



Institutional Review Board
72 E. Concord St., Robinson 4 – Suite 414
Boston, Massachusetts 02118-2307
Tel: 617-358-5372

Title of Study: Direct Peritoneal Resuscitation in Emergency General Surgery: A EAST Multicenter Trial
IRB Number: H-46410

RE: Initial Review Submission Form
Review Type: Exempt
Action: Exempt Determination

Date of Action: 11/26/2025
Status Check-In Due Date: 11/25/2028

Funding Source: Department/Internal

November 26, 2025

Dear Megan Janeway, MD,

A qualified member of the Institutional Review Board (IRB) staff has reviewed the above referenced submission and has determined that the study qualifies for an exemption determination under the policies and procedures of the Human Research Protection Program (<http://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#10.2.4>) under category 9.

This exemption determination is valid through the expiration date indicated above. You may close the study at any time when research activities are complete. You will be asked to file a brief status report prior to the above expiration date to indicate whether research activities are ongoing to renew this exemption determination.

This determination corresponds with the versions of the application and attachments in the electronic system most recently given an outcome of 'Reviewed' as of the date of this letter.

This determination was based on equivalent protections for research without external funding. You must submit an amendment to report obtaining any new funding within 14 days of learning of the funding change.

Protocol Specific Determinations

Waiver of HIPAA Authorization for Research approved per 45 CFR 164.512 (i) (2) (ii)

Approved HIPAA Data Sets:

Records Selection Criteria:

Inclusion Criteria: Patients eligible for inclusion must meet the following criteria:

- Adult patients (≥18 years) undergoing laparotomy for non-traumatic emergency general surgery diagnoses, including intra-abdominal sepsis, bowel perforation, bowel obstruction, pancreatitis, or intra-abdominal hypertension between 01/01/2021 and 12/31/2024
- Patients who require temporary abdominal closure with the need for re-exploration (open abdomen)
- Patients must be managed with either direct peritoneal resuscitation (DPR) or conventional resuscitation during their treatment.

Exclusion Criteria

- Pregnant patients
- Patients under 18 years of age
- Incarcerated individuals at the time of presentation

Records Date Range:

01/01/2021 and 12/31/2024

Records Data Fields:

- All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

Age

- Medical record numbers

All determinations regarding this project have been made based on the information submitted by the investigator. Any modifications to the research plan that would possibly change this exempt determination or that meet the criteria for amendment submission as outlined in Section 10.2.4.1 (for example, changes in recruitment procedures, confidentiality protections, or use of PHI) must be submitted to the IRB for review and confirmation of continued exempt status prior to initiation of the change.

As principal investigator, you are reminded that you must comply with the responsibilities listed here <http://www.bumc.bu.edu/irb/maintaining-irb-approval/responsibilities-of-the-principal-investigator/> with the exception of point #13. PLEASE NOTE: Minor changes to the study that do not affect the exempt determination do not need to be submitted to the IRB. You will be asked to summarize such changes if and when you renew the exemption determination.

Resources

The Clinical Research Resources Office (CRRO) has a number of tools, templated documents, and guidance available for the research community to use. These resources are highly recommended to help teams meet protocol adherence and regulatory standards. Please review the available resources at the CRRO Resource Library.

Sincerely,

Jerry Lu

IRB Analyst



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

**EAST MULTICENTER STUDY
DATA DICTIONARY**

**Direct Peritoneal Resuscitation in Emergency General Surgery: A EAST Multicenter Trial
Data Dictionary**

Data Entry Points and appropriate definitions / clarifications: Please clarify *missing* and *not applicable* for absent values.

Entry space	Definition / Instructions
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Standard Study Questions

Admit Date	Admission date of the patient enrolled
Admit Time	Admission time of the patient enrolled
Age	Age of patient enrolled at time of admission, in years

Case Information

Biological Sex	Sex of patient enrolled, male or female
Race	Self-reported Race of patient enrolled - report all
Ethnicity	Self-reported Ethnicity of patient enrolled, Non-Hispanic/Non-Latino or Hispanic/Latino
Language	Primary Language of patient enrolled
Insurance	Primary Insurance Carrier of the patient enrolled

Clinical Characteristics at Admission

Body Mass Index (BMI)	BMI of the patient enrolled
Smoking Status	Current smoking status of patient enrolled – active smoker, former smoker, nonsmoker
Recent Steroid Use	Steroid use within 7 days – yes/no
Charlson Comorbidity Index (CCI)	Calculated CCI of the patient enrolled, at admission
ASA Classification	Calculated ASA of the patient enrolled, at admission

Severe Organ Dysfunction

Presence of acute renal failure requiring HD, ARDS, Acute hepatic failure prior to OR, yes/no

Physiologic Data and Lab Values– During the 24 hours prior to index operation.

