Form 1

REVISE RCT170 Plate #001 Visit #000

Patient ID ☐☐☐☐☐☐☐ Patient Initials F ☐ L ☐ Date (dd/mm/yyyy) ☐☐ ☐☐ 2 0 ☐☐

SCREENING (Form 1)

	YES	NO
1. Inclusion Criteria (please mark the appropriate box with an '✖')		
1. Patient is ≥ 18 years of age	Y ☐	N ☐
2. Receiving invasive mechanical ventilation (endotracheal tube or tracheostomy) in an ICU and at the time of screening, in the opinion of the treating ICU physician, mechanical ventilation is expected to continue at least until the end of the day after tomorrow	Y ☐	N ☐
2. Exclusion Criteria (contraindications)		
1. MD considers Pantoprazole or placebo are indicated or contraindicated; reason: _____	Y ☐	N ☐
2. Pantoprazole contraindicated due to specific local product information	Y ☐	N ☐
Australia/New Zealand Sites Only: • Being treated with HIV protease inhibitors atazanavir (Reyataz) or nelfinavir (Viracept) • Being treated with high dose methotrexate defined as >300mg/day per chemotherapy • Documented cirrhosis or severe liver disease (e.g., INR > 5.0 due to liver disease) ***Canadian Sites Only:*** • Being treated with rilpivirine (Edurant) or atazanavir (Reyataz)		
3. Patient in whom a proton pump inhibitor (PPI) or a histamine-2 receptor antagonist (H_2RA) is indicated due to active bleeding or increased bleeding risk, defined as:		
a. Acute gastrointestinal bleeding (ICU physician's clinical opinion)	Y ☐	N ☐
b. Peptic ulcer bleeding within last 8 weeks of screening	Y ☐	N ☐
c. Severe esophagitis	Y ☐	N ☐
d. Current or recent Barrett's esophagus	Y ☐	N ☐
e. Zollinger-Ellison syndrome	Y ☐	N ☐
f. Any previous hospital admission for upper GI bleeding (receiving PPIs for mild dyspepsia or mild gastroesophageal reflux or an uncertain indication are not excluded)	Y ☐	N ☐
4. Invasive mechanical ventilatation for ≥ 72 hours pre-screening (including referring ICU/ER)	Y ☐	N ☐
5. Patient received > 24hours of PPI or H_2RA (this ICU admission including referring ICU)	Y ☐	N ☐
6. Being treated with, or need for, dual antiplatelet therapy (e.g., ASA **and** clopidogrel)	Y ☐	N ☐
7. Admitted for palliative care or physician is not committed to life-sustaining therapies	Y ☐	N ☐
8. Known or suspected pregnancy	Y ☐	N ☐
9. Other (e.g., recent gastric bypass, anaphylaxis requiring H_2RA), specify: _____	Y ☐	N ☐
3. Eligible Non-Randomized Patients		
1. Patient declines a priori consent, reason: _____	Y ☐	N ☐
2. Substitute decision maker (SDM) declines a priori consent, reason: _____	Y ☐	N ☐
3. Patient unable to consent, no SDM available and no deferred consent allowed	Y ☐	N ☐
4. MD declined, reason: _____	Y ☐	N ☐
5. Other reason patient/SDM not approached, specify: _____	Y ☐	N ☐
6. Randomized previously in REVISE Trial	Y ☐	N ☐

4. Patient Status (please check ONE box only) ☐ **Included,** proceed to **Randomization** ☐ **Eligible, non-randomized**

Proceed to Randomization

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Form 2

REVISE RCT170 Plate #003 Visit #000

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials F [ ] L [ ]

CONSENT (Form 2)

1. Consent Encounter

A. Consent timing: ☐ A priori (pre-randomization) ☐ Deferred

B. Consent request by: ☐ Research Coordinator ☐ Site Investigator ☐ ICU Physician

2. Was verbal or written informed consent obtained?

		In ICU	In Hospital	Post Hospital	Date (dd/mm/yyyy)	Consent Method: In-person	Telephone
☐ Yes, consent obtained from:	Patient	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐
	Substitute decision maker (SDM)	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐
	Other, specify:	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐

_____

In New Zealand, discussion of patient wishes with family or friend documented? ☐ Yes ☐ No

		In ICU	In Hospital	Post Hospital	Date (dd/mm/yyyy)	Consent Method: In-person	Telephone
☐ No, consent declined by:	Patient	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐
	Substitute decision maker (SDM)	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐
	Other, specify:	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]	☐	☐

Reason for decline, specify: ☐ Prefers PPI ☐ Prefers placebo ☐ Distressed SDM ☐ Family discord ☐ Other, specify: _____

☐ No consent, patient lacked capacity to provide consent and no SDM available throughout hospital stay

☐ No consent, patient deceased and was never competent to provide consent, and no SDM available throughout hospital stay

3. Consent obtained then revoked?

		In ICU	In Hospital	Post Hospital	Date (dd/mm/yyyy)
☐ No, not applicable	Patient	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]
☐ Yes, consent by:	Substitute decision maker (SDM)	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]
	Other, specify:	☐	☐	☐	[ ][ ] [ ][ ] 20[ ][ ]

_____

Details (check ALL that apply):

☐ Allow retention of data collected prior to refusal/revocation
☐ Decline retention of data collected prior to refusal/revocation
☐ Allow data collection after refusal/revocation
☐ Decline data collection after refusal/revocation
☐ Decline further study drug
☐ Other, specify _____

4. If no consent was obtained, has the REC/REB approved the use of this patient's data as provided?

☐ Not applicable, consent obtained

☐ No
- ☐ Yes, in original REC/REB submission → ☐ All data collection / ☐ Vital Status ONLY
- ☐ Yes, by recent REC/REB correspondence → ☐ Other, specify: _____

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Form 3

REVISE RCT170 Plate #005 Visit #000

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials F [ ] L [ ] Randomization Date (dd/mm/yyyy) [ ][ ] [ ][ ] 2 0 [ ][ ]

RANDOMIZATION (Form 3) - CANADA

FOR RESEARCH COORDINATOR

1. Pre-Hospital H_2RA or PPI receipt?
(including home, retirement home or nursing home)

H_2RAs: ranitidine (Zantac), cimetidine (Tagamet), famotidine (Pepcid) or nizatidine (Axid)

