Demographics

Record ID	_____
Admission Age	_____ (enter 999 if unknown or >89)
Age greater than 89?	◯ Yes ◯ No
Sex	◯ Female ◯ Male
Race	☐ White or Caucasian ☐ Black or African American ☐ American Indian or Alaskan Native ☐ Asian ☐ Native Hawaiian or other Pacific Islander ☐ Patient Refused ☐ Unknown ☐ Other
Ethnicity	◯ Hispanic ◯ Not Hispanic ◯ Unknown
Height	_____ (in cm)
Weight	_____ (in kilograms)
BMI	_____
Comorbidities	☐ Hx of MI ☐ CHF ☐ PVD ☐ Hx CVA or TIA ☐ Hemiplegia ☐ Dementia ☐ Chronic Pulmonary Disease ☐ Rheum/Connective tissue disease ☐ Peptic Ulcer Disease ☐ Liver Disease ☐ CKD (Cr >3) ☐ ESRD ☐ Diabetes ☐ Solid Tumor ☐ Leukemia/Lymphoma ☐ AIDS

Liver Disease category	◯ Mild ◯ Mod to Severe (mild=chronic hepatitis or cirrhosis without portal hypertension. mod/sever = cirrhosis with portal hypertension)
Diabetes Category	◯ Uncomplicated ◯ DM with End-Organ Damage
Solid Tumor category	◯ Localized ◯ Metastatic
On anti-platelet medication?	◯ Yes ◯ No ◯ Unknown
Antiplatelet med	☐ Aspirin ☐ Plavix ☐ Brilinta ☐ Other
Were the meds continued during admission?	◯ Yes ◯ No
Which meds were continued?	☐ Aspirin ☐ Plavix ☐ Brilinta ☐ Other
Active tobacco use	◯ Yes ◯ No ◯ Unknown

Admission Data

Admission Date/Time	_____
Discharge Date/Time	_____
Admission diagnosis	_____
Did patient undergo an operation during admission?	◯ Yes ◯ No
OR Date/Time	_____ (first operation date/time if multiple)
Operation approach	◯ Open ◯ Lap ◯ Robot
Operation	_____ (first operation if multiple during admission)
Total number of operations during admission	_____

VTE Prophylaxis Data

Initial Lovenox Dose	◯ 30mg daily ◯ 40mg daily ◯ 30 BID ◯ 40 BID ◯ 60 BID ◯ Other
If other, please describe:	_____
# consecutive doses prior to AXa level	_____
Date/time of lovenox dose prior to AXa level date/time	_____ (dose immediately prior to Axa level)
First AXa level date/time	_____
AXa Level result:	_____
Was lovenox dosing adjusted after first AXa level?	◯ Yes ◯ No, appropriate AXa level ◯ No, other reason
What was other reason for no dosing change?	◯ Patient discharged before regimen changed ◯ Not changed when should have ◯ Other
If other, please describe	_____
2nd Lovenox Dose (after adjustment)	◯ 30mg daily ◯ 40mg daily ◯ 30 BID ◯ 40 BID ◯ 60 BID ◯ Other (after first Axa level and dose adjustment)
If other, please describe new lovenox dose	_____
2nd AXa level obtained after dose adjustment?	◯ Yes ◯ No
Reason for no 2nd AXa level	◯ Discharged prior to obtaining second level ◯ Not done but should have ◯ Other
If "other", please describe reason for no 2nd AXa level	_____

# consecutive doses prior to 2nd AXa level	_____
Date/time of lovenox dose prior to 2ND AXa level date/time	_____ (dose immediately prior to 2nd Axa level)
2nd AXa level date/time	_____
2nd AXa level	_____
Was lovenox dosing adjusted after second AXa level?	◯ Yes ◯ No, appropriate level ◯ No, other reason
What was other reason for no dosing change?	◯ Patient discharged before regimen changed ◯ Not done when should have ◯ Other
If other, please describe	_____
3rd Lovenox Dosing (after 2nd adjustment)	◯ 30mg daily ◯ 40mg daily ◯ 30 BID ◯ 40 BID ◯ 60 BID ◯ Other (after first Axa level and dose adjustment)
If other, please describe new lovenox dose	_____
3rd AXa level obtained after dose adjustment?	◯ Yes ◯ No
Reason for no 3rd AXa level	◯ Discharged prior to obtaining second level ◯ Not done but should have ◯ Transitioned to full anticoagulation ◯ Other
If "other", please describe reason for no 3rd AXa level	_____
# consecutive doses prior to 3rd AXa level	_____
Date/time of lovenox dose prior to 3RD AXa level date/time	_____ (dose immediately prior to 2nd Axa level)
3rd AXa level date/time	_____

