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February 25, 2021

Cristina Feather, MHS, MD
Anne Arundel Medical Center
2000 Medical Parkway
Annapolis, Maryland 21401

Dear Dr. Feather:

SUBJECT: IRB EXEMPTION— HIPAA FULL WAIVER OF AUTHORIZATION AND
REGULATORY OPINION
Investigator Contact: Cristina Feather, MHS, MD
Protocol Title: Wound Management in Emergency Colorectal Surgery: To Close
or Not to Close?

On February 25, 2021, WCG IRB **approved** a request for a waiver of authorization for use and disclosure of protected health information (PHI) for the above-referenced research. This review was conducted through expedited review.

WAIVER OF HIPAA AUTHORIZATION

WCG IRB determined that documentation received from you satisfies the three requirements for a waiver of authorization. These requirements are:

1. The use or disclosure of the PHI involves no more than minimal risk to the individuals, based on the following elements:
 - a. An adequate plan to protect identifiers from improper use and disclosure;
 - b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and
 - c. Adequate written assurances that the PHI will not be reused or redisclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.
2. The research could not be practicably conducted without access to and use of the PHI; and
3. The research could not practicably be conducted without the waiver.

The Board has determined that this waiver of authorization for the use and access of the protected health information as described in the above referenced protocol, and in the information provided in the submitted waiver of authorization form, is necessary for conduct of this research.

REVIEW OF EXEMPTION REQUEST

This is in response to your request for an exempt status determination for the above-referenced protocol. WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance.

We believe the study is exempt under 45 CFR § 46.104(d)(4), because the research involves the use of identifiable private information/biospecimens; and information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

This exemption determination can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. You are responsible for ensuring that each site to which this exemption applies can and will accept WCG IRB's exemption decision.

WCG IRB's determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Please discuss with the local IRB authorities in the country where this activity is taking place to determine if local IRB review is required.

Please note that any future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date on its IRB exemption determinations.

If you have any questions, or if we can be of further assistance, please contact Tanna M. MacReynold, C.I.P., at 360-269-5584, or e-mail RegulatoryAffairs@wirb.com.

Sincerely,

 for

Kelly FitzGerald, PhD
Vice President, IRB Affairs

TMM:ts

D4-Exemption-Feather (02-25-2021)

cc: Elizabeth Harris, Anne Arundel Medical Center
John Moxley, Anne Arundel Research Institute
Lun Chen, Anne Arundel Health System Research Institute
WCG IRB Accounting
WCG IRB Work Order # 1-1405005-1



Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY DATA COLLECTION TOOL

Multicenter Study: Wound Management in Emergency Colorectal Surgery: To Close or Not to Close?

1. Enrolling Center: _____
2. Patient Number: _____

The following sheets are for annotation. All data will be entered electronically at each site into REDCap for secure/encrypted electronic sharing with the coordinating site.

Demographics (3-7):

3. Age _____
4. Sex _____
5. Race:

Asian	Native Hawaiian or Other Pacific Islander	Black or African American
White	American Indian	Other

6. Ethnicity: Hispanic or Latino Not Hispanic or Latino
7. BMI _____

Past Medical History (8-24) (Circle all that apply)

Diabetes Mellitus	Liver disease	AIDS
Chronic Kidney Disease	Chronic Steroid Use	Congestive Heart Failure
Myocardial Infarction	Chronic Pulmonary Disease	Peripheral Vascular disease
Stroke	Chronic Anticoagulation/dual antiplatelet therapy	Current Smoking
Rheumatic or Connective tissue disorder	Previous Abdominal Surgery	Cancer
Chemotherapy		

Charlson Comorbidity Index Score _____

Lab values/Pre-operative exam (use worst value prior to index operation) (25-42):