PPIs: pantoprazole (Pantoloc, Tecta), omeprazole (Losec), lansoprazole (Prevacid), dexlansoprazole, (Dexilant), rabeprazole (Pariet) or esomeprazole (Nexium)

☐ **NO**
Patient will be in **Start/No Start stratum** (no pre-Hospital PPI or H_2RA use)

☐ **YES**
Patient will be in **Continue/Discontinue stratum** (had pre-Hospital PPI or H_2RA use)

2. How was pre-hospital stress ulcer prophylaxis verified? (not all are needed, but check ALL that apply):

- ☐ Chart review including list of home meds
- ☐ Chart review but no list of home meds available
- ☐ Conversation with SDM about home meds
- ☐ Conversation with patient about home meds
- ☐ Conversation with outpatient pharmacy about home meds
- ☐ Hospital pharmacy reconciliation
- ☐ Provincial/state drug database review (e,g., Netcare, Dossier Santé Québec)

3. Date of birth: [ ][ ] [ ][ ] [ ][ ][ ][ ] (dd/mm/yyyy)

FOR RESEARCH PHARMACIST ONLY - Randomization

via web: www.randomize.net

4. Trial assignment (please select one): ☐ Pantoprazole ☐ Placebo

5. Time of randomization (24 hour clock): [ ][ ]:[ ][ ]

6. Study Pharmacist initals: [ ][ ] F L

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Form 3

REVISE RCT170 Plate #006 Visit #000

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials F [ ] L [ ] Randomization Date (dd/mm/yyyy) [ ][ ] [ ][ ] 2 0 [ ][ ]

RANDOMIZATION (Form 3) - CANADA

FOR RESEARCH PHARMACIST

1. Pre-Hospital H_2RA or PPI receipt?
(including home, retirement home or nursing home)

H_2RAs: ranitidine (Zantac), cimetidine (Tagamet), famotidine (Pepcid) or nizatidine (Axid)

PPIs: pantoprazole (Pantoloc, Tecta), omeprazole (Losec), lansoprazole (Prevacid), dexlansoprazole, (Dexilant), rabeprazole (Pariet) or esomeprazole (Nexium)

☐ **NO**
Patient will be in **Start/No Start stratum** (no pre-Hospital PPI or H_2RA use)

☐ **YES**
Patient will be in **Continue/Discontinue stratum** (had pre-Hospital PPI or H_2RA use)

2. Date of birth: [ ][ ] [ ][ ] [ ][ ][ ][ ] (dd/mm/yyyy)

FOR RESEARCH PHARMACIST ONLY - Randomization

via web: www.randomize.net

4. Trial assignment (please select one): ☐ Pantoprazole ☐ Placebo

5. Time of randomization (24 hour clock): [ ][ ]:[ ][ ]

6. Study Pharmacist initals: [ ][ ] F L

Please DO NOT return to the Research Coordinator or s/he will become unblinded.
Thanks for your help!

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Form 3B

REVISE RCT170 Plate #008 Visit #000

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials F [ ] L [ ]

STRATIFICATION ERROR FORM (Form 3B)

1. Patient randomized as:

   ☐ **Start/No Start stratum**, as Patient **had NO** Pre-hospital H_2RA or PPI use

   ☐ **Continue/Discontinue stratum,** as Patient **did have** Pre-hospital H_2RA or PPI use

2. Patient should have been randomized to:

   ☐ **Start/No Start stratum**, as Patient **had NO** Pre-hospital H_2RA or PPI use

   ☐ **Continue/Discontinue stratum,** as Patient **did have** Pre-hospital H_2RA or PPI use

3. Comments:

_____

_____

_____

_____

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Form 4

REVISE RCT170 Plate #010 Visit #000

Patient ID 1 Patient Initials F L

BASELINE (Form 4)

1. **Study hospital admission date** dd/mm/yyyy 20 **Study hospital admission time** (24 hour clock) :
2. **Study ICU admission date** 20 **Study ICU admission time** :
3. **Intubation date** 20 **Intubation time** (approximate) :
4. **Sex** ☐ Female ☐ Male
5. **APACHE II Score** (24 hrs pre-rand) (Calculated based on 24 hrs prior to randomization including pre-ICU location)
6. **Admission diagnosis code** (if admitted from OR or PARR code should be 48-85) If "other" diagnosis code selected, specify:
7. **Location immediately prior to this ICU admission** (check ONE box):
   - ☐ Accident and Emergency Department
   - ☐ Hospital Floor/Ward (including Step-Down Unit)
   - ☐ Other Hospital Emergency, admit date:
   - ☐ Other Hospital ICU, admit date:
   - ☐ Other Hospital Ward, admit date:

   Other hospital admit date: dd/mm/yyyy 20
   - ☐ Operating Theatre /Recovery Room specify:
     - ☐ Emergency Surgery
     - ☐ Elective Surgery
   - ☐ Other, specify:
8. **Pre-hospital history of the following** (check ALL that apply):
   - ☐ NONE
   - ☐ Bleeding ulcer
   - ☐ Bleeding varices
   - ☐ Cirrhosis
   - ☐ *Clostridioides difficile* infection
   - ☐ *Helicobacter pylori*
   - ☐ Hemodialysis
   - ☐ COVID-19 confirmed
9. **Patient received medically prescribed PPI or H_2RA prior to randomization?**
   - ☐ No ☐ Yes, specify drug and location:
   - ☐ Unknown pre-hospital (home) medication so presumed no acid suppression

   Proton Pump Inhibitor (PPI):

Home	Ward	ICU (pre-randomization)
☐	☐	☐ lansoprazole (Prevacid, lanzol relief, Zoton, Zopral)
☐	☐	☐ dexlansoprazole (Dexilant)
☐	☐	☐ pantoprazole (Pantoloc, Tecta, Panzop relief, Somac Salpraz, Gastenz, Ozpan, Panto, Pantofast, Panthron)
☐	☐	☐ esomeprazole (Nexium, Nexazole, Nexole, Noxicid)
☐	☐	☐ omeprazole (Losec, Omazol relief, Dr Reddy's Omeprazole, Midwest, Omazol IV, Acimax, Meprazole, Omepral, Ozmep, Maxor, Pemzo, Probitor)
☐	☐	☐ rabeprazole (Pariet, Parbezol, Parzole, Razit, Zabep)

