Certificate of Action

Investigator Name: Damien Carter, MD	**Board Action Date:** 06/22/2018
Investigator Address: 887 Congress St. Portland, ME 04102, United States	**Approval Expires:** 06/22/2019 **Continuing Review Frequency:** Annually
Sponsor: University of Washington **Institution Tracking Number:** 1218443	**Sponsor Protocol Number:** None **Amended Sponsor Protocol Number:**
Study Number: 1186971	**IRB Tracking Number:** 20161339
Work Order Number: 1-1090380-1	**Panel:** 2
Protocol Title: The Comparison of Outcomes of Antibiotic Drugs and Appendectomy (CODA) Trial	

THE FOLLOWING ITEMS ARE APPROVED:

Investigator
24 Hour 1 and 2 Week Voicemail Follow Up #14602462.1 - As Submitted
Advertisement - Handout - Appendicitis is a common infection #14590172.0 - As Submitted
Advertisement - Handout - Treatment Options for Appendicitis #14590166.0 - As Submitted
Advertisement - Handout (neg) - What is appendicitis Appendicitis is #16535756.0 - As Submitted
Advertisement - Handout (pos) - What is appendicitis Appendicitis is #16535758.0 - As Submitted
Advertisement - Poster - Patient with Appendicitis #17872798.0 - As Submitted
Advertisement - Slides - Appendectomy vs Antibiotics The CODA #14787465.0 - As Submitted
Advertisement - Video Script - CODA Video Script #14596225.0 - As Submitted
Automated Messaging, IVR, Email, and Phone Reminders #16535761.0 - As Submitted
Baseline EMR Forms #14602465.2 - As Submitted
Baseline Questionnaire #14590171.2 - As Submitted
CODA Calendar Magnet #17872799.0 - As Submitted
CODA Research Coordinator Patient Approach Script #14602473.0 - As Submitted
CODA Week 4 Non-Surgical Questionnaire #14783573.0 - As Submitted
CODA Week 4 Surgical Questionnaire #14783574.0 - As Submitted
DSMB Charter (07-13-2017) #16535743.0 - As Submitted
EMR Forms #14602488.0 - As Submitted
Follow-Up EMR Forms #14602472.2 - As Submitted
Follow-Up Reminder #14590173.1 - As Submitted
Follow-up Survey Mailer #16535752.0 - As Submitted
Incentive Cover Letter #14602489.0 - As Submitted
Month 12 Follow-up Assessment #14590169.1 - As Submitted
Month 18-Month 24 Follow-up Assessment #14590170.1 - As Submitted
Month 6-Month 9 Follow-up Assessment #14590168.1 - As Submitted
Protocol (04-03-2016) Version 3.5
Recruitment of Subjects Under the Grant PCS-1409-24099 (Comparing Outcomes of Drugs and Appendectomy (CODA))
Revised Protocol (04-2017) Version 5.0
Screening Appendix #16535763.0 - As Submitted
Screening Form #14602463.0 - As Submitted
Serious Adverse Events Clinical Report Form #14602477.1 - As Submitted
Slides - Presenting CODA to Patients #17872819.0 - As Submitted
Study Staff Screening Form #14602479.2 - As Submitted
Teleprompter Script #16535740.0 - As Submitted
Week 1-Week 2 Follow-up Assessment #14602483.1 - As Submitted

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Week 4-3 Month Follow-up Assessment #14602484.1 - As Submitted
Weeks 1 and 2: Appendicitis Treatment #15471653.0 - As Submitted
Consent Form - Observational [IN2]
Consent Form - Randomization [IN2]
CODA Pocket Card #17872797.0 - As Submitted
Slides - Clinician Short Version - Appendectomy vs Antibiotics The CODA #17872820.0 - As Submitted
Slides - Residents - Appendectomy vs Antibiotics The CODA #17872818.0 - As Submitted

Please note the following information:
The Board requires that all subjects must be able to consent for themselves to be enrolled in this study. This means that you cannot enroll incapable subjects who require enrollment by consent of a legally authorized representative.

NOTE: WIRB currently has CEFAZOLIN For Injection (no date), CLAFORAN® (cefotaxime) Injection Prescribing Information (02-2015), MEFOXIN® (Cefoxitin) Injection Prescribing Information (10-2006), Ceftriaxone Sodium Prescribing Information (05-2013), Cefuroxime Prescribing Information (01-2007), Ciprofloxacin Hydrochloride Prescribing Information (02-2009), Cleocin Prescribing Information (11-2005), Invanz Prescribing Information (02-2012), Levaquin (levofloxacin) Prescribing Information (09-2008), FLAGYL® (metronidazole) (Tablets) Prescribing Information (08-2003), AVELOX (moxifloxacin) Prescribing Information (12-1999), TIMENTIN Prescribing Information (6-2014), and TYGACIL Prescribing Information (07-2010) on file.

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Maine Medical Center, 22 Bramhall Street, Portland, Maine 04102

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:
As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions
    - For research subject to federal oversight other than FDA:
- No additional identifiable private information about the subjects is being obtained
- Analysis of private identifiable information is completed
- If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.

- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. ”

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
Contact, Company
Erin Carney, University of Washington
Heather Harris, University of Washington
Damien Carter, MD, Maine Medical Partners Surgical Care