Vital Signs: Tmax: ____°C HR: ____ bpm RR: ____ /min SBP: ____ mmHg

MAP: ____ mmHg

Glasgow Coma Scale (3-15): ____ Intubated: YES NO

Continuous Vasopressors YES NO If YES, please specify: ____

ASA PS Classification I II III IV V

WBC ____x10 ³ /μL	Hgb ____g/dL	Hct ____%	Platelet ____10 ³ /μL
pH ____	Base Exc ____mmol/L	PT ____	PTT ____
INR ____	Albumin ____g/dL	Creatinine ____mg/dL	Bilirubin ____mg/dL
Lactate ____mmol/L			

Indication for operation (43) (Circle One):

Obstruction	Hernia	Ischemia
Diverticulitis	Infectious Colitis	Intestinal Arterial Ischemia of Bowel
Bleeding	Other ____	

AAST Organ-Specific EGS Grade (44) (Circle One): I II III IV V N/A

Management Variables

Intra-Operative Variables (45-46) (index operation):

Length of index operation: ____minutes

Antibiotic prophylaxis

Administration: YES NO

Redosing: YES NO N/A

Total Intra-op blood products/Fluid given (47-52):

PRBC _____units	FFP _____units	Platelets _____packs
Cryo _____units	Non-blood Colloid _____mL	Crystalloid _____mL

Estimated Blood Loss (53): _____mL

Intra-operative physiology (54-56):

Hypotension (single measurement of SBP <90mmHg):	YES	NO
Vasopressor therapy (IV infusion at any time intra-op):	YES	NO
Hypothermia (single body temperature recording <36°C):	YES	NO

Procedure type (57-60):

Right Colon	Left Colon	Rectum
Other _____		

Wound Classification (61-64):

Clean	Clean - Contaminated	Contaminated
Dirty/Infected		

Damage control/open abdomen (65-68) (proceed to Outcomes if fascia closed at index operation):

Indication for open abdomen (*circle best that applies*):

Coagulopathy	Contamination burden	Shock
Abdominal Compartment syndrome	Second look	Other _____

Total number of operations prior to fascial/mesh/skin closure (*index operation = 1*) _____

Primary fascial closure achieved: YES NO

Skin closed at time of fascial closure: YES NO

Creation of stoma (69): YES NO

Wound management technique (70-73):

Skin closed	Skin loosely closed	Skin open
Other _____		

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Negative Pressure Wound Therapy within 24 hours of fascial closure (74): YES
NO

Outcomes:

Post-Operative Variables (75-76):

Delayed Primary Closure: YES NO

If yes: POD to DPC ____

Post-op steroid use: YES NO

Intra-abdominal complication (77-87) (Check all that apply, include post-operative day)

____ Intra-abdominal abscess (organ-space)	Post-operative day diagnosed ____
____ Superficial surgical site infection	Post-operative day diagnosed ____
____ Deep-incisional surgical site infection	Post-operative day diagnosed ____
____ Enteric fistula	Post-operative day diagnosed ____
____ Fascial dehiscence	Post-operative day diagnosed ____
____ Intra-abdominal hematoma	Post-operative day diagnosed ____
____ Superficial hematoma	Post-operative day diagnosed ____
____ Deep-incisional hematoma	Post-operative day diagnosed ____

Need for unplanned operative intervention for one or more of the above (*Circle one*):

YES NO

Need for placement of a percutaneous drain for one or more of the above (*Circle one*):

YES NO

Need for ultrasound guided aspiration for one or more of the above (*Circle one*):

YES NO

Need for initiation of antibiotic therapy for one or more of the above (*Circle one*):

YES NO

Other Complications (88-94) (circle all that apply):

Acute Renal Failure	ARDS	Deep Vein Thrombosis	Transfusion Reaction
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Myocardial Infarction	Stroke	Pulmonary Embolism
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Post-operative blood products (95-98) (administered within 72 hours of index operation):

PRBC ____units	FFP ____units	Platelets ____packs
Cryo ____units	Other _____	

Discharge Parameters (99-104):