   Histamine 2 Receptor Antagonists (H_2RA):

Home	Ward	ICU (pre-randomization)
☐	☐	☐ cimetidine (Tagamet, Magicul)
☐	☐	☐ ranitidine (Zantac,Ausran, Ulcaid, Rani2, Peptisoothe)
☐	☐	☐ famotidine (Pepcid, Ausfam, Pepzan)
☐	☐	☐ nizatidine (Axid, Nizac, Tacidine, Tazac)

   Other PPI or H_2RA, specify: ☐ ☐ ☐
10. **Drugs that may affect bleeding risk within the last 3 days prior to randomization?**

	Prophylactic Dose	Intermediate Dose	Therapeutic Dose
☐ Unfractionated heparin, specify:	☐	☐	☐
☐ Low molecular weight heparin, specify:	☐	☐	☐

   ☐ None
   - ☐ Warfarin (Coumadin)
   - ☐ Aspirin (ASA), specify: ☐ ≤ 325mg daily ☐ > 325mg daily
   - ☐ Clopidogrel (Plavix)
   - ☐ Non-steroid anti-inflammatory drug (NSAID)
   - ☐ New oral anticoagulants (NOAC) (e.g.,RivaroxibanApixaban, Dabigatran, Edoxaban)
   - ☐ Others (e.g., Dipyridamole (Persantine), Ticlodipine (Ticlid), Tirofiban (Aggrastat), Eptifatide (Integrilin), Direct thrombin inhibitors (Bivalirudin), Prasugrel, Ticagrelor, Cangrelor, specify:
11. **Oral or IV corticosteroids in the week preceding randomization** (e.g., prednisone, hydrocortisone, solumedrol, dexamethasone)**?** ☐ No ☐ Yes, specify: ☐ IV ☐ Oral

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REVISE RCT170 Plate #012 Visit #100

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials [ ][ ]

COVID-19 - Additional Data (Form 4B - COVID)

(Patients treated for Covid during this REVISE hospital admission)

1. Vaccinated pre-ICU: ☐ No ☐ Unknown ☐ Yes, 1 dose ☐ Yes, 2 doses ☐ Yes, 3 doses

2. COVID-related tests (during this index hospitalization, including pre-ICU admission)

	Date (dd/mm/yyyy)	Results		Not Done
D Dimer Level (highest)	[ ][ ]/[ ][ ]/20[ ][ ]	[ ][ ][ ][ ][ ]	ug/L	☐
CRP Level (highest)	[ ][ ]/[ ][ ]/20[ ][ ]	[ ][ ][ ].[ ]	mg/L	☐
Ferritin Level (highest)	[ ][ ]/[ ][ ]/20[ ][ ]	[ ][ ][ ][ ][ ]	ug/L	☐

	Not Done	No	Yes	Date (dd/mm/yyyy)	
CT Scan **positive** for PE (first date scanned positive)	☐	☐	☐ →	[ ][ ]/[ ][ ]/20[ ][ ]	Specify location:
US **positive** for DVT (first date scanned positive)	☐	☐	☐ →	[ ][ ]/[ ][ ]/20[ ][ ]	Specify location:
US **positive** for DVT (If second DVT identified)	☐	☐	☐ →	[ ][ ]/[ ][ ]/20[ ][ ]	Specify location:
Bowel Ischemia (radiographic or intraoperative documentation)	☐	☐	☐ →	[ ][ ]/[ ][ ]/20[ ][ ]	Specify location:

3. COVID-related treatments (during this index hospitalization, including pre-ICU admission).
Please complete whether treatment given as part of a trial or not.

		Start Date (dd/mm/yyyy)	
Tocilizumab	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
Sarilumab	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
Convalescent plasma	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
Oseltamivir or Remdesivir	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	Oseltamivir ☐ Remdesivir ☐
Dexamethasone or high dose steroid	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	Dexamethasone ☐ High dose steroid ☐
Statin	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
IV Vitamin C	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
ACE2 Renin-Angiotensin RAS	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
Azithromycin	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
ECMO	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	
Other (e.g., interferon, kinase inhibitors, hydroxychloroquine), specify:	☐ No ☐ Yes →	[ ][ ]/[ ][ ]/20[ ][ ]	

4. Tracheostomy: ☐ No ☐ Yes → [ ][ ]/[ ][ ]/20[ ][ ]

5. Comments: _____

Please note: Coagulation tests and anticoagulation doses are captured on Daily Data Form

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Form 6.1 of 2

REVISE RCT170 Plate #030

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ ☐☐ (dd/mm/yyyy) 2 0 ☐☐

DAILY DATA STUDY DAYS 1-14 (Form 6.1 of 2)

1. Advanced life support strategies received today

1. Invasive mechanical ventilation ☐ No ☐ Yes
2. Non-invasive mechanical ventilation (BiPAP): ☐ No ☐ Yes
3. Inotropes or vasopressor infusions ☐ No ☐ Yes
   (e.g., dopamine, norepinephrine, phenylephrine, epinephrine, milrinone, vasopressin)
4. Was renal replacement therapy used today?
   ☐ No ☐ Yes, specify: → ☐ intermittent (IHD) ☐ sustained low efficiency (SLED) ☐ continuous (CRRT) ☐ peritoneal

2. Was study drug administered today? ☐ No ☐ Yes

Time Study Day 1 ONLY ☐☐:☐☐ (24 hr clock)

If a dose of study drug was not received today, please indicate why:

- ☐ Randomized late in the day
- ☐ Discharged from ICU or died
- ☐ Not mechanically ventilated (ICU physician discretion) **If patient re-intubated during this ICU admission, restart REVISE study drug.**
- ☐ No IV access
- ☐ Expected to die, palliative measures only
- ☐ Suspected/proven diagnosis of another exclusion criterion, specify: _____
- ☐ GI bleeding (submit **Bleed Form 9**)
- ☐ Error, missed/probably missed dose (submit **Protocol Deviation Form 12**)
- ☐ Patient declined dose
- ☐ Consent withdrawn, drug stopped (continue data collection)
- ☐ Other, specify: _____

3. Any enteral, parenteral or oral nutrition today? ☐ No ☐ Yes, specify: (check ALL that apply) ☐ Enteral → ☐☐☐☐☐ ☐ Parenteral → ☐☐☐☐☐ ☐ Oral
total daily ml

