THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

Informed Consent

UT M.D. Anderson Cancer Center
Institutional Review Board Approved

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Understanding Patient's Knowledge and Use of Acetaminophen 2008-0577

Subtitle: Focus Groups

Study Chair: Maria Suarez-Almazor

1. _____ _____
Participant's Name Medical Record Number

You are being asked to take part in this health services research study at The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"). This consent form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you take over-the-counter Tylenol® (acetaminophen) at home.

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

The goal of this health services research study is to learn more about the ways people take acetaminophen. Researchers also want to learn more about the

knowledge, attitudes, and beliefs of people who take acetaminophen.

Optional Procedures: You are being asked to complete a health questionnaire that will be developed using the information collected at the focus group sessions during this study.

3. DESCRIPTION OF STUDY

If you agree to take part in this study, you will take part in 1 focus group session. A focus group is like a group interview where each participant may respond and interact with both the instructor and other participants.

Focus Group Session

The focus group session will be led by a trained interviewer. There will also be a research staff member present. During the focus group sessions, the interviewer will ask the group questions about acetaminophen, the directions on the packaging, beliefs about the benefits and risks of taking acetaminophen, and when and how often you use acetaminophen. Each focus group session should last about 90-120 minutes and will have 6-8 participants. The study chair will decide which focus group you will participate in. You will take part in 1 of the following groups:

- Parents of children less than 8 years old will meet to talk about how acetaminophen is given to children.
- Adults will meet to talk about your beliefs about the benefits and risks of taking acetaminophen, how you take acetaminophen, and how often you take acetaminophen.

The focus group sessions will be audiotaped (recorded) and transcribed (typed) by the research staff at M. D. Anderson. To protect your confidentiality, only first names will be used during the focus group sessions and names will be coded when typed. The audio recordings will be destroyed by the researchers once study results have been published.

Length of Study

Your participation on this study will be over when the focus group session is complete.

This is an investigational study. There will be no cost to you for taking part in this study. Parking validation will be provided to you.

At the end of the study, you will receive a $30 gift card as compensation for participating in this study.

Up to 124 people will be enrolled in this multicenter study. All will be enrolled by M. D. Anderson research staff. Participants will be recruited from outpatient pediatrics and primary care clinics at Kelsey-Seybold and Harris County Hospital District.

Optional Procedures: If you agree, you will complete a health questionnaire that will be developed using the information collected at the focus group sessions during this study. The health questionnaire will take about 15-20 minutes to complete.

There will be no cost to you for completing the questionnaire.

You do not have to agree to take part in the optional procedures in order to be enrolled in this study.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

Focus group discussions may contain questions and topics that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the survey, you are encouraged to contact your doctor or the study chair.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy. All audio recordings will be stored on a password-protected computer that will only be available to the study chair or research staff. Only your first name will be used during the focus group sessions. All names will be coded in the typed transcripts to protect your confidentiality.

This study may involve unpredictable risks to the participants.

Optional Procedures: Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

5. POTENTIAL BENEFITS

Future patients may benefit from what is learned. There are no benefits for you in this study.

Optional Procedures: There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned.

6. ALTERNATE PROCEDURES OR TREATMENTS

You may choose not to take part in this study.

Optional Procedures: You may take part in this study without taking part in the optional procedures.

I understand that the following statements about this study are true:

7. M. D. Anderson may benefit financially from my participation and/or from what is learned in this study.

8. I may ask the study chair any questions I have about this study, including questions about costs. I may contact the study chair, Dr. Maria Suarez-Almazor, at 713-745-4516. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with any questions that have to do with this study or my rights as a study participant.

9. My participation in this study is strictly voluntary. I may refuse to take part in this study without any penalty or loss of benefits to which I am otherwise entitled. I may also withdraw from participation in this study at any time without any penalty or loss of benefits.

10. I understand that the study may be changed or stopped at any time by the study chair, or the IRB of M. D. Anderson.

11. I will be informed of any new findings that might affect my willingness to continue taking part in the study.

12. M. D. Anderson will take appropriate steps to keep my personal health information private. However, there is no guarantee of absolute privacy. Health authorities, and the IRB of M. D. Anderson might review my record to collect data or to check that the research is being done safely and correctly. In some situations, health authorities could be required to reveal the names of participants.

13. If I suffer injury as a direct result of taking part in this study, M. D. Anderson will provide medical care. However, this medical care will be billed to my insurance provider or me in the ordinary manner. I understand that I will not be reimbursed for expenses or compensated financially by M. D. Anderson for this injury. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with questions about study-related injuries.

14. Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (HMO, health insurance company, etc.), will be my responsibility.

15. I understand that there are no plans to provide any compensation to me for any patents or discoveries that may result from my participation in this research.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at M. D. Anderson will be collecting information about you that they may share with the parties named in Section E below.

B. If you refuse to provide your authorization to disclose your protected health information, you will not be able to participate in this research project.