Hospital LOS: _____Days

ICU LOS: _____Days

Time to last follow-up: _____Days

Disposition (Circle one):

Home	Acute Rehab	Skilled nursing facility	Hospice
Against medical advice	Morgue		

If Morgue, indicate the primary cause of death as indicated on the death certificate: ____

30 Day Unplanned Readmission: YES NO



EAST MULTICENTER STUDY DATA DICTIONARY

Wound Management in Emergency Colorectal Surgery: To Close or Not to Close?– Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

1. Enrolling center	A de-identifying letter assigned by the PI to each site
2. Patient number	A de-identifying number assigned by each site to each patient

Demographics

3. Age	Age of the patient enrolled in the study at time of surgery
4. Sex	Sex of the patient enrolled in the study
5. Race	Race of the patient enrolled in the study
6. Ethnicity	Ethnicity of the patient enrolled in the study
7. BMI	Body Mass Index of the patient enrolled in the study at the time of surgery

Past Medical History: *Select all that apply*

8. Diabetes Mellitus	Includes all patients with diabetes treated with insulin or oral hypoglycemic agents, but not diet alone. End organ-damage includes retinopathy, neuropathy, nephropathy, or brittle diabetes. Select NO if patient is controlled with diet-modification alone. Diabetes during pregnancy alone should not be counted
9. Liver disease	Mild disease includes chronic hepatitis (B or C) or cirrhosis without portal hypertension. Moderate disease consists of cirrhosis with portal hypertension, but without bleeding. Severe disease consists of patients with ascites, chronic jaundice, portal hypertension, a history of variceal bleeding, or those with prior liver transplant.
10. AIDS	Acquired immune deficiency syndrome includes patients with definite or probable AIDS. Does not include those who are HIV positive, asymptomatic, and well-managed with medical therapy
11. Chronic kidney disease	Baseline elevation of serum creatinine ≥ 3.0 mg/dL, need for outpatient hemodialysis, or prior renal transplant.
12. Chronic Steroid Use	Use of systemic steroids for greater than 3 months at the time of surgery.
13. Congestive heart failure	Heart failure in which the heart is unable to maintain adequate circulation of blood in the bodily tissues or to pump out the venous blood returned. This includes

	patients who have had exertional or paroxysmal nocturnal dyspnea and who have responded symptomatically (or on physical examination) to digitalis, diuretics, or afterload reducing agents. Additionally, chest x-ray showing pulmonary vascular redistribution would qualify.
14. Myocardial infarction	Documented history of a myocardial infarction. Should not be based solely on EKG changes
15. Chronic pulmonary disease	Chronic pulmonary disease includes patients with asthma, chronic bronchitis, emphysema, and other chronic lung disease who have ongoing symptoms such as dyspnea or cough with mild or moderate activity. This includes patients who are dyspneic with slight activity, with or without treatment and those who are dyspneic with moderate activity despite treatment, as well as patients who are dyspneic at rest, despite treatment, those who require constant oxygen, those with CO2 retention, and those with a baseline PO2 below 50 Torr.
16. Peripheral vascular disease	Peripheral vascular disease includes patients with intermittent claudication or those who had a bypass for arterial insufficiency, those with gangrene or acute arterial insufficiency, and those with a treated or untreated aortic aneurysm (6 cm or larger).
17. Stroke	Stroke includes patients with a documented history of an intracerebral hemorrhage or thrombus. Transient ischemia attacks should be included in this population
18. Anticoagulant or Dual Anti-platelet use	The current use of Dabigatran/Pradaxa, Rivaroxaban/Xarelto, Apixaban/Eliquis for any cause. The current use of warfarin/Coumadin at any goal INR OR two of the following: aspirin, Clopidogrel/Plavix, or ticagrelor/Brilinta for any cause.
19. Current Smoking	Patient reports smoking 100 cigarettes in his/her lifetime and who currently smokes cigarettes.
20. Rheumatic or Connective tissue disorder	Rheumatologic disease includes patients with systemic lupus erythematosus, polymyositis, mixed connective tissue disease, rheumatoid arthritis, polymyositis, polymyalgia rheumatic, vasculitis, sarcoidosis, Sjögrens syndrome, or any other systemic vasculitis.
21. Previous Abdominal Surgery	Any previous operative procedure in which the abdominal cavity was opened
22. Cancer	Lymphoma includes patients with Hodgkins, lymphosarcoma, Waldenstrom's macroglobulinemia, myeloma, and other lymphomas. Leukemia includes patients with acute and chronic myelogenous leukemia, acute and chronic lymphocytic leukemia, and polycythemia vera. Solid tumor consists of patients with solid tumors including breast, colon, lung, prostate, melanoma, stomach, etc. Specify which solid tumor the patient had. Indicate whether the patient had a metastatic solid tumor
23. Chemotherapy	Pt enrolled is currently receiving chemotherapy
24. Charlson Comorbidity Index (CCI) Score	Numerical value for CCI score 0-37. Weighted calculation via https://www.mdcalc.com/charlson-