4. Physiology/Laboratory results today

☐☐☐ N/A hemoglobin (g/L) (lowest)

☐☐☐☐ N/A platelets (x10 ^{9}/L) (lowest)

☐☐.☐ N/A INR (highest)

☐☐☐.☐ N/A PTT (s) (highest)

creatinine (umol/L) (highest) ☐☐☐☐ N/A

5. Did the patient receive packed red blood cells today? ☐ No ☐ Yes → ☐☐☐☐ ☐ units in total ☐ ml in total

6. Post randomization, did any of the following outcomes occur today?

Major gastrointestinal bleeding ☐ No ☐ Yes, please complete the **Bleeding Outcome Form 9**
(Complete only one form for each discrete new major bleeding event documented)

Clostridioides difficile infection ☐ No ☐ Yes, please complete the ***Clostridioides Difficile* Outcome Form 10**

Respiratory infection ☐ No ☐ Yes, please complete the **Respiratory Infection Outcome Form 11**
(Complete form with new events only but not necessary on Study Day 1 for prevalent events)

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Form 6.2 of 2

REVISE RCT170 Plate #031

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ (dd/mm/yyyy) ☐☐ 2 0 ☐☐

DAILY DATA STUDY DAYS 1-14 (Form 6.2 of 2)

7. Did the patient receive any of the following today (post-randomization)?

1. H_2RA No ☐ Yes ☐ [e.g., **cimetidine** (Tagamet, Magicul), **famotidine** (Pepcid, Ausfam, Pepzan), **ranitidine** (Zantac, Ausran, Ulcaid, Rani2, Peptisoothe), **nizatidine** (Axid, Nizac, Tacidine, Tazac)]

   ☐ Check if H_2RA given for allowable reason (i.e., GI bleeding, patient extubated or consent withdrawn) (If yes and patient mechanically ventilated, submit **Protocol Deviation Form 12** for non-protocolized reason for H_2RA)

2. Open label PPI

   No ☐ Yes ☐ [e.g., **lansoprazole** (Prevacid, lanzol relief, Zoton, Zopral), **esomeprazole** (Nexium, Nexazole, Nexole, Noxicid), **dexlansoprazole** (Dexilant), **omeprazole** (Losec, Omazol relief, Dr Reddy's Omeprazole, Midwest, Omazol IV, Acimax, Meprazole, Omepral, Ozmep, Maxor, Pemzo, Probitor), **pantoprazole** (Pantoloc, Tecta, Panzop relief, Sōmac, Salpraz, Gastenz, Ozpan, Panto, Pantofast, Panthron), **rabeprazole** (Pariet, Parbezol, Parzole, Razit, Zabep)]

   ☐ Check if PPI given for allowable reason (i.e., GI bleeding, patient extubated or consent withdrawn) (If yes and patient mechanically ventilated, submit **Protocol Deviation Form 12** for non-protocolized reason for open-label PPI)

3. Other stress ulcer prophylaxis

   No ☐ Yes ☐ [e.g., sulcrafate (Carafate), antacid (e.g., Maalox, Gaviscon)]

4. Anticoagulant or antiplatelet agent

	Prophylactic Dose	Intermediate Dose	Therapeutic Dose
☐ Unfractionated heparin, specify: →	☐	☐	☐
☐ Low molecular weight heparin, specify: →	☐	☐	☐

☐ None

☐ Warfarin (Coumadin)

☐ Aspirin (ASA), specify: ☐ ≤ 325mg daily ☐ > 325mg daily

☐ Clopidogrel (Plavix)

☐ Non-steroid anti-inflammatory drug (NSAID)

☐ New oral anticoagulants (NOAC) (e.g.,Rivaroxiban Apixaban, Dabigatran, Edoxaban)

☐ Others [e.g., Dipyridamole (Persantine), Ticlodipine (Ticlid), Tirofiban (Aggrastat), Eptifatide (Integrilin), Direct thrombin inhibitors (Bivalirudin), Prasugrel, Ticagrelor, Cangrelor] specify: _____

5. Oral or IV corticosteroids (e.g., prednisone, hydrocortisone, solumedrol, dexamethasone) No ☐ Yes, specify: ☐ IV ☐ Oral ☐

6. Probiotics

   No ☐ Yes ☐ If open-label probiotics, specify: _____

8. Was there an adverse event today believed by either the ICU physician or Site Investigator to be directly related to enrolment in the study?

☐ No ☐ Yes If yes, please notify the REVISE Methods Center **within 24 hours** of becoming aware of the Adverse Event. An **Adverse Event Directly Related to the Study Form 17 is required** and please ask the ICU physician to sign it and send to the REVISE Methods Center

9. Was today the last day of study daily data collection?

☐ No

☐ Yes, patient died, was discharged to the ward, or drug stopped at 90 days (submit **Final Status Form 14**)

☐ Yes, consent withdrawn for further data collection (submit a **Final Status Form 14**)

29 December 2022

Form 7

REVISE RCT170 Plate #033

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ (dd/mm/yyyy) ☐☐ ☐☐ 2 0 ☐☐

DAILY DATA STUDY DAYS 15-90 (Form 7)

1. Advanced life support strategies received today

1. Invasive mechanical ventilation ☐ No ☐ Yes
2. Non-invasive mechanical ventilation (BiPAP): ☐ No ☐ Yes
3. Inotropes or vasopressor infusions ☐ No ☐ Yes
   (e.g., dopamine, norepinephrine, phenylephrine, epinephrine, milrinone, dobutamine, vasopressin)
4. Was renal replacement therapy used today?
   ☐ No ☐ Yes, specify: → ☐ intermittent (IHD) ☐ sustained low efficiency (SLED) ☐ continuous (CRRT) ☐ peritoneal

2. Laboratory results today:

☐☐☐ ☐ N/A hemoglobin (g/L) (lowest)
☐☐☐☐ ☐ N/A platelets (x10 ^{9}/L) (lowest)
☐☐.☐ ☐ N/A INR (highest)
☐☐☐.☐ ☐ N/A PTT (s) (highest)
☐☐☐☐ ☐ N/A creatinine (umol/L) (highest)

3. Was study drug administered today? ☐ No ☐ Yes, specify:

If a dose was not received today, please indicate why and submit a **Protocol Deviation Form 12** if applicable:

- ☐ Discharged from ICU or died
- ☐ Not mechanically ventilated (ICU physician discretion) **If patient re-intubated during this ICU admission, restart REVISE study drug.**
- ☐ No IV access
- ☐ Expected to die, palliative measures only
- ☐ GI bleeding (submit **Bleed Form 9**)
- ☐ Error, missed/probably missed dose (submit **Protocol Deviation Form 12**)
- ☐ Patient declined dose
- ☐ Consent withdrawn, drug stopped (continue data collection)
- ☐ Other, specify: _____
- ☐ Suspected/proven diagnosis of an other exclusion criterion, specify: _____

4. Any enteral, parenteral or oral nutrition today? ☐ No ☐ Yes, specify: (check ALL that apply) ☐ Enteral → ☐☐☐☐☐ ☐ Parenteral → ☐☐☐☐☐ total daily ml ☐ Oral

5. Was anticoagulation received today? ☐ No ☐ Yes, specify → ☐ Intermediate dose ☐ Full therapeutic dose ☐ Prophylactic dose

6. Post randomization, did any of the following outcomes occur today?

Major gastrointestinal bleeding ☐ No ☐ Yes, please complete the **Bleeding Outcome Form 9**
(Complete only one form for each discrete new major bleeding event documented)

Clostridioides difficile infection ☐ No ☐ Yes, please complete the ***Clostridioides Difficile* Outcome Form 10**

Respiratory infection ☐ No ☐ Yes, please complete the **Respiratory Infection Outcome Form 11**
(Complete Form with new events only)

7. Was there an adverse event today believed by either the ICU physician or Site Investigator to be directly related to enrolment in the study?

☐ No ☐ Yes If yes, please notify the REVISE Methods Center **within 24 hours** of becoming aware of the Adverse Event. An **Adverse Event Directly Related to the Study Form 17 is required** and please ask the ICU physician to sign it and send to the REVISE Methods Center

8. Was today the last day of study daily data collection?

- ☐ No
- ☐ Yes, patient died, was discharged to the ward, or drug stopped at 90 days (submit **Final Status Form 14**)
- ☐ Yes, consent withdrawn for further data collection (submit a **Final Status Form 14**)

29 December 2022

Form 8

REVISE RCT170 Plate #035

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ (dd/mm/yyyy) ☐☐ ☐☐ 2 0 ☐☐

PHARMACY - DAILY DISPENSING RECORD (Form 8)

ALL STUDY PERSONNEL AND CLINICIANS MUST REMAIN BLINDED TO THE PATIENT'S ALLOCATION. PHARMACISTS, PLEASE MAINTAIN A COPY FOR YOUR CONFIDENTIAL RECORDS. Thanks!

1. Please indicate which study drug was dispensed:

☐ **Study Drug (pantoprazole)** **OR** ☐ **Placebo**

Indicate company:

- ☐ Sandoz
- ☐ Fresenius Kabi
- ☐ Takeda
- ☐ Auro Pharma
- ☐ Pharmascience
- ☐ Generic Medical Partners
- ☐ Other, specify: _____

2. Please indicate "yes" if a drug dispensing error was made today that you are aware of:

■ No ☐ Yes → please submit a **Protocol Deviation (Pharmacy) Form 13** and provide explanation below

3. Comments: _____

Please DO NOT return to the Research Coordinator or s/he will become unblinded. Thanks for your help!

29 December 2022

Form 9

REVISE RCT170 Plate #040

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐☐ L Date of Study Day ☐☐ ☐☐ (dd/mm/yyyy) 2 0 ☐☐

GASTROINTESTINAL BLEEDING OUTCOME (Form 9)

1. Bleeding presentation (check ALL that apply):
- ☐ NG blood
- ☐ NG Coffee ground emesis
- ☐ Melena
- ☐ Hematemesis (vomiting blood)
- ☐ Hematochezia (bright red blood per rectum)
- ☐ Other, specify: _____

2. Bleeding severity (check ALL that apply):

☐ 1. Life threatening bleeding resulting in hypovolemic shock

☐ 2. Clinically important bleeding is overt bleeding and one of the following within 24 hours in the absence of other causes (e.g., sepsis, propofol bolus) →
- ☐ Decrease in Hgb ≥20 g/L
- ☐ PRBC ≥ 2 units
- ☐ Decrease in SBP ≥ 20mmHg or HR increase ≥ 20bpm
- ☐ Initiation of vasopressor (e.g., norepinephrine, epinephrine, vasopressin, dopamine, phenylephrine, dobutamine)
- ☐ Increase of vasopressor
- ☐ Other (specify): _____

☐ 3. Bleeding that requires an invasive intervention specify:

☐ Upper GI **diagnostic** endoscopy, specify findings:
- ☐ gastric ulcer
- ☐ duodenal ulcer
- ☐ esophageal ulcer
- ☐ *Helicobactor pylori*
- ☐ gastritis/erosions
- ☐ duodenitis/erosions
- ☐ esophagitis/erosions
- ☐ gastric varices
- ☐ duodenal varices
- ☐ esophageal varices
- ☐ Portal hypertensive gastropathy
- ☐ Normal
- ☐ Other, specify: _____

☐ Upper GI **therapeutic** endoscopy, specify interventions:
- ☐ injection
- ☐ clips
- ☐ hemospray
- ☐ banding
- ☐ thermal coagulation
- ☐ glue
- ☐ argon plasma coagulation
- ☐ Blakemore/Minnesota tube
- ☐ Other, specify: _____

☐ Colonoscopy

☐ Sigmoidoscopy

☐ Angiogram

☐ Angiogram with embolization/coiling

Helicobacter pylori serology positive? ☐ No ☐ Yes

☐ Surgery, specify: _____

☐ Other, specify: _____

3. Bleed Started: ☐ **unknown** ☐☐ ☐☐ 2 0 ☐☐ Date (dd/mm/yyyy)

TO

Bleed Stopped: ☐ **unknown** ☐ **bleeding ongoing** ☐☐ ☐☐ 2 0 ☐☐ Date (dd/mm/yyyy)

4. Direct consequences of the bleeding event (check ALL that apply)

☐ 1. Total transfusion (total # units infused) : (confirm # units reported with your hospital blood bank records) RBC ☐☐☐ FFP ☐☐ platelets ☐☐ cryoprecipitate ☐☐☐