C. Your protected health information will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point.

D. All identifying information such as your name and address will be kept private. This information may be kept at M. D. Anderson forever. You will be assigned a code number so that your name will not be used. The research team at M. D. Anderson will be able to link the code number to your name. In some instances, in order to ensure the scientific value of the study, the parties named in Section E below will be able to view your study record but will not be permitted to copy any identifying information contained in your record.

E. Your information may be shared with the following parties:

- The University of Pennsylvania, Baylor College of Medicine, Kelsey-Seybold, and Harris County Hospital District
- The Office for Human Research Protections (OHRP) (a regulatory agency that oversees research in humans)
- The IRB of M. D. Anderson
- Officials of M. D. Anderson
- Study monitors who verify the accuracy of the information
- Individuals who put all the study information together in report form

F. You have the right to see and reproduce your records related to the research study, and ask for corrections, for as long as this information is held by the study chair and/or M. D. Anderson. However, in some studies, in order to ensure the scientific value of the study, participants are not able to view or reproduce their study records until the research has been completed with all participants in the study.

G. There is no expiration date for the use of your information as stated in this authorization. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the M. D. Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study, and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related personal health information to preserve the scientific value of the study. The parties listed in Section E above may use any study data that were collected before you canceled your authorization.

CONSENT/PERMISSION/AUTHORIZATION FOR STUDY WITH OPTIONAL PROCEDURES

(Mark choice(s) with an "X")

I elect to ____ or not to ____ to complete the health survey as an optional procedure.
Participant's Initials _____

Having read and understood the above and having had the chance to ask questions about this study, think about the study, and talk with others as needed, I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I have been given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

I was present during the explanation of the research to be performed under Protocol **2008-0577**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

_____ _____
SIGNATURE OF PERSON RESPONSIBLE & RELATIONSHIP DATE

I have discussed this health services research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
SIGNATURE OF STUDY CHAIR OR PERSON OBTAINING CONSENT DATE

Translator

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people obtaining/providing
(Name of Language)
consent by translating all questions and responses during the consent process for this participant.

_____	_____	_____
NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)

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INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Understanding Patient's Knowledge and Use of Acetaminophen 2008-0577

Subtitle: Individual Interviews

Study Chair: Maria Suarez-Almazor

1. _____ _____
Participant's Name Medical Record Number

You are being asked to take part in this health services research study at The University of Texas M. D. Anderson Cancer Center ("M. D. Anderson"). This consent form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you take over-the-counter Tylenol® (acetaminophen) at home.

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you," "your," "I," or "me" appear, it is meant to apply to the potential participant.

DESCRIPTION OF RESEARCH

2. PURPOSE OF STUDY

The goal of this health services research study is to learn more about the ways people take acetaminophen. Researchers also want to learn more about the

knowledge, attitudes, and beliefs of people who take acetaminophen.

3. DESCRIPTION OF STUDY

Individual Interviews
If you agree to take part in this study, you will take part in individual interview session. The interviews will be conducted by phone and audiotaped (recorded) and transcribed (typed) by the research staff at M. D. Anderson.

You will be asked a series of questions about your knowledge of acetaminophen, views about the packaging, beliefs about the benefits and risks of taking acetaminophen, and when and how often you use acetaminophen. You will also be asked about what you have heard from other people about using acetaminophen and what types of experiences other people that you talked to about acetaminophen have had. The interview should last about 30 minutes.

To protect your confidentiality, only first names will be used during the interview sessions. Your name and any identifiable information will be removed when the audio recordings are typed. The audio recordings will be stored in a password protected file that only the study chair and research staff will have access to. The audio recordings will be destroyed by the researchers once study results have been published.

Length of Study
Your participation in this study will be over after the interview is complete.

This is an investigational study. There will be no cost to you for taking part in this study.

A $20 gift card, as compensation for participating in this study, will be mailed to you after you complete the telephone interview.

Up to 124 people will be enrolled in this multicenter study. All will be enrolled by M. D. Anderson research staff. Participants will be recruited from outpatient pediatrics and primary care clinics at Kelsey-Seybold and Harris County Hospital District.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

Individual interviews may contain questions and topics that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the interview, you are encouraged to contact your doctor or the study chair.

Researchers will take appropriate steps to keep your information private. However, there is no guarantee of absolute privacy. All audio recordings will be stored on a password-protected computer that will only be available to the study chair or research staff. Only your first name will be used during the interview sessions.

This study may involve unpredictable risks to the participants.

5. POTENTIAL BENEFITS

Future patients may benefit from what is learned. There are no benefits for you in this study.

6. ALTERNATE PROCEDURES OR TREATMENTS

You may choose not to take part in this study.

I understand that the following statements about this study are true:

7. M. D. Anderson may benefit financially from my participation and/or from what is learned in this study.

8. I may ask the study chair any questions I have about this study, including questions about the costs. I may contact the study chair, Dr. Maria Suarez-Almazor, at 713-745-4516. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with any questions that have to do with this study or my rights as a study participant.