3rd AXa level	_____
Did the patient have any missed/held doses of lovenox during admission?	◯ Yes ◯ No
# of missed/held doses	_____
Reason for missed/held doses	☐ Held for pre-procedure reason ☐ Held for bleeding concern ☐ Patient refused ☐ Patient in OR/Procedure at time dose due ☐ Other
What procedure?	_____
If "other", please describe reason for missed/held dose	_____
Did patient require transfusion associated with the bleeding concern?	◯ Yes ◯ No
How many units (RBCS) were transfused?	_____

Outcomes

Required ICU admission?	◯ No ◯ Yes
ICU Length of Stay	_____ (days)
Discharge Disposition	◯ Home ◯ Skilled Nursing Facility (SNF) ◯ LTACH ◯ Sub acute Rehab ◯ Inpatient Rehab ◯ Hospital Mortality ◯ Hospice ◯ AMA ◯ Transfer ◯ Other
Was imaging ordered to evaluate for VTE?	◯ Yes, during admission ◯ Yes, in 30d follow up ◯ No
Was imaging ordered for clinical concern or routine screening?	◯ Clinical concern ◯ Routine screening
Bleeding event?	◯ Yes, during admission ◯ Yes, in 30d follow up ◯ No (please only include bleeding events that required transfusion (not including transfusions for routine clinical care - only include transfusions for clinical concern of bleeding))
How many units were transfused with bleeding event?	_____
Diagnosed with DVT?	◯ Yes, during admission ◯ Yes, in 30d follow up ◯ No
Diagnosed with PE?	◯ Yes, during admission ◯ Yes, in 30d follow up ◯ No
30 day mortality?	◯ Yes ◯ No

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

EAST MULTICENTER STUDY
DATA DICTIONARY

Anti Factor Xa Monitoring of Venous Thromboembolism Prophylaxis in Emergency General Surgery Patients: A prospective multi-center study

Data Dictionary

Form	Variable name	Definition/Instructions	Additional Instructions
Demographics	Admission Age	Age at time of admission	Enter 999 if unknown or pt age >89 then specify if greater than 89yo
	Sex	Sex of patient enrolled	
	Race	Choose appropriate race of patient enrolled	Select appropriate choices
	Ethnicity	Ethnicity of patient enrolled	Select one: Hispanic Not Hispanic Unknown
	Height	Heigh in centimeters (cm) of patient at time of admission	
	Weight	Weight in kilograms (kg) of patient at time of admission	
	BMI	Auto calculated based on height/weight provided	
	Co-Morbidities	Choose of comorbidities listed that patient has hx or present at time of admission	Select all that are applicable to patient
	Liver Disease Category	Distinguish type of liver disease (if liver disease selected in comorbidities)	Moderate = chronic hepatitis or cirrhosis without portal hypertension Mod/Severe = cirrhosis with portal hypertension and subsequent sequelae
	Diabetes Category	Distinguish type of diabetes (if diabetes selected)	Select one: Uncomplicated = no end organ damage from diabetes End Organ Damage = pt with diabetes and end organ damage (neuropathy, renal disease, etc)

	Solid Tumor Category	Distinguish type of solid tumor (if selected in comorbidities)	Select one if patient has active diagnosis of solid tumor at time of admission: Localized Metastatic
	On antiplatelet medication?	Select if patient on any anti-platelet at time of admission	
	Anti-Platelet medication	Select which medication patient is on at admission	
	Were meds continued admission?	Select whether any/the antiplatelet meds were continued through admission	
	Which meds?	Select medication that was continued on admission	
	Active tobacco use	Select if patient actively using tobacco at time of admission	
Admission Data	Admission Date/Time	Date and time of admission for patient	(Month/Day/Year 00:00)
	Discharge Date/Time	Date and time of discharge for patient	(Month/Day/Year 00:00)
	Admission diagnosis	Free text for EGS diagnosis of admission	List general EGS diagnosis(es) patient had for admission
	Did patient undergo operation?	Select if patient had an operation during admission	
	OR Date/Time	Date and time of operating room entry	(Month/Day/Year 00:00) – choose entry time for first operation if multiple on admission
	Operation Approach	Choose initial approach of operation: Lap Robot Open	
	Operation	Free text for operation patient underwent	Describe first operation if patient had multiple on admission
	Total number of operations during admission	Total number of operations	
VTE Prophylaxis Data	Initial Lovenox Dose	Select initial dose and timing of lovenox from options: 30mg daily	