Lab values/Pre-operative exam: *(Use worst value prior to index operation)*

25. Vital signs	Indicate TMAX (° C), heart rate (HR; beats/minute), respiratory rate (RR; respirations/minute), systolic blood pressure (SBP; mmHg), and mean arterial pressure (MAP; mmHg)
26. Glasgow coma scale	Numerical value for Glasgow Coma Scale (3-15).
27. Intubated	Select yes if patient had oral or nasal airway in place prior to procedure initiation.
28. Continuous vasopressor infusion	Select YES if the patient required a continuous vasopressor infusion to maintain a target mean arterial pressure. Include the use of any of the following agents: norepinephrine, vasopressin, dopamine, dobutamine, neosynephrine, milrinone, epinephrine. Indicate which agent(s) was used.
29. ASA PS Classification	Specify ASA Physical Status Classification based on definitions below

ASA PS Classification	Definition	Adult Example
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include: current smoker, social alcohol drinker, pregnancy, obesity, well controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include: morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD with regularly scheduled dialysis, history of MI, CVA, TIA, or CAD/stents
ASA IV	A patient with severe systemic disease this is a constant threat to life	Examples include: recent MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis.
ASA V	A moribund patient who is not expected to survive without the operation	Examples include: ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in face of significant cardiac pathology or multiple organ/system dysfunction

30. WBC count	Numerical value for white blood cell (WBC) count (x103 /uL)
31. Hgb	Numerical value for hemoglobin (g/dL)
32. Hct	Numerical value for hematocrit (%)
33. Platelet count	Numerical value for platelet count (x103 /uL).
34. pH	Numerical value for arteria blood pH. If no pH was obtained enter 999- do not enter 0
35. Base excess	Enter the numerical value for the arterial base excess (mmol/L). If no base excess was obtained, enter 999- do not enter 0
36. PT	Numerical value for prothrombin time
37. PTT	Numerical value for partial thromboplastin time
38. INR	Numerical value for International Normalized Ratio (INR)
39. Albumin	Numerical value for Albumin (g/dL). If no albumin was obtained, enter 999- do not enter 0
40. Creatinine	Numerical value for creatinine (mg/dL); enter 999 if patient is receiving preoperative renal replacement therapy.
41. Bilirubin	Numerical value for bilirubin (mg/dL). If no bilirubin was obtained, enter 999- do not enter 0
42. Lactate	Numerical value for lactate (mmol/L). If no Lactate was obtained, enter 999 – do not enter 0.

Indication for operation

43. Diagnosis	Single choice for best description of diagnosis. Choose from: obstruction, hernia, ischemia, diverticulitis, infectious colitis, intestinal arterial ischemia of bowel, bleeding, other. Please specify "other"
44. AAST Organ-Specific EGS Grade for Anatomic Severity of Disease	For diagnoses of diverticulitis, obstruction, ischemic bowel, intestinal arterial ischemia of the bowel, or infectious colitis indicate the AAST grade. Please specify grade based on operative findings as outlined below.

