about what information people need to during decision making with regard to medicines.

This process will be repeated for a total of 144 trials. If you become tired during testing and need a break, just wait until you have finished a trial and don't move on to the next one. The research team can help you with this if you have any questions

3. POTENTIAL BENEFITS

You will not directly benefit from your participation in this study. However, the study does carry benefit to society. Using the data generated in this study, it is our hope that we can design Over-the-Counter labels that are easier to use and that will facilitate correct choices.

4. POTENTIAL RISKS

There are limited risks associated with participation in this study. We will ask you to read aloud a series of words. It is possible that you may not be familiar with these words and this will be embarrassing to you. In the event that you are uncomfortable with any of the tasks, you may elect to skip a portion of the study, or discontinue altogether.

If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research-related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility.

The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

5. PRIVACY AND CONFIDENTIALITY

The data for this project will be kept confidential. All information will be tied to a subject number; collected information will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information retrieved during this entire study will be protected on a password protected computer or in a locked file cabinet on the campus of Michigan State University for a minimum of three years after the close of the project.

Only the appointed researchers and the Institutional Review Board will have access to the research data. Within these restrictions, results of the study will be made available to you at your request.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

6. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

You have the right to say no to participate in the research. You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

You will receive \$50 in exchange for your participation in this study. Even if you do not complete some portions of the study or choose to withdraw from this study altogether, you will still receive the \$50

8. CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, [REDACTED] 448 Wilson Road East Lansing, MI 48824 [REDACTED]

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

9. DOCUMENTATION OF INFORMED CONSENT.

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

You will be given a copy of this form to keep.

Research Participant Information and Consent Form

Study 3b: Optimizing OTC labels for older adults: Empirical evaluation of labels designed to provide older users the information they need to to minimize adverse drug reactions using Cross Product Comparisons

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

1. PURPOSE OF RESEARCH

The purpose of this research study is to investigate how different labeling formats of Over-the-Counter (OTC) drugs influence information processing using a forced choice task.

You have been asked to participate in this study because you are:

- *65 or older*
- *Are a consumer of Over-the-Counter drugs*
- *Manage your own medication*
- *Legally Sighted (not legally blind)*

Your participation in this study will take no longer than 1.5 hour.

2. WHAT YOU WILL DO

As part of this research, we will record your gender, ethnicity, educational background, and age.

We will also ask you to read several words aloud as a measure of your ability to read medical labels. We will ask you a series of basic questions; we will ask you to read a series of numbers made of colored dots; we will also ask you to read the smallest line of a card consisting of a series of lines of text as a measure of your visual acuity (20/20, 20/30, etc.).

Experiment Procedure

You will see a series of trials on a computer screen, which will consist of two labels that are identical with the exception of one aspect of the critical labeling information; specifically, they differ either in active ingredient or warnings related to the same. You will be instructed to select one of the products (e.g. select the product with active ingredient XX; OR select the product that you could take if you were hypertensive) as quickly as possible by depressing either left arrow or right arrow on a keypad that you will be provided.

This process will be repeated for a total of 72 trials. If you become tired during testing and need a break, just wait until you have finished a trial and don't move on to the next one. The research team can help you with this if you have any questions

3. POTENTIAL BENEFITS

You will not directly benefit from your participation in this study. However, the study does carry benefit to society. Using the data generated in this study, it is our hope that we can design Over-the-Counter labels that are easier to use and that will facilitate correct choices.

4. POTENTIAL RISKS

There are limited risks associated with participation in this study. We will ask you to read aloud a series of words. It is possible that you may not be familiar with these words and this will be embarrassing to you.

We will also ask you to read a series of words aloud. It is possible that you may not be familiar with some of these words, and this may be embarrassing to you. In the event that you are uncomfortable with any of the tasks, you may elect to skip a portion of the study, or discontinue altogether.

If you are injured as a result of your participation in this research project, researchers from Michigan State University will assist you in obtaining emergency care, if necessary, for your research-related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility.

The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort unless required by law to do so. This does not mean that you are giving up any legal rights you may have.

5. PRIVACY AND CONFIDENTIALITY

The data for this project will be kept confidential. All information will be tied to a subject number; collected information will not be identified by name and your confidentiality will be maintained to the maximum extent of the law. Information retrieved during this entire study will be protected on a password protected computer or in a locked file cabinet on the campus of Michigan State University for a minimum of three years after the close of the project.

Only the appointed researchers and the Institutional Review Board will have access to the research data. Within these restrictions, results of the study will be made available to you at your request.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

6. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

You have the right to say no to participate in the research. You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

7. COSTS AND COMPENSATION FOR BEING IN THE STUDY

You will receive \$50 in exchange for your participation in this study. Even if you do not complete some portions of the study or choose to withdraw from this study altogether, you will still receive the \$50

8. CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, [REDACTED] 448 Wilson Road East Lansing, MI 48824 [REDACTED]

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

9. DOCUMENTATION OF INFORMED CONSENT.

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

You will be given a copy of this form to keep.