		40mg daily 30mg BID 40mg BID 60mg BID Other	
	If other describe	Free text if select "other" above to indicate the initial lovenox dose/timing	
	# consecutive doses prior to AXa level	Number of consecutive doses on regimen specified above prior to obtaining AXa level	(Axa = Anti Factor Xa)
	Date/Time Lovenox dose prior to AXa level	Date/Time of lovenox dose administered just prior to AXa level obtained	(Month-Day-Year 00:00)
	First Axa Level Date/Time	Date/Time of first AXa level obtained	(Month-Day-Year 00:00)
	AXa Level result:	First AXa level result (IU/mL)	To 2 decimal points
	Was lovenox dosing adjusted after first AXa level?	Select appropriate choice if any change to lovenox regimen made after first AXa level: Yes No, appropriate Axa level No, other reason	Appropriate level within appropriate prophylactic range
	What was other reason for no dosing change?	Select following: Patient discharged before regimen changed Not changed when should have Other	"Not changed when should have": based on institutional protocol dosing should have been changed, but no clear reason it was not and was missed Other: please elaborate on reason (i.e. team decided against changing reason for … reason, patient transitioned to SQH or anticoagulation for … reason)
	2nd Lovenox Dose	Select new dose/timing of lovenox if changed after initial Axa level	Same regimen options as prior Will only show if answered yes to dosing changed
	2nd Axa level obtained after dose adjustment?	Select yes or no if additional Axa level obtained after a dose adjustment	
	Reason for no 2nd AXa level	Select reason for no 2nd AXa level obtained:	Describe other if chosen

		Discharged prior to obtaining Not done but should have Other	
	# consecutive doses prior to 2nd AXa level	Number of consecutive doses on changed regimen specified above prior to obtaining the second AXa level	
	Date/Time Lovenox dose prior to second AXa level	Date/Time of lovenox dose administered just prior to second AXa level obtained	(Month-Day-Year 00:00)
	2nd AXa level date/time	Date/Time of second AXa level obtained	(Month-Day-Year 00:00)
	2nd Axa level	Second AXa level result (IU/mL)	To 2 decimal points
	Was lovenox dosing adjusted after second AXa level?	Select appropriate choice if any change to lovenox regimen made after first AXa level: Yes No, appropriate Axa level No, other reason	Appropriate level within appropriate prophylactic range
	What was other reason for no dosing change?	Select following: Patient discharged before regimen changed Not changed when should have Other	"Not changed when should have": based on institutional protocol dosing should have been changed, but no clear reason it was not and was missed Other: please elaborate on reason (i.e. team decided against changing reason for … reason, patient transitioned to SQH or anticoagulation for … reason)
Sequence above repeats for a third time if necessary/appropriate			
	Did the patient have any missed/held doses of lovenox during admission?	Yes or No if patient had any missed or intentionally held doses once initiated on dvt ppx	

	# of missed/held doses	Total number of missed/held doses throughout admission	
	Reason for missed/held doses	Select all of following that apply to patient's admission: Held for pre-procedure reason Held for bleeding concern Patient refused Patient in OR/Procedure at time dose due Other	
	What procedure?	Free text response: If held for pre-procedure reason list procedure(s) that DVT ppx was held for	
	Describe if "other"	Free text response to describe why missed/held doses happened	
	Did patient require transfusion associated with the bleeding concern?	If "held for bleeding concern" checked – select yes or no if patient required transfusions associated with concern for bleeding event	
	How many units (RBCS) were transfused?	Number of units transfused	
Outcomes			
	Required ICU admission?	Select yes or no if patient required ICU care	
	ICU LOS	In number of days	
	Discharge Disposition	Select where patient was sent upon leaving the hospital: Home Skilled Nursing Facility (SNF) LTACH Sub acute Rehab Inpatient Rehab Hospital Mortality Hospice AMA Transfer Other	LTACH = long term acute care hospital AMA = left against medical advice Transfer = transferred to another hospital