9. My participation in this research study is strictly voluntary. I may refuse to take part in this study without any penalty or loss of benefits to which I am otherwise entitled. I may also withdraw from participation in this study at any time without any penalty or loss of benefits. I should first discuss leaving the study with my doctor. If I withdraw from this study, I may still be treated at M. D. Anderson.

10. I understand that the study may be changed or stopped at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) (a regulatory agency that oversees research in humans), or the IRB of M. D. Anderson.

11. I will be informed of any new findings that might affect my willingness to continue taking part in the study.

12. M. D. Anderson will take appropriate steps to keep my personal health information

private. However, there is no guarantee of absolute privacy. Federal agencies (such as the FDA and the OHRP), and the IRB of M. D. Anderson might review my record to collect data or to check that the research is being done safely and correctly. In some situations, the FDA could be required to reveal the names of participants.

13. If I suffer injury as a direct result of taking part in this study, M. D. Anderson will provide medical care. However, this medical care will be billed to my insurance provider or me in the ordinary manner. I understand that I will not be reimbursed for expenses or compensated financially by M. D. Anderson for this injury. I may also contact the Chair of M. D. Anderson's IRB at 713-792-2933 with questions about study-related injuries.

14. Certain tests, procedures, and/or medications that I may receive as part of this study may be without cost to me because they are for research purposes only. However, my insurance provider or I may be financially responsible for the cost of supportive care and treatment of any complications resulting from the research tests, procedures, and/or medications, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that I receive under this research study will be billed to my insurance provider and/or me in the ordinary manner. I should learn before taking part in this study which parts of the research-related care will be provided without charge, which costs my insurance provider will pay for, and which costs will be my responsibility. I may ask to speak with a financial counselor about the costs of this study.

15. I understand that there are no plans to compensate me for any patents or discoveries that may result from my participation in this research.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at M. D. Anderson will be collecting information about you. This information may include your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section E below.

B. If you refuse to provide your authorization to disclose your protected health information, you will not be able to participate in this research study.

C. Your protected health information will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point.

D. All identifying information such as your name and address will be kept private. This

information may be kept at M. D. Anderson forever. You will be assigned a code number so that your name will not be used. The research team at M. D. Anderson will be able to link the code number to your name. In some instances, in order to ensure the scientific value of the study, the parties named in Section E below will be able to view your study record but will not be permitted to copy any identifying information contained in your record.

E. Your information may be shared with the following parties:

- The University of Pennsylvania, Baylor College of Medicine, Kelsey-Seybold, and Harris County Hospital District
- The FDA
- The OHRP
- The IRB of M. D. Anderson
- Officials of M. D. Anderson
- Clinical study monitors who verify the accuracy of the information
- Individuals with medical backgrounds who determine the effect that the study procedures may have on the disease
- Individuals who put all the study information together in report form

F. You have the right to see and reproduce your records related to the research study, and ask for corrections, for as long as this information is held by the study chair and/or M. D. Anderson. However, in some studies, in order to ensure the scientific value of the study, participants are not able to view or reproduce their study records until the research has been completed with all participants in the study. If possible for this study, your doctor will be able to discuss your clinical test results with you.

G. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the M. D. Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study and the study chair and staff will no longer use or disclose your protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related protected health information to preserve the scientific value of the study. The parties listed in Section E above may use any study data that were collected before you canceled your authorization.

CONSENT/PERMISSION/AUTHORIZATION FOR TREATMENT

Having read and understood the above and having had the chance to ask questions about this study, think about the study, and talk with others as needed, I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I have been given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT _____ DATE _____

I was present during the explanation of the research to be performed under Protocol **2008-0577**.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) _____ DATE _____

SIGNATURE OF PERSON RESPONSIBLE & RELATIONSHIP _____ DATE _____

I have discussed this health services research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

SIGNATURE OF STUDY CHAIR OR PERSON OBTAINING CONSENT _____ DATE _____

ASSENT OF MINOR ***(this entire section must be completed if the participant's intellectual age is at least seven and less than eighteen years.)***

If assent is not obtained on an age-appropriate participant, check reason why not:

___ 1.) The participant's intellectual age is less than seven.
___ 2.) The participant dissented, but the participant's guardian felt that the possibility of a direct benefit, important to the health and/or well being of the participant, is available only in the context of this research.
___ 3.) Other _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to discuss the study and ask questions. My questions have been answered. I agree to be in this study and do what I am asked to do so long as I continue in this study. I give the study chair permission to enroll me on this study. By signing this assent, I am not giving up any of my legal rights. I have been given a copy of this document.

_____ _____
SIGNATURE OF MINOR DATE

I was present during the explanation of the research to be performed under Protocol **2008-0577**. The child participant was also present. In my opinion, the child assented to participate in the research.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

Translator

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people obtaining/providing
(Name of Language)
consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)