OBSERVATIONAL / EMR CONSENT FORM

Title: The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) Trial

Protocol No.: None
WIRB® Protocol #20161339
1218443

Sponsor: University of Washington

Principal Investigator Damien Carter, MD, 887 Congress St., Portland, Maine 04102

Emergency Phone (24 hours): Damien Carter, MD: 206-234-6828

Researchers' statement

We have already asked if you were interested in the randomization option for this study. Now, we'd like to ask if you would be interested in an alternative way that you can still participate in this research.

University of Washington will be referred to as sponsor throughout this document.

PURPOSE OF THE STUDY

You are being asked to take part in this study because you have appendicitis. Appendicitis is due to inflammation of the appendix, which is a small tube about three inches long that is attached to your intestine and is located in the right lower area of your abdomen. Appendicitis is most likely caused by bacteria that grow and collect in the appendix, causing pain and swelling. The purpose of this study is to see whether 10 days of antibiotics is just as good as an appendectomy in the treatment of appendicitis.

STUDY PROCEDURES

If you decide to volunteer for the study, you will receive either the surgical treatment (appendectomy) or the antibiotics treatment. You and your doctor will decide which treatment is best for you. Your participation in this study does not involve randomization.

There are two options if you decide to participate in this study.

Option 1: Observational Study. For this option, you would complete a survey today and at different time points for two years that will ask questions about the treatment you received, your current health status, and your quality of life. At the end of the two-year follow-up, we may contact you to ask if you would be willing to participate in a longer-term study with yearly surveys. In addition, we would like to use some of the information you provide in this study for future research related to understanding the characteristics of surgical patients (across many types of surgeries) and their outcomes. We would also collect information from your medical records as described in Option 2 below.

Option 2: Electronic Medical Review Only. For this option, we would collect information from your medical records. You would not need to answer any survey questions today or in the future. Instead, we would record information about you before and after your appendicitis treatment date and other information like your age, insurance status, and smoking history. We will also record information from your medical record including your medical history, laboratory and imaging tests, medications you are taking, information about your treatments, hospitalizations and any clinical outcomes that occur after your treatment.

Study Activities

Option 1. Observational Study.

There will be additional phone-based, email-based, or text-message follow-up questions after today, but you will not need to come back to the hospital or clinic to complete this study. You will be paid for your time to complete these studies.

A day or two after you leave the hospital, the study coordinator will contact you to answer any questions you have about the study and to review the follow-up survey schedule. Study staff will also remind you of your follow-up appointment with your medical care team.

The table below describes when you will be contacted for research visits.

	Follow-Up Surveys								
	Year 1							**Year 2**	
	First 4 Weeks			**Month**					
Enrollment Visit	1	2	4	3	6	9	12	18	24
Today	X	X	X	X	X	X	X	X	X

You will be followed-up with once a week for two weeks and you will be asked to complete a short questionnaire with the study coordinator on the phone. These questionnaires will ask you to answer questions about your appendicitis symptoms, your medication use, and if you have returned to see a doctor. The surveys for Weeks 1 and 2 will take about 10 minutes to complete.

At the Week 4 follow-up, you will be asked to complete questionnaires about your quality of life, and experience. We will ask you about your pain level and severity, your symptoms, your satisfaction with your treatment, and your ability to return to your work, school or daily activities. Altogether, the Week 4 survey will take about 20 minutes.

After the first three follow-ups, the next follow-up will be about 3 months from today. You will be contacted every three months from then on for the first year (6-, 9-, and 12-months from today). After the first year of study participation, we will contact you twice more: about 18-months and 24-months from today. Study staff will contact you to complete surveys by phone, by mail, or they may provide you with information on how to answer the survey questions on the internet. The questionnaires will take about 15 minutes to complete. You will be asked to answer questions about the following:

- If you have had any new symptoms related to your appendicitis;
- If you went to see a doctor about your appendicitis;
- How much time and money your medical care cost;
- Your work productivity;

- Your pain level;
- Your satisfaction with your treatment;
- Your gastrointestinal health and your overall quality of life; and
- If you have any new contact information.

During the study, you will be monitored for complications and other illnesses in addition to appendicitis. We would like to record information from your medical records. We will record information about you before and after your treatment date and other information like your age, insurance status, and smoking history. We will also record information that doctors record in your medical record including your medical history, laboratory and imaging tests, medications you are taking, information about your treatments, hospitalizations and any clinical outcomes that occur after your treatment. If you visited another facility for care related to your appendicitis during the study, you may be asked to provide your consent to release those medical records to the study team. While we will only contact you for up to two years to complete surveys, we may continue to collect information from your health records.

The information that you provide in these follow-up questionnaires is confidential and will not be shared back with your physician unless you report any symptoms suggesting appendicitis-related health concerns.

