Official Title: Complex And Simple Appendicitis: REstrictive or Liberal Post-operative Antibiotic eXposure (CASA RELAX) Using Desirability of Outcome Ranking (DOOR) and Response Adjusted for Duration of Antibiotic Risk (RADAR)
NCT05746520
IRB Approval Date: 06/27/2025

Consent to Participate in a Clinical Research Study

Title of Study:	Complex and Simple Appendicitis: Restrictive or Liberal post-operative Antibiotic eXposure (CASA RELAX) Using Desirability of Outcome Ranking (DOOR) and Response Adjusted for Duration of Antibiotic Risk (RADAR) – A Randomized Controlled Trial
Principal Investigator:	Rafael A. Torres Fajardo, MD/JD
Department:	Trauma and Acute Care Surgery Department
Office Number:	[redacted]
Email Address:	[redacted]

This consent form contains important information so that you can decide if you wish to take part in this study. If you have any questions that remain unanswered, please ask the study doctor or one of the research study personnel before signing this form.

You are being asked to participate in a research study. Before you give your consent to be part of this study, please read the following and ask as many questions as necessary to be sure that you understand what your participation will involve.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

PURPOSE
The purpose of this study is to see if we can decrease the amount of antibiotics after appendicitis surgery in order to decrease the risk of adverse effects associated with antibiotics while at the same time ensuring your safety.

NUMBER OF STUDY PARTICIPANTS
If you decide to be in this study, you will be one of approximately 400 people in this research site.

PROCEDURES
If you agree to participate in the study and would like to be involved in one of the study's treatment plans, you will be randomly assigned to an intervention plan based on the diagnosis made in surgery. The treatment you get will be chosen by chance, like flipping a coin. If you are found to have simple (uncomplicated) appendicitis, you will be assigned to either a group that

will not receive any post-operative antibiotics ("restrictive" group) or to a group that will receive antibiotics for only 24 hours after surgery ("liberal" group). If you are found to have complicated appendicitis (i.e. gangrenous or perforated), you will be assigned to either a group that will receive post-operative antibiotics for up to 24 hours ("restrictive" group) or a group that will receive antibiotics for 4 days after surgery ("liberal" group).

The study will not require any additional tests or medication administration that are not included in the standard of care after appendicitis surgery, but the care team in charge may still order any tests or medications deemed necessary to ensure your safety.

If you agree to participate in the study, you also agree to receive telephone calls from study team members and will be required to answer a number of questions related to your recovery at least 30 days after surgery.

How is being in this study different from my regular healthcare? If you take part in this study and you are found to have simple (uncomplicated) appendicitis, the main difference between your regular care and the study is the administration of antibiotics in the 24-hour period after surgery. If you take part in this study and you are found to have complicated appendicitis (i.e. gangrenous or perforated), the main difference between your regular care and the study is the duration of administration of antibiotics in the 4-day period after surgery.

DURATION OF STUDY

The duration of your participation will be from admission to hospital discharge and a follow-up period over the phone at least 30 days after surgery. We will gather information from your medical record about your medical and surgical history and clinical results related to your care.

RISKS AND DISCOMFORTS

Risks of a shorter duration of antibiotics after surgery include possible increased risk of abdominal and surgical site infections and complications related to such infections including, but not limited to, the formation of abscesses and skin infections.

Risks of a longer duration of antibiotics after surgery include growing resistant organisms ("super bugs'), side effects such as stomach cramps or diarrhea, and the expense of the medications.

BENEFITS

If you are randomized to the "restrictive" group, you may benefit from being part of this study by having a decreased risk of adverse effects caused by antibiotics, such as growing resistant organisms ("super bugs"), side effects such as stomach cramps or diarrhea, and the expense of the medications. If you are randomized to the "liberal" group, you may benefit from a lower chance of developing infections.

ALTERNATIVES
You have the choice not to participate in this study. You may choose for your doctor to treat you with antibiotics using their best clinical judgement. If you do participate, you can decide to stop participating in this study at any time. Not participating in this study **will not** affect your care during hospitalization.

COSTS
There will be no added costs related to enrollment in this study. Your insurance will be billed for all standard medical care while you participate in this study.

INCENTIVES/PAYMENTS TO PARTICIPANTS
You will not be paid for taking part in this study.

WHO IS SPONSORING THIS STUDY?
This study is being sponsored by Atrium Health Wake Forest Baptist. The sponsor is providing support to the medical team, researchers, and statisticians who are conducting and collecting data for this study. None of the involved staff or medical team hold a direct financial interest in the sponsor or the drugs being studied.

COMPENSATION FOR STUDY-RELATED ADVERSE EVENTS
Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services. You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Rafael Torres Fajardo at telephone number [redacted].

VOLUNTARY PARTICIPATION / WITHDRAWAL FROM STUDY
Participation in this study is voluntary. You do not have to take part if you do not want to, and you can leave the study at any time. Whatever you decide, you will not be penalized or lose benefits. This will not affect the medical care you receive from the study doctor or Atrium Health Hospital. You must tell the study doctor if you wish to stop taking part in the study. Your participation in this study may be discontinued, without your consent, at any time by the study doctor, if he/she believes that participation in the study is no longer in your best interest. The

Institutional Review Board (IRB), regulatory authorities, or the Principal Investigator may also discontinue your participation in the study.

If you decide to leave the study, the study team members and the study doctor will stop collecting your health information. Although they will stop collecting new information about you**,** they may need to use the information they have already collected to evaluate the study results. If you start the study and then you cancel your permission, you will not be able to continue to participate in the study. This is because the study team members and/or the study doctor would not be able to collect the information needed to evaluate the results anymore.

CONFIDENTIALITY

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other Atrium Health representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

We will remove identifiable information from the data we collect about you. After we remove all identifiers, we will place a code on the information. The code will be linked to your identity, but the link will be kept in a location that is separate from your study data.

We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

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 website will include a summary of the results. You can search this website at any time.

By signing this consent, you authorize the Investigator(s) and his/her/their staff to access your medical records and associated information as may be necessary for purposes of this study. Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The Investigator and his/her collaborators, staff will consider your records confidential to the extent permitted by law. The Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed for audit purposes by authorized Atrium Health employees or other agents who will be bound by the same provisions of confidentiality.

The monitors, auditors, the Atrium Health WFSOM Institutional Review Board (IRB), the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access.

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00086118
Meeting Date Approved 6/27/2025
Version Valid Until: 6/3/2026

Federal law provides additional protections of your medical records and related health information. These protections are described below, in the "What About My Health Information?" section.

What About My Health Information?
In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes demographic data, history of present illness data, physical exam data, laboratory data, radiographic data, pathology data, and operative data.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other

applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Rafael Torres Fajardo, MD/JD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Rafael A. Torres Fajardo, MD, JD
Department of General Surgery
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

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

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
If you have questions at any point in the study, you are more than welcome to reach out to Atrium Health at [redacted]. You may also reach out to the Principal Investigator Dr. Rafael Torres MD/ JD at any point by emailing him at [redacted] or calling him at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the IRB at [redacted] or the Research Subject Advocate at [redacted].

SIGNATURES

I have read this consent, which is printed in English (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedure and risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to take part in this study.

_____	_____
Signature of Participant	Date
_____	_____ AM PM
Printed Name of Participant	Time
_____	_____
Signature of Person Obtaining Consent	Date
_____	_____ AM PM
Printed Name of Person Obtaining Consent	Time

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