

**UNIVERSITY OF WASHINGTON  
CONSENT FORM**

**Treatment Individualized Appendicitis Decision-making (TRIAD)**

**Pre- Post Participant Surveys**

**Principal Investigator**

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**General Study Contact**

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**Researcher's Statement**

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

**PURPOSE OF THE STUDY**

We want to learn more about how patients who have appendicitis make decisions about their treatment. Appendicitis is diagnosed when the appendix, a part of the large intestine, becomes inflamed as the result of an infection. Symptoms of appendicitis include abdominal pain, nausea, vomiting, and fever or chills. Traditionally, when a patient had appendicitis, they were treated with surgery to remove the appendix (called an appendectomy). Recently, data from large clinical trials has showed us that it is often safe to treat appendicitis with antibiotic medicine instead of surgery.

The purpose of this study is to understand how patients make the decision to treat appendicitis with surgery or antibiotics. You can be in this study because you recently had appendicitis.

**STUDY PROCEDURES**

If you decide to join this study, we will ask you to respond to two brief surveys. The first survey will ask you questions about yourself in general, your experience in the emergency department, and a number of questions about the type of information you received in the emergency department and how it helped or did not help you make a decision about treating your appendicitis. Examples of the questions include "How much did the conversations with your physicians and any educational material they showed you prepare you to make a better decision?", or "Thinking back to when you were in the emergency department, how bad was your belly pain on a scale from 1 to 10?".

The second survey will take place 30 days after your experience in the emergency department and ask similar type of questions. Each survey will take about 10-20 minutes to complete. You do not have to answer every question.

## **RISKS, STRESS, OR DISCOMFORT**

There is no physical risk associated with being in this research 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 risk of a breach of confidentiality. A breach of confidentiality might mean that information collected about you during the study is shared with people outside the research team. The Confidentiality section below describes how we will protect you from this risk.

## **BENEFITS OF THE STUDY**

You may not directly benefit from taking part in this research study. We hope that the results of this study will help patients with appendicitis in the future understand their treatment options.

## **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, separate from the study information. If the results of this study or any future studies that utilize this data are published, we will not use any information that identifies you. Government or university staff sometimes 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.

## **USE OF INFORMATION AND SPECIMENS**

### **Commercial Profit**

The information collected as part of this research study will not be used for commercial profit.

### **Using Your Data in Future Research**

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share

study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

### OTHER INFORMATION

Taking part in this study is 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 wish to withdraw, please contact the researcher listed on page 1 of this consent form.

After the survey, you will be provided compensation for your time and inconvenience. You will receive a \$10 payment for each questionnaire for a total of \$20 via check or online card.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

### RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact a study coordinator at 206-616-6577.

#### 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 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, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. 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.

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- ☐ **I agree to participate in the study.** It is OK for you to ask me questions about my health and appendicitis. I am interested in participating in future research studies about my appendicitis treatment

☐ **I agree to participate in the study.** It is OK for you to ask me questions about my health and appendicitis. I am **NOT** interested in participating in future research studies about my appendicitis treatment

☐ **I do not want to participate in the study.**

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Printed name of subject

Signature of subject

Date

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Phone

Email