

Screening ID: ___-S___ Screening Date: 20___/___/___
 Obtain Screening ID at <http://codastudy.org>

Coordinator Initials: ___ #14602479.2

Surgery Residents complete sections "A" and "B" only

A. EMR Review (Complete this section based on EMR review for all patients **≥18 years of age** presenting to the Emergency Department (ED) with **FIRST clinical diagnosis of appendicitis**. If patient has previously been enrolled or previously treated for appendicitis, do not continue.

1. Date of ED Presentation: ___/___/20___ (MM/DD/YYYY) Time: ___ : ___ am/pm
2. Has patient previously been enrolled in CODA? Yes No (You may use Patient's MRN number to verify)
3. Is appendicitis indicated by clinical findings? Yes No
4. Has imaging been performed to support appendicitis diagnosis? Yes No ; Type: CT MRI US
5. If yes, are imaging findings consistent with diagnosis of appendicitis? Yes No N/A
6. If yes, are any of the following indicated as present in the radiology report?
 - a. Perforation: Yes No Maybe
 - b. Fecalith/Appendocolith (stones): Yes No
7. Demographics:
 - a. Age: _____ (years)
 - b. Sex: Male Female Non-binary/third gender Prefer to self-describe _____ Prefer not to say
 - c. Hispanic, Latino, or Spanish origin: Yes No
 - d. Race (check all that apply): White Black or African American American Indian or Alaska Native Asian Native Hawaiian or other Pacific Islander Some other race Declined to answer

Complete Q6 and continue with form.
 Patient is not excluded in this section.

B. Eligibility Criteria. Check 'Yes' or 'No' for all eligibility criteria listed below.

Inclusion Criteria	Yes	No
8. Diagnosis of appendicitis, supported by imaging, established within the last 24 hours (If no, do not continue)	<input type="checkbox"/>	<input type="checkbox"/>
Exclusion Criteria (Exclude patient if any of the below exclusion criteria is YES)	Yes	No
9. EMR indicates that patient does not speak either English or Spanish	<input type="checkbox"/>	<input type="checkbox"/>
10. Any of the following are indicated (coordinator to verify with clinical team): In the radiology report: <input type="checkbox"/> Free air (more than trace amount) <input type="checkbox"/> Defined abscess or walled off fluid collection concerning for an abscess <input type="checkbox"/> Diffuse ascites (Significant amounts of intra-abdominal fluid throughout abdomen (i.e., more than trace fluid)) <input type="checkbox"/> Imaging features of mucocele or tumor concerning for malignancy of the appendix or in other organs <input type="checkbox"/> Appendiceal soft-tissue mass or concern for any carcinomatosis <input type="checkbox"/> Severe phlegmon (Inflammation or adjacent organ involvement contraindicating appendectomy) On physical exam: <input type="checkbox"/> Diffuse peritonitis	<input type="checkbox"/>	<input type="checkbox"/>
11. Antibiotics started: ___/___/20___ MM/DD/YYYY ___ : ___ am/pm		
12. Research approach: ___/___/20___ MM/DD/YYYY ___ : ___ am/pm		
13. More than seven hours have transpired between the time patient received first parenteral dose of antibiotics and time of research approach	<input type="checkbox"/>	<input type="checkbox"/>
14. Any of the following known conditions (coordinator to verify with clinical team): <input type="checkbox"/> Evidence of severe sepsis or septic shock (e.g., new presumed sepsis-related organ dysfunction, elevated lactate, and/or fluid unresponsive hypotension); these patients can be enrolled if signs of sepsis resolve with fluid resuscitation and pain medication administration while in the ED.	<input type="checkbox"/>	<input type="checkbox"/>

Select all that apply
 If yes, do not continue

Select all that
 ← apply

<input type="checkbox"/> Immunodeficiency (e.g., absolute neutrophil count <500/mm ³ , chronic immunosuppressive drugs (e.g., corticosteroids, anti-TNF agents), or known AIDS [i.e., last CD4 count <200] assessed by patient history) <input type="checkbox"/> Active treatment for malignancy, not in remission (e.g., ongoing chemotherapy or plans for chemotherapy in the next 30 days excludes) <input type="checkbox"/> Concurrent illness that requires hospitalization <input type="checkbox"/> Active treatment of inflammatory bowel disease <input type="checkbox"/> Another infection requiring antibiotics <input type="checkbox"/> Expectant or concurrent hemodialysis, peritoneal dialysis, treatments using indwelling venous catheters, or conditions putting patient at risk for bacterial seeding <input type="checkbox"/> LVAD <input type="checkbox"/> Pregnancy <input type="checkbox"/> Abdominal/pelvic surgery in the past month <input type="checkbox"/> Uncompensated liver failure <input type="checkbox"/> Recent [within 90 days] placement of implant (e.g., pace maker, mechanical cardiac valve, or joint prosthesis) <i>(For further explanation on the above, see Screening Form Appendix)</i>	Select all that ← apply	
15. Contraindication to the following per clinical team specification: <input type="checkbox"/> Antibiotics (e.g., Known severe allergy or reaction to <u>all</u> of the proposed antibiotics - See Screening Form Appendix) <input type="checkbox"/> Surgery (e.g., advanced disease related to appendicitis such that patient is ineligible for surgery) <input type="checkbox"/> Explain: _____	<input type="checkbox"/> Select all that ← apply	<input type="checkbox"/>
16. Currently incarcerated in a detention facility or in police custody (<i>patients wearing a monitoring device can be enrolled</i>)	<input type="checkbox"/>	<input type="checkbox"/>
Exclude patient if any of the above exclusion criteria is <u>YES</u> .	<input type="checkbox"/> EXCLUDE	
Confirmation to Continue	Yes	No
17. Research Coordinator was available to screen patient after imaging-confirmed diagnosis of Appendicitis (<i>If no, do not continue</i>)	<input type="checkbox"/>	<input type="checkbox"/>
18. Member of the clinical team confirmed patient may be approached for study participation (<i>If no, provide explanation and do not continue</i>) <input type="checkbox"/> Explain: _____	<input type="checkbox"/>	<input type="checkbox"/> ← Explain