Sodium, Na ⁺	During 24-hour period prior to index operation, (in mEq/L)
Potassium, K ⁺	During 24-hour period prior to index operation, (in mEq/L)
Bicarb, CO ₂	During 24-hour period prior to index operation, (in mEq/L)
BUN	During 24-hour period prior to index operation, (in mg/dL)
Serum Creatinine, Serum Cr	During 24-hour period prior to index operation, (in mg/dL)
White Blood Cell Count, WBC	During 24-hour period prior to index operation, (x10 ⁹ /L)
Hematocrit, Hct	During 24-hour period prior to index operation, (%)
Platelets	During 24-hour period prior to index operation, (x 10 ³ /μL)
Base Deficit	During 24-hour period prior to index operation, (in mmol/L)
International normalized ratio, INR	During 24-hour period prior to index operation
Total Protein	During 24-hour period prior to index operation, (in g/dL)
Albumin	During 24-hour period prior to index operation, (in g/dL)
Total Bili	During 24-hour period prior to index operation, (in mg/dL)
AST	During 24-hour period prior to index operation, (in U/L)
ALT	During 24-hour period prior to index operation, (in U/L)
Alkaline Phosphate	During 24-hour period prior to index operation, (in U/L)
Lactate	During 24-hour period prior to index operation, (in mmol/L)
pH	During 24-hour period prior to index operation
Body Temperature	During 24-hour period prior to index operation, lowest value (in degrees Celsius)

Heart Rate, HR	During 24-hour period prior to index operation, (in beats per minute)
Systolic Blood Pressure, SBP	During 24-hour period prior to index operation, median value (in mmHg)
Diastolic Blood Pressure, DBP	During 24-hour period prior to index operation, median value (in mmHg)
Mean Arterial Pressure, MAP	Lowest documented value during 24-hour period prior to index operation, (in mmHg)
Respiratory Rate, RR (assisted/unassisted)	During 24-hour period prior to index operation, median value, (in breaths per minute)
PCO ₂ (venous)	During 24-hour period prior to index operation, (in mm Hg)
PaO ₂ (venous)	During 24-hour period prior to index operation, (in mm Hg)
PaO ₂ /FiO ₂ ratio	Lowest value during 24-hour period prior to index operation
SOFA score	During 24-hour period prior to index operation
APACHE II	During 24-hour period prior to index operation
SAPS II score	During 24-hour period prior to index operation
Organ Injury score	During 24-hour period prior to index operation
Vasopressor Use, n	First 24 hours, yes/no
Total crystalloid	During 24-hour period prior to index operation, Free text entry of total crystalloids infused in the 24 hours prior to surgery (in mL)
Transfusion volume	During 24-hour period prior to index operation, free text entry of total colloid infused in 24 hours prior to surgery. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin) (in mL)
Urine output	During 24-hour period prior to index operation, (in mL/hour)
Blood Products Transfused	During 24-hour period prior to index operation, yes/no

Procedural Variables at Index Operation

ICD-10 Primary Operative Diagnosis	Indication for operation, numeric
CPT Index operation	CPT code for index operation
Time to Operative Intervention	Numerical value from admission to OR, (in hours). >0.5hours, round up, if exact time is not clear, best estimate based on documentation available.
Indication for leaving abdomen open	Select primary indication: <ul style="list-style-type: none">▪ Bowel discontinuity/staged reconstruction.▪ Visceral edema/intraabdominal hypertension/pancreatitis▪ Damage control; performed in setting of triad of acidosis / hypothermia / coagulopathy or hemodynamic instability▪ Second look; early re-exploration to evaluate for bowel viability, ischemia▪ Other: Open field
Intra-operative blood loss (mL)	Recorded intra-operative blood loss (in mL)
Intra-operative crystalloid Volume given	Recorded intra-operative crystalloid given (in mL)
Total intra-operative blood products given	Total volume of intra-operative blood products given during the initial operation (PRBC, FFP, Platelets, cryoprecipitate) (in mL)
Total fluid balance from OR	Calculated from prior values
Intra-operative peritoneal soiling	Presence of peritoneal contamination
Malignancy Identified	Yes/No
Operative Interventions	Check all that apply <ul style="list-style-type: none">▪ Gastric Repair▪ Large Bowel Resection▪ Small Bowel Resection▪ Number of resections (each segment =1 resection)▪ Left in discontinuity▪ Other
Type of temporary closure utilized	Primary temporary closure technique <ul style="list-style-type: none">▪ Direct Peritoneal Resuscitation▪ Wittman Patch▪ Suture Traction▪ ABRA System▪ Negative pressure dressing (NPWT)