Grade	AAST Disease Grade Description	Intestinal obstruction (Small and large bowel)	Ischemic Bowel	Diverticulitis
I	Disease confined to the organ with minimal abnormality	Partial obstruction	Ischemia without tissue loss	Colonic inflammation
II	Confined to the organ with severe abnormality	Complete obstruction without bowel ischemia	Ischemia with mucosal ulceration only- no transmural infarction	Colon microperforation or pericolic phlegmon without abscess
III	Local extension beyond the organ	Complete obstruction, bowel ischemic but viable	Segmental transmural infarction without perforation	Localized pericolic abscess
IV	Regional extension beyond the organ	Complete obstruction with gangrenous bowel OR perforation with local spillage	Segmental transmural infarction with perforation	Distant abscesses
V	Widespread extension beyond the organ	Perforation with diffuse peritoneal contamination	Pan-intestinal infarction	Free colonic perforation with

			generalized peritonitis
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Grade	Hernia (Internal or Abdominal Wall)	Intestinal Arterial Ischemia of the Bowel	Infectious Colitis
I	Reducible	Bowel ischemia without tissue loss	Mucosal disease with positive cultures or other confirmatory laboratory test
II	Incarcerated without bowel ischemia	Bowel ischemia with mucosal ulceration only, without transmural infarction	Localized colon wall thickening by radiographic imaging OR pseudomembranes on endoscopy
III	Incarcerated with bowel ischemia but viable	Segmental transmural bowel infarction without perforation	Colon wall thickening with ascites OR diffuse colonic dilation OR diffuse coalescing pseudomembranes
IV	Incarcerated with gangrenous bowel OR perforation with local spillage	Segmental transmural bowel infarction with perforation	Localized colonic necrosis with or without perforation or abscess
V	Incarcerated with perforation and diffuse peritoneal contamination	Pan-intestinal infarction	Diffuse transmural colonic necrosis with or without perforation or abscess

Management Variables

Intra-Operative Variables

45. Length of index operation	Enter in minutes the duration of the index operation
46. Antibiotic prophylaxis	Administration: Select YES if given within 60 min of incision (or with vancomycin or levofloxacin within 120 min). Redosing: Select YES if using cefazolin and cefoxitin and was administered 4 hours or 2 hours post initial dose respectively. Select NO if using cefazolin and cefoxitin and was not administered 4 hours or 2 hours post initial dose respectively. Select NA if other antibiotic was used OR procedure was less than time needed to redose.

OR Blood Products/Fluids administered: *How many units or mL of each of the following did the patient receive intraoperatively*

47. PRBC	Numerical value for the units of packed red blood cells transfused
48. FFP	Numerical value for the units of fresh frozen plasma transfused
49. Platelets	Numerical value for the packs of platelets transfused

50. Cryo	Numerical value for the units of cryoprecipitate transfused
51. Non-blood colloid	Numerical value for non-blood colloid transfused (albumin, hespan, hextend, other colloid; mL)
52. Crystalloid	Numerical value for all crystalloid administered

Estimated Bloos Loss:

53. Estimated blood loss	Numerical value for the total amount of blood loss in the operating room (mL)
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Intra-operative physiology: *Indicate whether the following criteria were met at any time intra-operatively*

54. Hypotension	Select YES if there was at least one episode of SBP < 90mmHg
55. Vasopressor therapy	Select YES if any of the following agents were used as continuous infusions: norepinephrine, vasopressin, dopamine, dobutamine, neosynephrine, milrinone, epinephrine
56. Hypothermia	Select YES if the patient's body temperature was below 36.0°C for at least one recorded time point