☐ 2. Drugs: ☐ PPI ☐ Octreotide ☐ Tranexamic acid ☐ desmopressin (DDAVP)
☐ Other, specify: _____

☐ 3. Major morbidity (e.g., myocardial infarction, stroke), specify: _____

☐ 4. Death ☐ 5. **NONE**

5. Reports sent to the REVISE Methods Center (check ALL that apply)
- ☐ Endoscopy
- ☐ Surgical
- ☐ Radiology
- ☐ Clinical Notes

☐ **Reports not sent, Investigator review only:**

_____ Reviewing Investigator Name _____ Investigator Signature ☐☐ ☐☐ 2 0 ☐☐ Date Investigator reviewed (dd/mm/yyyy)

29 December 2022

Form 11

REVISE RCT170 Plate #060

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials ☐☐ Date of Study Day (positive *C Difficile*) ☐☐ ☐☐ 2 0 ☐☐

CLOSTRIDIOIDES DIFFICILE **OUTCOME (Form 10)**

1. Which test performed was positive for *Clostridioides difficile* (Please check ALL that apply)?

- ☐ ELISA (enzyme-linked immunosorbent assay)
- ☐ PCR (polymerase chain reaction)
- ☐ Cell Culture Cytotoxicity Assay
- ☐ LAMP (loop-mediated isothermal amplification)
- ☐ Other, specify: _____

2. *Clinical presentation of Clostridioides difficile* (Please check ALL that apply):

- ☐ Diarrhea ≥ 3 episodes of unformed stools in ≤24 hours
- ☐ Rectal tube in place, stools loose and difficult to quantitate
- ☐ Colonscopic findings demonstrating pseudomembranous colitis
- ☐ Histopathological findings of pseudomembranous colitis
- ☐ Toxic megacolon

3. Treatments implemented for the *Clostridioides difficile* infection?

- ☐ Metronidazole (Flagyl)
- ☐ Vancomycin (Vancocin)
- ☐ Fidaxomicin (Dificid, Dificlir)
- ☐ Colectomy
- ☐ Fecal transplantation
- ☐ Other (e.g., probiotics), specify: _____
- ☐ NONE

4. Other consequences of the *Clostridioides difficile* infection?

- ☐ NONE
- ☐ Ileus
- ☐ Hypotension
- ☐ Septic Shock
- ☐ Bowel perforation
- ☐ Death
- ☐ Other, specify: _____

5. Society for Healthcare Epidemiology of America (SHEA 2018) *Clostridioides Difficile* Infection Severity for Initial Infection (as per clinical impression of ICU physician)

- ☐ **Non-Severe** [defined as white cell count ≤ 15.0 x 10^9/L (or <15,000 mm^3) and creatinine < 1.5 mg/dl (<133umol/L)]
- ☐ **Severe** [defined as white cell count ≥ 15.0 x 10^9/L (or >15,000 mm^3) **OR** creatinine **>** 1.5 mg/dl (<133umol/L)]
- ☐ **Fulminant** (defined as hypotension, shock, ileus or megacolon)

29 December 2022

REVISE RCT170 Plate #050 Study Day

Patient ID 1 Patient Initials F L

RESPIRATORY INFECTION OUTCOME (Form 11)

2 Days Prior to Respiratory Infection:
(~ 24-48 hour period Pre-Resp Infection day reported) 20 (dd/mm/yyyy)

☐ N/A, data unavailable pt not in hospital

Highest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Lowest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Highest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Lowest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Bands present? ☐No ☐Yes

ARDS present? ☐No ☐Yes

Lowest PaO_2/FIO_2 ☐☐☐☐ ☐N/A

Tracheal secretions: ☐None/minimal ☐Moderate ☐Large

Purulent or mucopurulent? ☐No ☐Yes

New, progressive or persistent CXR infiltrate? (Check ALL that apply)
☐None or no CXR ☐Patchy/diffuse ☐Lobar/bilobar ☐Consolidation ☐Cavitation

Potential Pathogen cultured? ☐No ☐Yes

Nasopharyngeal swab (NPS) positive? ☐No ☐Yes

1 Day Prior to Respiratory Infection:
(~ 24 hour period Pre-Resp Infection day reported) 20 (dd/mm/yyyy)

☐ N/A, data unavailable pt not in hospital

Highest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Lowest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Highest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Lowest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Bands present? ☐No ☐Yes

ARDS present? ☐No ☐Yes

Lowest PaO_2/FIO_2 ☐☐☐☐ ☐N/A

Tracheal secretions: ☐None/minimal ☐Moderate ☐Large

Purulent or mucopurulent? ☐No ☐Yes

New, progressive or persistent CXR infiltrate? (Check ALL that apply)
☐None or no CXR ☐Patchy/diffuse ☐Lobar/bilobar ☐Consolidation ☐Cavitation

Potential Pathogen cultured? ☐No ☐Yes

Nasopharyngeal swab (NPS) positive? ☐No ☐Yes

DAY OF RESPIRATORY INFECTION:
20 (dd/mm/yyyy)

Highest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Lowest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Highest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Lowest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Bands present? ☐No ☐Yes

ARDS present? ☐No ☐Yes

Lowest PaO_2/FIO_2 ☐☐☐☐ ☐N/A

Tracheal secretions: ☐None/minimal ☐Moderate ☐Large

Purulent or mucopurulent? ☐No ☐Yes

New, progressive or persistent CXR infiltrate? (Check ALL that apply)
☐None or no CXR ☐Patchy/diffuse ☐Lobar/bilobar ☐Consolidation ☐Cavitation

Potential Pathogen cultured? ☐No ☐Yes

Nasopharyngeal swab (NPS) positive? ☐No ☐Yes

24 hours POST Respiratory Infection:
20 (dd/mm/yyyy)

Highest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Lowest temp °C ☐☐.☐ ☐N/A ☐PO ☐Ax or Tymp ☐Core/Rectal

Highest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Lowest WBC count (10^9/L) ☐☐☐☐.☐ ☐N/A

Bands present? ☐No ☐Yes

ARDS present? ☐No ☐Yes

Lowest PaO_2/FIO_2 ☐☐☐☐ ☐N/A

Tracheal secretions: ☐None/minimal ☐Moderate ☐Large

Purulent or mucopurulent? ☐No ☐Yes

Calculated REVISE Methods Center CPIS Score: ☐☐

New, progressive or persistent CXR infiltrate? (Check ALL that apply)
☐None or no CXR ☐Patchy/diffuse ☐Lobar/bilobar ☐Consolidation ☐Cavitation

Potential Pathogen cultured? ☐No ☐Yes

Nasopharyngeal swab (NPS) positive? ☐No ☐Yes

29 December 2022

Form 5.1

REVISE RCT170 Plate #015 Visit #000

Patient ID 1 Patient Initials

☐ **No cultures performed**

CULTURE REPORT (Form 5.1)

Please list all gram stains and cultures performed in the ICU related to Pulmonary Infections (including from sputum, endotracheal aspirate, bronchoscopy, pleural fluid, nasopharyngeal swab for virus, urine Legionella) and blood culture considered to be related to the pneumonia (i.e., Same organism identified in blood and respiratory specimen).