Physiologic Data and Lab Values– at 24-hours post index operation AND 48-hours post index operation

Sodium, Na ⁺	At 24 hours and 48 hours post index operation, (in mEq/L)
Potassium, K ⁺	At 24 hours and 48 hours post index operation, (in mEq/L)
Bicarb, CO ₂	At 24 hours and 48 hours post index operation, (in mEq/L)
BUN	At 24 hours and 48 hours post index operation, (in mg/dL)
Serum Creatinine, Serum Cr	At 24 hours and 48 hours post index operation, (in mg/dL)
White Blood Cell Count, WBC	At 24 hours and 48 hours post index operation, (x10 ⁹ /L)
Hematocrit, Hct	At 24 hours and 48 hours post index operation, (%)
Platelets	At 24 hours and 48 hours post index operation, (x 10 ³ /μL)
Base Deficit	At 24 hours and 48 hours post index operation, (in mmol/L)
International normalized ratio, INR	At 24 hours and 48 hours post index operation
Total Protein	At 24 hours and 48 hours post index operation, (in g/dL)
Albumin	At 24 hours and 48 hours post index operation, (in g/dL)
Total Bili	At 24 hours and 48 hours post index operation, (in mg/dL)
AST	At 24 hours and 48 hours post index operation, (in U/L)
ALT	At 24 hours and 48 hours post index operation, (in U/L)
Alkaline Phosphate	At 24 hours and 48 hours post index operation, (in U/L)
Lactate	At 24 hours and 48 hours post index operation, (in mmol/L)
pH	At 24 hours and 48 hours post index operation
Body Temperature	At 24 hours and 48 hours post index operation, (in degrees Celsius)
Heart Rate, HR	At 24 hours and 48 hours post index operation, median value (in beats per minute)

Systolic Blood Pressure, SBP	At 24 hours and 48 hours post index operation, median value (in mmHg)
Diastolic Blood Pressure, DBP	At 24 hours and 48 hours post index operation, median value (in mmHg)
Mean Arterial Pressure, MAP	At 24 hours and 48 hours post index operation, median value (in mmHg)
Respiratory Rate, RR (assisted/unassisted)	At 24 hours and 48 hours post index operation, median value (in breaths per minute)
PCO ₂ (venous)	At 24 hours and 48 hours post index operation, (in mm Hg)
PaO ₂ (venous)	At 24 hours and 48 hours post index operation, (in mm Hg)
PaO ₂ /FiO ₂ ratio	At 24 hours and 48 hours post index operation
SOFA score	At 24 hours and 48 hours post index operation
APACHE II	At 24 hours and 48 hours post index operation
SAPS II score	At 24 hours and 48 hours post index operation
Organ Injury score	At 24 hours and 48 hours post index operation
Vasopressor Use, n	At 24 hours and 48 hours post index operation, yes/no
Total crystalloid	At 24 hours and 48 hours post index operation. Free text entry of total crystalloids infused in the 24 hours post index operations and total crystalloids infused in the 48 hours post index operation surgery (in mL)
Transfusion volume	Volume infused from index operation to 24 hours and index operation to 48 hours. Free text entry of total colloid infused. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin, hespan, hextend) (in mL)
Urine output	At 24 hours and 48 hours post index operation, (in mL/hour)
Blood Products Transfused	At 24 hours and 48 hours post index operation, yes/no

Procedural Variables at Subsequent Operation(s)

Total number of re-explorations

Total number of re-explorations after initial operation

Interval time to first re-exploration

Free entry of time from index operation to first re-exploration (in hours)

Operative Interventions

Check all that apply

- Gastric Repair
- Large Bowel Resection
- Small Bowel Resection
- Number of resections (each segment =1 resection)
- Left in discontinuity
- Bowel anastomosis
- Other

Definitive Closure Achieved

Yes/No

Indication for leaving abdomen open

Select primary indication:

- Bowel discontinuity/staged reconstruction.
- Visceral edema/intraabdominal hypertension/pancreatitis
- Damage control; performed in setting of triad of acidosis / hypothermia / coagulopathy or hemodynamic instability
- Second look; early re-exploration to evaluate for bowel viability, ischemia
- Other: Open field

Fascial traction/abdominal closure techniques

Type of temporary/definitive closure utilized. Check all that apply

- Direct Peritoneal Resuscitation
- Wittman Patch
- Suture Traction
- ABRA System
- Negative pressure dressing (NPWT)
- Progressive Partial Facial Closure
- Complex Abdominal Wall Reconstruction/Component Separation
- Fascial Bridge Closure - Bridging Mesh Closure with biologic prostheses/synthetic absorbable mesh/skin grafting
- Planned Ventral Hernia – May utilize bridging Mesh with biologic prostheses/synthetic absorbable mesh/skin grafting
- Other

Interval time to second re-exploration

Free entry of time from first re-operation to second re-exploration (in hours)

Operative Interventions

Check all that apply

- Gastric Repair
- Large Bowel Resection
- Small Bowel Resection
- Number of resections (each segment =1 resection)
- Left in discontinuity

- Bowel anastomosis
- Other

Definitive Closure Achieved Yes/No

Indication for leaving abdomen open Select primary indication:

- Bowel discontinuity/staged reconstruction.
- Visceral edema/intraabdominal hypertension/pancreatitis
- Damage control; performed in setting of triad of acidosis / hypothermia / coagulopathy or hemodynamic instability
- Second look; early re-exploration to evaluate for bowel viability, ischemia
- Other: Open field

Fascial traction/abdominal closure techniques

Type of temporary/definitive closure utilized. Check all that apply

- Direct Peritoneal Resuscitation
- Wittman Patch
- Suture Traction
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- Negative pressure dressing (NPWT)
- Progressive Partial Facial Closure
- Complex Abdominal Wall Reconstruction/Component Separation
- Fascial Bridge Closure - Bridging Mesh Closure with biologic prostheses/synthetic absorbable mesh/skin grafting
- Planned Ventral Hernia – May utilize bridging Mesh with biologic prostheses/synthetic absorbable mesh/skin grafting
- Other

Outcomes

Primary Fascial Closure

Yes or No. Primary fascial closure is defined as closure of the fascia, without bridging material between fascial edges (synthetic or biologic) over the enteric contents.

Time to Abdominal Closure

Number of hospital days from index laparotomy to abdominal closure – abdominal closure may be primary fascial closure or delayed fascial closure with bridging techniques.

Number of Operations to Closure

Number of operations from index laparotomy to abdominal closure

Total Number of Trips to OR

Total number of trips to OR for any indication during admission

Intra-abdominal Complications

Check all that apply:

- Anastomotic leak
- Missed enterotomy
- Intra-abdominal bleeding requiring intervention
- Intra-abdominal abscess requiring intervention
- Enterocutaneous fistula formation - Defined as free communication between the skin or outside surface of an open abdomen and any portion of the enteric tract
- Evisceration / Dehiscence

Other Complications	<p>Check all that apply:</p> <ul style="list-style-type: none"> ▪ Surgical Site Infection ▪ Deep Vein Thrombosis (DVT), Pulmonary embolism (PE). Diagnosis must be confirmed radiographically ▪ Acute respiratory distress syndrome. ▪ Acute Renal Failure: Defined for the purpose of this study as new need for renal replacement therapy. ▪ Ventilator Associated Pneumonia ▪ Hospital Acquired Pneumonia ▪ Delirium
Unplanned Re-operation	Unplanned return to OR before or after closure – free text indication for return
Interval Procedure of Abdomen	Any non-operative procedure related to a complication of the index operations. For example, interventional radiology drainage of intra-abdominal or abdominal wall abscess, opening of skin, SSI management. Free text
Total Ventilator Days	Total days of mechanical ventilation after index operation.
Total ICU Days	Total days in the intensive care unit after index operation.
Total Hospital Days	Total days in the hospital for the admission.
Total net volume from index operation to closure	Total volume change (includes resuscitation and diuresis, crystalloid and colloid), net fluid balance per chart review of total I/O balance.
Discharge Disposition	Select from home, home with home PT, subacute rehab, acute rehab, skilled nursing facility, long term care, other facility
Presence of Incisional Hernia	If definitive fascial closure, was incisional hernia present at 3-6 months post- index operation.
30-day Mortality	Did patient expire within 30-days of admission, yes/no