Procedure Type: *Select all that apply*

57. Right Colon	Procedure involved resection of cecum, ascending colon or mid transverse colon
58. Left Colon	Procedure involved resection of distal transverse colon, descending colon, sigmoid colon
59. Rectum	Procedure involved resection of rectum
60. Other	Procedure involved resection of colon not specified, please explain

Wound Classification: *Select one that applies*

61. Clean	Select if <i>initial</i> operative findings have an uninfected operative wound without inflammation; respiratory, alimentary, genital or uninfected urinary tracts are not entered
62. Clean-Contaminated	Select if <i>initial</i> operative findings in the respiratory, alimentary, genital or uninfected urinary tracts are electively entered; without unusual contamination
63. Contaminated	Select if <i>initial</i> operative findings have open, fresh, accidental wounds, with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered
64. Dirty	Select if <i>initial</i> operative findings have old traumatic wounds with retained devitalized tissue or those that involve existing clinal infection or perforated viscera

Damage control/open abdomen: *Proceed to outcomes if fascia closed at index operation*

65. Indication for open abdomen	Select based on operative note documentation: coagulopathy, contamination burden, shock, abdominal compartment syndrome, to facilitate a second look (ie-
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	early re-exploration for bowel viability), other. Please specify if OTHER is chosen
66. Total number of surgical operations	Total number of surgical operations until closure achieved. Index operation = 1. Do not include procedures done by radiologists or interventional radiologists
67. Primary fascial closure	Select YES if primary fascial closure was achieved during the hospital course
68. Skin closed at time of fascial closure	Select YES if skin was closed at the time of fascial closure

Stoma:

69. Creation of stoma	Select YES if creation of stoma was formed during any procedures between index operation and fascial closure.
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Wound management technique: *Select one that applies*

70. Skin closed	Select if skin was completely closed with staples or suture at fascial closure
71. Skin loosely closed	Select if skin was closed, but incompletely to allow for packing or drainage at fascial closure
72. Skin open	Select if no portion of the skin was closed at fascial closure
73. Other	Specify other technique used for skin management at fascial closure

Wound VAC

74. Negative Pressure Wound Therapy	Select YES if negative pressure wound therapy was used to manage wound within 24 hours of fascial closure
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Outcomes

Post-operative variables

75. Delayed Primary Closure	Select YES if delayed primary closure was completed and indicate post-operative day completed
76. Post-op Steroid Use:	Select YES if systemic steroids were administered post-operatively at any point during hospitalization

Intra-abdominal complications: *Check all that apply and document the post-operative day that the complication first occurred*

77. Intra-abdominal abscess	Infection occurs within 30 days of the operation if no implant is left in place or within 1 year if implant is in place and involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure, and patient has at least one of the following: 1. Purulent drainage from a drain that is placed into the organ/space. (e.g., closed suction drainage system, open drain, T-tube drain, CT guided drain) 2. Organisms are identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment
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	3. An abscess or other evidence of infection involving the organ/space detected on gross anatomical or radiographic examination. May be diagnosed through a combination of clinical indicators such as pain or peritonitis and biochemical markers such as fever or tachycardia WITH either intraoperative findings OR radiologic studies showing fluid collections or gas-containing collections
78. Superficial surgical site infection	Infection occurs within 30 days of the operation and involves only skin and subcutaneous tissue of the incision with at least one of the following: 1. Purulent drainage from the incision 2. Organisms isolated from an aseptically obtained fluid culture or tissue from the superficial incision 3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture negative.
79. Deep-incisional surgical site infection	Infection occurs within 30 days of the operation if no implant is left in place or within 1 year if implant is in place and infection appears to be related to the operation. Infection involves deep soft tissues (fascial and muscle layers) of the incision with at least one of the following: 1. Purulent drainage from deep incision but not from the organ/space component of the surgical site 2. A deep incision spontaneously dehisces or is deliberately opened when the patient has at least one of the following signs or symptoms: fever (body temperature >38o C), localized pain or tenderness 3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation or radiographic examination
80. Enteric fistula	Enterocutaneous or entero-atmospheric fistula: Clinical diagnosis, defined as free communication between the skin or outside surface of an open abdomen and any portion of the GI tract.
81. Fascial dehiscence	Separation of the surgical wound at the level of the fascia. May be clinically OR radiographically diagnosed.
82. Intra-abdominal hematoma	Bleeding within the abdominal cavity occurring within 30 days of the operation or other procedure involving the abdomen (ie- drain placement, paracentesis).
83. Superficial hematoma	Bleeding that occurs at the site of the operation and involves only the layers of the skin
84. Deep-incisional hematoma	Bleeding that occurs at the site of the operation and involves the deep soft tissue (fascial and muscle layers) of the incision.
85. Need for unplanned operative intervention	Select YES if the patient required unplanned re-operative intervention for one of these complications (76-83).
86. Need for placement of a percutaneous drain	Select YES if the patient required unplanned placement of a percutaneous drain for one of these complications (76-83).
87. Need for ultrasound guided aspiration	Select YES if the patient required unplanned ultrasound guided aspiration for one of these complications (76-83).