PRE-TEST

SUBJECT #:_____

DEMOGRAPHIC INFORMATION

() 1. What is your sex?

☐ Female ☐ Male ☐ other _____

() 2. What is your current age?

() 3. What is your race?

3b. What is your ethnicity?

() 4. What is your highest educational level?

☐ Middle School ☐ Bachelor Degree
☐ High School ☐ Master Degree
☐ Associate Degree ☐ Doctor Degree

() 5. What is your native language?

☐ English ☐ Spanish ☐ Others:
☐ French _____
☐ Russian ☐ Chinese
☐ Japanese

() 6. What is your estimated, annual household income?

\$ _____

Near Point Visual Acuity

Visual Acuity	
---------------	--

-----No answers in the tables above-----

Visual Acuity: “I want you to hold this card at about 16 inches from your eyes and try to read the lowest line on this card.”

20/800: D T 4

20/400: L E S 3

20/250: R F X B N

20/200: P O 5 7 A

20/100: 8 C V L M

20/70: 3 7 S Z K

20/50: E X R T N

20/40: D M P R O F

20/30: F H G J X V

20/20: 3 A S R E P

Result: 20/_____

Ability to See Color: (Ask the participant to read the number inside the circles for plates 1-16)

Incorrect Response: ____/16

REALM-R

Instructions - *Sometimes in healthcare medical words are used that many people are not familiar with. I would like to get an idea of what medical words you are familiar with. Please read aloud each word. If you are not familiar or comfortable with a word, feel free to indicate "pass."*

Fat, Flu, and Pill are not scored. We have previously used a score of 6 or less to identify patients at risk for poor literacy.

fat		fatigue	_____
flu		directed	_____
pill		colitis	_____
allergic	_____	constipation	_____
jaundice	_____	osteoporosis	_____
anemia	_____		

Short Blessed Test

SCORE _____

SHORT BLESSED TEST

"Now I would like to ask you some questions to check your memory and concentration. Some of them may be easy and some of them may be hard."

	Correct	Incorrect
1. What year is it now?	0	1
2. What month is it?	0	1

Please repeat this name and address after me:

John Brown, 42 Market Street, Chicago

John Brown, 42 Market Street, Chicago

John Brown, 42 Market Street, Chicago

(underline words repeated correctly in each trial)

Trials to learn _____ (if unable to do in 3 trials = C)

"Good, now remember that name and address for a few minutes."

3) Without looking at your watch or clock, tell me what time it is.

(If response is vague, prompt for specific response)

Within one hour Correct (0) Incorrect (1)

4) Count aloud backwards from 20 to 1 0 1 2 Errors

Mark correctly sequenced numerals. If subject starts counting forward or forgets the task, repeat instructions and score one error

20 19 18 17 16 15 14 13 12 11 10 9 8 7 6 5 4 3 2 1

5) Say the months of the year in reverse order 0 1 2 Errors

If the tester needs to prompt with the last name of the month of the year, one error should be scored – mark correctly sequenced months.

D N O S A JL JN MY AP MR F J

6) Repeat the name and address you were asked to remember.

John Brown, 42 Market Street, Chicago 0 1 2 3 4 5 Errors

Check Correct Items ("street" not required)

SCORING

Item # Final	Errors (0 - 5)	Weighting Factor	Item Score
1		X 4	
2		X 3	
3		X 3	
4		X 2	
5		X 2	
6		X 2	
Sum Total = (Range 0 – 28)			

INTERPRETATION

0-4 = normal cognition

5-9 = questionable impairment

≥ 10 = Impairment consistent with dementia

Prior Familiarity and Appropriateness

For each line of the following table, please indicate if you were familiar with each of these drugs (prior to this study). **AND**, considering your current health status (and the drugs you take), whether or not each is an appropriate choice for you.

Ingredients	Familiar with this drug prior to the study?		
	Yes	No	Not Sure
Acetaminophen			
Ibuprofen			
Naproxen			
Dextromethorphan			
Phenylephrine			
Guaifenesin			
Omeprazole			
Ranitidine			
Cimetidine			
Diphenhydramine			

Ingredients	Considering your current health status (and the drugs you take), is this drug appropriate for you to take?		
	Yes	No	Not Sure
Acetaminophen			
Ibuprofen			
Naproxen			
Dextromethorphan			
Phenylephrine			
Guaifenesin			
Omeprazole			
Ranitidine			
Cimetidine			
Diphenhydramine			