	Date of Specimen (dd/mm/yyyy)	Result	Organism Code(s) (Please list all today) If more than 3 organisms to report, use additional line.
1.	20	☐ positive ☐ negative	
	Specify Location		
2.	20	☐ positive ☐ negative	
	Specify Location		
3.	20	☐ positive ☐ negative	
	Specify Location		
4.	20	☐ positive ☐ negative	
	Specify Location		
5.	20	☐ positive ☐ negative	
	Specify Location		
6.	20	☐ positive ☐ negative	
	Specify Location		
7.	20	☐ positive ☐ negative	
	Specify Location		

☐ **Please check if additional forms are required for reporting positive cultures**

29 December 2022

Form 12

REVISE RCT170 Plate #070

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ ☐☐ 2 0 ☐☐

PROTOCOL DEVIATION - RESEARCH COORDINATOR REPORT (Form 12)

1. Protocol deviation (check ALL that apply)

- ☐ 1. Randomization of ineligible patient (only submit to local REB upon review with Methods Center and as per local guidelines)
- ☐ 2. Missed dose of study drug
- ☐ 3. Received wrong study drug
- ☐ 4. Open label PPI administered (e.g., not study drug)
- ☐ 5. H_2RA administered
- ☐ 6. Other (specify): _____

2. Explanation: _____

3. Were there any consequences to the patient? ☐ No ☐ Yes, specify: _____

4. Actions taken, specify: _____

29 December 2022

Form 13

REVISE RCT170 Plate #071

Study Day

Patient ID 1

Patient Initials F L

Date of Study Day 2 0

PROTOCOL DEVIATION - PHARMACY REPORT (Form 13)

1. **Protocol deviation** (check ALL that apply)

- ☐ 1. Missed dose of study drug
- ☐ 2. Dispensed wrong study drug (e.g., pantoprazole given instead of placebo or vice versa)
- ☐ 3. Open label PPI administered (e.g., not study drug)
- ☐ 4. H_2RA administered
- ☐ 5. Other (specify): _____

2. **Explanation:** _____

3. **Were there any consequences to the patient?** ☐ No ☐ Yes, specify: _____

4. **Actions taken, specify:** _____

29 December 2022

Form 14

REVISE RCT170 Plate #080

Study Day

Patient ID 1

Patient Initials F L

FINAL STATUS (Form 14)

1. Patient discharged from ICU?

☐ Yes, survived ICU — Date of ICU Discharge (dd/mm/yyyy) 20

☐ No, died in ICU — Date of Death (dd/mm/yyyy) 20

☐ Unknown (e.g., consent revoked), specify: _____

Proximate cause of death in ICU (select one option)

☐ Other, specify: _____

Underlying cause of death in ICU (select up to 3 options)

☐ Other, specify: _____

☐ Other, specify: _____

☐ Other, specify: _____

2. Patient READMITTED to ICU during this index hospital admission?
(NOTE: No need to restart study drug with patient ICU readmission)

	Date of ICU Readmission (dd/mm/yyyy)	Date of ICU Discharge (dd/mm/yyyy)	If yes, was readmission for Upper GI bleeding?
☐ No ☐ Yes →	20	20	☐ No ☐ Yes
	20	20	☐ No ☐ Yes

If Yes, patient readmitted to ICU for upper GI bleeding, please complete **Gastrointestinal Bleeding Outcome Form 9**)

3. Patient discharged from Hospital?

☐ Yes, survived → Date of Hospital Discharge (dd/mm/yyyy) 20

- ☐ Yes, home
- ☐ Yes, acute care facility (non-REVISE site)
- ☐ Yes, long term care facility
- ☐ Yes, rehabilitation center
- ☐ Other, specify: _____

☐ No, died → Date of Death (dd/mm/yyyy) 20

Proximate cause of death in hospital (select one option)

☐ Other, specify: _____

☐ Unknown (e.g., consent revoked), specify: _____

Underlying cause of death in hospital (select up to 3 options)

☐ Other, specify: _____

☐ Other, specify: _____

☐ Other, specify: _____

4. Was this patient confirmed COVID positive anytime from hospital admission up to hospital discharge?

☐ Yes → Date confirmed positive, if applicable (dd/mm/yyyy)

☐ No

5. Vital status at 90 days following randomization?

☐ Alive →
- ☐ Home
- ☐ Study hospital
- ☐ Chronic care, long term care facility
- ☐ Other acute care facility (non-REVISE site)
- ☐ Palliative care hospital or facility
- ☐ Inpatient rehabilitation center
- ☐ Other, specify: _____

☐ Deceased

How was the 90 day vital status obtained?