RISKS, STRESS, OR DISCOMFORT

If you participate in Option 1, Observational Study, you may feel discomfort when completing the survey questions. You are free to skip any questions that you do not want to answer. There is also a possibility that there could be a loss of confidentiality. Every effort will be made to ensure your confidentiality is protected throughout the duration of the study.

Some people do not want information from their medical records used for research. We have addressed concerns about confidentiality below.

This study may pose risks that we do not currently know about.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate, you will be treated for your appendicitis. You would not be asked to complete the study surveys if you choose the Electronic Medical Review Only Study option. We would not collect information from your medical records if you choose not to participate altogether.

BENEFITS OF THE STUDY

You will not receive direct benefit from your participation in the study; however, you will contribute to medical knowledge that may help improve future patient choices in their treatment decisions about appendicitis.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the Patient-Centered Outcomes Research Institute (PCORI).

CONFIDENTIALITY OF RESEARCH INFORMATION

The researchers will keep your study information confidential. We will assign a unique study code to your study information. Information that identifies you will be kept in a secure location. We will destroy any link between the study information and your identity once the study has ended. If the results of this study are published, we will not use any information that identifies you.

Government regulators, such as the U.S. Food and Drug Administration (FDA), university staff, and agents for the sponsor; agents for the study doctor, and Western Institutional Review Board ® (WIRB®) review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your study information or research records may be examined. The reviewers will protect your privacy. Your study information or research record will not be used to put you at legal risk of harm.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your coded research information will be combined with information from other sites at the Data Coordinating Center located at the University of Washington. The Data Coordinating Center will store information that can identify you in a separate location.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Western Institutional Review Board® (WIRB®)
- Employees of Maine Medical Center Office of Research compliance

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Will the information collected as part of this study be destroyed when it is no longer needed?
It is difficult for sponsor or investigator to know how long your information will be kept. Your information will be kept at least until the data are sent to FDA/data collection center/sponsor, but most likely it will be kept on the database at sponsor for an indefinite length of time. We do not know when your information will no longer be used, and there is no expiration date after which it will be discarded.

OTHER INFORMATION

Your participation in this study is completely voluntary. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, the study doctor will still be able to use the information collected about you prior to your withdrawal from the study. Information that has already been sent to the study sponsor may not be able to be withdrawn.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason.

You will be told about any new information that might change your decision to be in this study.

If you decide to participate in this study, your clinical treatment will not be affected in any way whatsoever. You and your doctor will decide what treatment is best for you. Your participation will not impact the cost of your clinical treatment.

You are responsible for the cost of your clinical care that includes, but is not limited to, the costs for surgery and/or antibiotics. These treatments are considered routine treatments for appendicitis. All medications, laboratory fees, physician fees, and hospital costs will be charged to you in the same way as if you were not a part of this study. You are responsible for either paying for or having your insurance pay for all the clinical care you receive during the study.

The following information applies to those who decide to participate in the Observational Cohort Study. This study option includes completing research surveys.

If you decide to participate in the Observational Study, you will receive a total of $125 for completing the surveys related to the study. You will receive $20 for completing the questionnaires today. You will receive $10 for both the Week 1 and Week 2 follow-up surveys and $20 for the Week 4 survey for a total of $40. You will receive $10 for each of the quarterly follow-up visits (3-, 6-, 9-, and 12-months) for a total of $40. You will receive $10 for the 18-month call and $15 for the final 24-month call.

RESEARCH-RELATED INJURY

If you become sick or injured during your participation in this study, Damien Carter, MD will arrange or provide medical care. Medical treatment is available and will be provided at the usual charge.

The sponsor of this research is a part of the federal government/foundation. It is University of Washington policy, that if you are injured or become ill as a result of research procedures, medical treatment will be provided to you but University of Washington will not pay for this treatment. If any research activity resulted in an injury, treatment will be available, including first aid, emergency treatment and follow up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

However, this does not take away your rights to seek or collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

You or your insurance company will be responsible for any costs resulting from underlying disease or treatments provided to you outside of this research study.

If you think that you have suffered a research related injury, let the study physicians know right away. If you have any questions or concerns about the legal responsibility of University of Washington please call Damien Carter, MD at 206-234-6828 at Maine Medical Center.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions, concerns, or complaints later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, or questions, concerns, or complaints about the research, I can contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, I may contact WIRB if the research staff cannot be reached or if I wish to talk to someone other than the research staff.

I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Please indicate which study you would like to participate in by checking **one** box below:

☐ Observational Study. I understand that I will be asked to complete a survey today; after week 1, week 2, and week 4; and then, every few months for two years.

☐ Electronic Medical Record Review. I understand that research staff will record information from my medical records. I will not be asked to complete surveys for this research study and I will not receive payment for my participation in this study.

Printed name of subject	Signature of subject	Date

Printed name of study staff obtaining consent	Signature	Date

Copies to: Researcher
Subject