Please do not look back at your previous work from this point forward



Health Status

Please check all that apply to your CURRENT health status

Health condition inquiry	Yes	No	Not sure
(1) 3 or more alcoholic drinks everyday			
(2) have trouble or pain swallowing food, vomiting with blood, or bloody or black stools			
(3) diabetes			
(4) high blood pressure			
(5) any thyroid disease			
(6) any kidney disease			
(7) any liver disease like liver cirrhosis			
(8) any heart surgery			
(9) any stomach problems like ulcers or bleeding			
(10) any troubles with urinating due to an enlarged prostate gland			

Prior Familiarity

Brand	Familiar with this drug prior to the study?		
	Yes	No	Not Sure
Tylenol			
Advil			
Aleve			
Robitussin			
Sudafed			
Mucinex			
Prilosec			
Zantac			
Tagamet			
Benadryl			

Appropriateness

Ingredients	Considering your current health status (and the drugs you take), is this drug appropriate for you to take?		
	Yes	No	Not Sure
Tylenol			
Advil			
Aleve			
Robitussin			
Sudafed			
Mucinex			
Prilosec			
Zantac			
Tagamet			
Benadryl			



Please hand this paper back to a member of the research team.
They will help you to complete the study



Health History.

Please provide the research team with any prescription drugs/OTC drugs that you have brought today.

Researcher:

“The purpose of this portion of the study is to gather information from you about your health status and the types of medicines that you take. I am going to record the conversation to be sure that I get everything down. Everything that you tell me will remain confidential; we will only record your information by participant number, not your name. Also, if you would like to opt out of answering a specific question, feel free to do so.”

- If questions regarding medication come up during the course of the conversation, that is good. Remind participants that our goal is to create labeling that provides critical information in the best way possible to consumers and that you are not a healthcare professional. Encourage the participant to discuss the question with their doctor and their pharmacist.
- If participants do not wish to answer any of the following questions, indicate DNA next to the question

“Let’s start with your prescription medications; those are the medicines that a doctor or other medical provider has prescribed to you.”

“Which prescription medicines do you take on a scheduled basis? Are there others that you take that aren’t here?” And, for each one they have brought: “How often and when do you take (medication name)?”

[illegible]

“Which prescription medicines do you take on an as needed basis”? Are there others that you take that aren’t here?” And, for each one they have brought: “How often and when do you take (medication name)?”

[illegible]

Imagine that you are looking inside your medicine cabinet or drawer. What other medicines may be in there that we haven't listed yet.

What vitamins do you take?

Vitamins					
Drug name	Strength	Dose	Frequency	To treat what?	Any problems

What herbal supplements do you take?

Herbal supplements					
Drug name	Strength	Dose	Frequency	To treat what?	Any problems

To be sure that we've covered everything that you have on hand, I just have a few more question. Do you take anything (that we haven't already listed)

For pain?

To help you sleep?

For allergy symptoms?

For cough and cold symptoms?

For stomach upset or heartburn?

For constipation or diarrhea?

“This concludes our survey. All of your information will remain private and on a password protected computer. It is not affiliated with your name, just the number that we gave you. Thank you so much for your time helping us today.”



Thanks and please PROVIDE incentives and unsigned consent form. Collect signatures for incentive distribution.



Recruitment for a study of Over-the-Counter Medication Labels



Building inclusive communities is a University-wide initiative that reflects MSU's core value of inclusion and its rich history of supporting all people in our community. We encourage a diverse array of participants who meet eligibility criteria to contact us to schedule participation.

About the Study

Basic demographic information will be recorded as well as a test of your ability to see color. your visual acuity and your health literacy status. You will sit at a computer with screen flashing between two package labels with only one difference. We will ask you to select where the difference occurs record your choices. Testing will take no longer than 1.5 hours.

Participation Requirements



At least 65
years old



Not legally
blind



Buy & administer
your medication

Participation Exclusions



History of seizures

To Make a Study Appointment Contact

██████████ Phd
Student

██████████ or

████████████████████

***Participants will
receive \$50 for the
study***

**For questions or concerns:
Contact:**

██████████████████
██████████████████
██████████████████

OR

██████████████████
██████████████████
██████████████████

Recruitment for a study of Over-the-Counter Medication Labels



Building inclusive communities is a University-wide initiative that reflects MSU's core value of inclusion and its rich history of supporting all people in our community. We encourage a diverse array of participants who meet eligibility criteria to contact us to schedule participation.

About the Study

Basic demographic information will be recorded as well as a test of your ability to see color, your visual acuity and your health literacy status. We will record your choices as you choose medications based on scenarios. Testing will take no longer than 1.5 hours.

To Make a Study Appointment Contact

[REDACTED] Phd
Student

[REDACTED]
[REDACTED]

***Participants will
receive \$50 for the
study***

**For questions or concerns:
Contact:**

[REDACTED]
[REDACTED]
[REDACTED]

OR

[REDACTED]
[REDACTED]
[REDACTED]

Participation Requirements



At least 65
years old



Not legally
blind



Buy & administer
your medication