- ☐ Medical record
- ☐ Phone call to other hospital, care facility or family MD
- ☐ Phone call to patient, SDM or family member
- ☐ Other, specify: _____
- ☐ Not obtained, explain: _____

Date of contact (dd/mm/yyyy)

Date of Death, if applicable (dd/mm/yyyy)

29 December 2022

REVISE RCT170 Plate #095 Visit #000

Patient ID [ ][ ][ ] 1 [ ][ ][ ] Patient Initials F [ ] L [ ]

COENROLMENT (Form 15)

1. Was patient coenrolled in another study in ICU? ☐ No ☐ Yes, please specify name, design and funding:

Study name:	Design: RCT	Design: observ	Funding: academic	Funding: industry	Funding: local	Informed Consent (1 = A priori, 2 = Deferred, 3 = Waived)	Consent Timing (1 = REVISE 1st, 2 = Concurrent, 3 = REVISE after)	Methods Center Internal Study Code
a. _____	☐	☐	☐	☐	☐	☐	☐	☐☐☐
b. _____	☐	☐	☐	☐	☐	☐	☐	☐☐☐
c. _____	☐	☐	☐	☐	☐	☐	☐	☐☐☐
d. _____	☐	☐	☐	☐	☐	☐	☐	☐☐☐
e. _____	☐	☐	☐	☐	☐	☐	☐	☐☐☐

29 December 2022

Form 16

REVISE RCT170 Plate #100

Study Day

Patient ID 1

Patient Initials F L

Date of Study Day 2 0

NOTE TO FILE (Form 16)

REVISE RCT170 Plate #085

Study Day ☐☐

Patient ID ☐☐☐1☐☐☐ Patient Initials F ☐ L ☐ Date of Study Day ☐☐ ☐☐ 20☐☐

ADVERSE EVENT - DIRECTLY RELATED TO THE STUDY (Form 17.1 of 3)

1. **Onset date and time of Adverse Event:** Date (dd/mm/yyyy) ☐☐ ☐☐ 20☐☐ / (24 hour clock) ☐☐:☐☐
   ☐ Unknown

2. **Type of Event:** ☐ Adverse Drug Reaction (ADR) ☐ Serious Adverse Drug Reaction (SADR) ☐ Suspected Unexpected Serious Adverse Reaction (SUSAR)

3. **Was the event attributed to any of the following outcomes (check ALL that apply)**
   - ☐ Death
   - ☐ Life threatening (i.e., immediate risk of death)
   - ☐ Prolongation of this hospitalization
   - ☐ Persistent or significant disability or incapacity
   - ☐ Congenital anomaly or birth defect
   - ☐ Medically significant and may require intervention (treatment) to prevent one of the prior outcomes, specify: _____
   - ☐ Adverse Drug Reaction only, no other conditions judged as serious (ADR)

4. **Description of event or diagnosis:** _____

5. **Relationship to study treatment: (In the opinion of the Attending Physician or Site Investigator)** ☐ Possibly Related ☐ Probably Related ☐ Definitely Related

6. **Date and time study drug last administered:** Date (dd/mm/yyyy) ☐☐ ☐☐ 20☐☐ / (24 hour clock) ☐☐:☐☐

7. **Action taken regarding the study treatment** (check ALL that apply)
   - ☐ None required
   - ☐ Study drug interrupted, specify when resumed Date (dd/mm/yyyy) ☐☐ ☐☐ 20☐☐ / (24 hour clock) ☐☐:☐☐
   - ☐ Study drug permanently discontinued

8. **Overall outcome of the event, at time of hospital discharge or death (check one only)**
   - ☐ Recovered spontaneously, specify date of resolution: Date (dd/mm/yyyy) ☐☐ ☐☐ 20☐☐
   - ☐ Recovered with treatment, specify date of resolution: ☐☐ ☐☐ 20☐☐
   - ☐ Recovered with sequelae (specify): _____
   - ☐ Death, specify date and time: (24 hour clock) ☐☐ ☐☐ 20☐☐ / ☐☐:☐☐
   - ☐ No resolution (ongoing), specify: _____
   - ☐ Unknown

Form 17.2

REVISE RCT170 Plate #087

Study Day

Patient ID 1

Patient Initials F L

ADVERSE EVENT - DIRECTLY RELATED TO THE STUDY (Form 17.2)

9. Medication Log (within 24 hours of event)

Generic Name: **Dose** **Units** **Frequency** **Route**

1. _____ . **(if other route, specify)**

Start date (dd/mm/yyyy) 20 End date (dd/mm/yyyy) 20 Ongoing

Indication (to treat event OR pre-event): _____

Generic Name: **Dose** **Units** **Frequency** **Route**

2. _____ . **(if other route, specify)**

Start date (dd/mm/yyyy) 20 End date (dd/mm/yyyy) 20 Ongoing

Indication (to treat event OR pre-event): _____

Generic Name: **Dose** **Units** **Frequency** **Route**

3. _____ . **(if other route, specify)**

Start date (dd/mm/yyyy) 20 End date (dd/mm/yyyy) 20 Ongoing

Indication (to treat event OR pre-event): _____

Generic Name: **Dose** **Units** **Frequency** **Route**

4. _____ . **(if other route, specify)**

Start date (dd/mm/yyyy) 20 End date (dd/mm/yyyy) 20 Ongoing

Indication (to treat event OR pre-event): _____

Generic Name: **Dose** **Units** **Frequency** **Route**

5. _____ . **(if other route, specify)**

Start date (dd/mm/yyyy) 20 End date (dd/mm/yyyy) 20 Ongoing

Indication (to treat event OR pre-event): _____

☐ **Please check if additional forms are required for reporting Medication Log**

29 December 2022

Form 17.3 of 3

REVISE RCT170 Plate #086

Study Day ☐☐

Patient ID ☐☐☐ 1 ☐☐☐ Patient Initials F ☐ L ☐

ADVERSE EVENT - DIRECTLY RELATED TO THE STUDY (Form 17.3 of 3)

10. Potential confounding factors/relevant medical history: _____

_____

_____

_____

_____

11. Was the study treatment unblinded? ☐ No ☐ Yes, please complete the **Code Break Form 18**

12. Does the Investigator or Site Investigator believe that this event is directly related to the REVISE study drug?

☐ No ☐ Yes, specify reason: _____

_____

_____

13. Reporter Name: _____ **Reporter Signature:** _____

Reporter Designation: _____ **Reporter Telephone:** _____

Date (dd/mm/yyyy)

Date of Report: ☐☐ ☐☐ 2 0 ☐☐ **Methods Center Contacted?** ☐ No ☐ Yes

14. I have reviewed this report and agree with its contents

Date (dd/mm/yyyy)

_____ ☐☐ ☐☐ 2 0 ☐☐

ICU Physician name **ICU Physician signature**

_____ ☐☐ ☐☐ 2 0 ☐☐

Site Investigator name **Site Investigator signature**

Please fax (+1-905-308-7223) or scan this form immediately to the REVISE Methods Center at REVISE@stjosham.on.ca and call the REVISE Methods Center (+1-905-512-5935)

29 December 2022