Other Complications: *Select all that apply*

88. Acute renal failure	Post-operative elevation of serum creatinine \geq 2.0 mg/dL
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	in a patient without antecedent renal dysfunction OR acute need for renal replacement therapy.
89. Acute respiratory distress syndrome	Mild ARDS: The PaO ₂ /FiO ₂ is > 200 mmHg, but ≤ 300 mmHg, on a ventilator with a positive end-expiratory pressure (PEEP) or continuous positive airway pressure ≥ 5 cm H ₂ O. Moderate ARDS: The PaO ₂ / FiO ₂ is > 100 mmHg, but ≤ 200 mmHg, on a ventilator with a PEEP ≥ 5 cm H ₂ O. Severe ARDS: The PaO ₂ / FiO ₂ is ≤ 100 mmHg on a ventilator with a PEEP ≥ 5 cm H ₂ O.
90. Deep vein thrombosis	Presence of one or more thrombi in the deep veins. Can include upper or lower extremity as diagnosed by ultrasound or CT scan
91. Transfusion reaction	Indicate if the patient had a documented blood transfusion reaction
92. Myocardial infarction	Detection of a rise of cardiac biomarker values (preferably troponin) with at least one of the following: - Symptoms of ischemia - New or presumed new significant ST-segment changes or new left bundle branch block - New Q waves in the EKG - Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality - Identification of intracoronary thrombus
93. Stroke	Confirmed stroke (hemorrhagic or thrombotic) confirmed by MRI or CT scan
94. Pulmonary embolism	Evidence of a clot within the pulmonary system and confirmed with imaging (i.e.- CT, V/Q scan)

Post-operative blood products: *How many units or mL of each of the following did the patient receive within 72 hours of the index operation*

95. PRBC	Numerical value for the units of packed red blood cells transfused
96. FFP	Numerical value for the units of fresh frozen plasma transfused
97. Platelets	Numerical value for the packs of platelets transfused
98. Cryo	Numerical value for the units of cryoprecipitate transfused

Discharge parameters: *Note: for calculation of days, refer to day of admission as hospital day number 1. (ICU = Intensive Care Unit, LOS = length of stay)*

99. Hospital LOS	Free text entry for number of consecutive hospitalized days
100. ICU LOS	Free text entry of number of consecutive days spent in ICU.
101. Time to last follow-up	Free text entry of number of days from initial operation to last documented follow-up. If there was no follow-up after discharge, then calculate time from initial operation to time to discharge.
102. Discharge Disposition	Select from the following: home, acute care facility, skilled nursing facility, other healthcare facility, hospice, left against medical advice, deceased.
103. If morgue, indicate cause of death	If the patient's discharge disposition was morgue, free text the primary cause of death as indicated on the death certificate
104. 30 day unplanned readmission	Any unplanned readmission for any cause within 30 days of the discharge date for the index admission.