	Imaging ordered to evaluate for VTE?	Select if any imaging was ordered to evaluate for a VTE during patient's admission or in 30d of follow up from discharge	
	Imaging ordered for clinical concern or routine screening?	Select one from following: Clinical concern Routine screening	"Clinical concern" = concern for a DVT/PE and thus imaging ordered
	Bleeding event?	Select if patient experienced a bleeding event (required blood transfusion) during patient's admission or in 30d of follow up from discharge	Only include transfusions for concern of bleeding (not routine transfusions for a slow drift in Hgb that reaches transfusion threshold or pre op optimization etc)
	How many units were transfused with bleeding event?	Number of RBC units transfused	
	Diagnosed with DVT?	Select if patient was diagnosed with a DVT during patient's admission or in 30d of follow up from discharge	
	Diagnosed with PE?	Select if patient was diagnosed with a PE during patient's admission or in 30d of follow up from discharge	
	30day mortality?	Yes/No question if patient died within 30 day follow up period	

MEDICAL COLLEGE OF WISCONSIN

Medical College of Wisconsin
Institutional Review Board

To: Patrick Murphy, MD
Anna Tatakis
CC: Courtney Pokrzywa

Date: **5/6/2025**

Re:	**Project Title**:	Anti Factor Xa Monitoring of Venous Thromboembolism Prophylaxis in Emergency General Surgery Patients: A Prospective Multicenter Study
	IRB Approval Date:	5/6/2025
	PRO ID:	PRO00055236

The MCW Institutional Review Board #5 has granted an exemption from IRB oversight for the above-referenced submission in accordance with 45 CFR 46.104(d)(4).

The items listed below were submitted and reviewed when the IRB approved this submission. Research must be conducted according to the IRB approved documents listed below:

EAST AXa screening log (1)
AXa DCF Redcap variables
AXa Proposal-IRB

Given that the current project does not involve direct contact with subjects, an informed consent process is not required. The IRB has granted approval of a waiver of HIPAA authorization requirements at 45 CFR 164.

Consent and authorization for use of data was addressed in the MCW IRB-approved banking project: Clinical Research Data Warehouse (PRO00013874).

Decedent data may be accessed in accordance with 45 CFR 164.512.

The Principal Investigator is responsible for notifying the IRB via Amendment prior to initiation of any additions or modifications made to this project. On an annual basis, you will be asked to complete an exempt status update report, so that the IRB can maintain an accurate record of all current projects. **If a response is not received within one year, the project will be automatically completed within the system and any activities conducted after closure will be considered research conducted without IRB approval.**

Exempt Category #4 projects no longer require Froedtert Office of Clinical Research and Innovative Care Compliance (OCRICC) review and approval.

In order to meet the requirement of accounting for all use and disclosures of Protected Health Information (PHI) for the purpose of research without patient authorization, research staff must complete an Accounting Log specific to that project's disclosure. This must be completed electronically via the web-based Accounting Log Form located here. Upon completion, this log will be submitted directly to Froedtert Health Information Management (HIM) and will be considered valid for the length of the IRB Approval of the study. At time of government audit or other administrative request, researchers must be able to produce their less than 50 screening list within 48 business hours, if requested. Principal Investigators are ultimately accountable for the conduct of their research.

Be advised:

1. MCW Researchers are required to use the Medical College of Wisconsin (MCW) Clinical Translational Science Institute (CTSI) Clinical Research Data Warehouse (CRDW) resources and tools for obtaining formal Reports of PHI data, images, etc.
2. Requests for financial, cost or other data not yet available through the CRDW: MCW researchers will need to complete an F&MCW Reports, Data & Analysis Request https://remedy-prod-smartit.s1.fchhome.com/ux/myitapp/#/catalog/home. Researchers must attach a copy of the project IRB Registration Letter & the Data Collection Form (DCF) to your Report Request. This process does require a Froedtert network account. To obtain Froedtert network access, work with your Department Administrative personnel.
3. Questions regarding access to FH data or OCRICC review and approval, please contact OCRICC office: ocricc@froedtert.com

Please complete your project within eBridge when all project activities have been completed.

If you have any questions, please contact the IRB Coordinator II for this IRB Committee, Chris Koceja, at 414-955-2603 or ckoceja@mcw.edu.