C. Eligibility Criteria to be Confirmed In-Person

**Here you should say to the patient: "I am going to show you a video describing a new study that you may be invited to take part in, but first I have just a few questions to confirm your eligibility".*

Eligibility criteria to be confirmed with patient	Yes	No
19. Did patient agree to be approached for this study?	<input type="checkbox"/>	<input type="checkbox"/> Skip to Section E
20. Do you feel comfortable reading, writing, and verbally communicating in either English or Spanish? <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> Both – default to English	<input type="checkbox"/> ← Select one	<input type="checkbox"/>
21. Are you able to access a phone or the internet regularly so that we may follow up with you in regards to the study?	<input type="checkbox"/>	<input type="checkbox"/>
Exclude patient if any of the above exclusion criteria is <u>NO</u> . Continue completing this form for data completeness		<input type="checkbox"/> EXCLUDE
22. Do you plan on participating in another study over the next 4 weeks that requires you to use another investigational drug or vaccination?	<input type="checkbox"/>	<input type="checkbox"/>
23. If female and of child bearing age, are you pregnant or planning on becoming pregnant over the next 30 days?	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> (Male)
Exclude patient if any of the above exclusion criteria is <u>YES</u> . If any of the above exclusion criteria is YES, do not continue	<input type="checkbox"/> EXCLUDE	

**Here you may now show the video to the patient and afterwards provide them with the consent forms to review and sign if interested in study participation.*

24. Did patient watch the study video or review study pamphlet? Please mark which video the participant watched: <input type="checkbox"/> ODD <input type="checkbox"/> EVEN	<input type="checkbox"/>	<input type="checkbox"/> Protocol Deviation
25. Did the patient agree to hear more about this study? *If you discussed the study consent forms after the video with the participant, this should be marked YES*	<input type="checkbox"/>	<input type="checkbox"/> Skip to Section E

D. Research Study Approach

26. Did patient meet all the above requirements for study eligibility and participation?	<input type="checkbox"/> Yes <input type="checkbox"/> No (<i>do not continue</i>)
27. Did patient sign the consent form to participate in this research study?	<input type="checkbox"/> Yes <input type="checkbox"/> No (<i>Skip to Section E</i>)
28. To which study group did the participant consent?	<input type="checkbox"/> Randomized trial (<i>Skip to question 32</i>) <input type="checkbox"/> Observational Follow-up (<i>Skip to question 29</i>) <input type="checkbox"/> EMR Review Only (<i>Skip to question 32</i>)
29. For participants in the observational cohort, which treatment did they select? (<i>If quarterly quota not met, skip to 32</i>)	<input type="checkbox"/> Antibiotics <input type="checkbox"/> Appendectomy
30. Did the patient agree to participate in the observational cohort but the quarterly quota (as see in on the reports page of the study portal) for the treatment preference had already been met?	<input type="checkbox"/> Yes <input type="checkbox"/> No
31. After being denied participation in the observational cohort, did the patient consent to the EMR only cohort?	<input type="checkbox"/> Yes, the patient consented to the EMR only cohort <input type="checkbox"/> No, the patient did not consent to participate in the study
32. CODA Study Participant ID (<i>obtain through CODA Portal: https://www.coda-trial.org/portal</i>)	_____
33. For participants in the RCT, to which study arm was the participant randomized or for participants in the observational cohort, which treatment did they select?	<input type="checkbox"/> Antibiotics <input type="checkbox"/> Appendectomy

E. Participation or Randomization Refusal. Complete only for patients declining study participation or randomization.

34. Indicate reason for refusal (<i>check all that apply</i>)	<input type="checkbox"/> Treatment preference for appendectomy <input type="checkbox"/> Treatment preference for antibiotics <input type="checkbox"/> Concern over other health issues <input type="checkbox"/> Concern over research staff accessing medical records <input type="checkbox"/> Concern over impact on caregiving responsibilities <input type="checkbox"/> Concern over treatment costs <input type="checkbox"/> Study incentives not great enough <input type="checkbox"/> Lack of interest <input type="checkbox"/> Unknown <input type="checkbox"/> Other: _____
35. Please expand on your refusal, in your own words. (e.g., Travel plans, prior bad experiences with surgery or antibiotics, family/friend opinions).	