- To: Marc De Moya, MD Patrick Murphy, MD
- CC: Elise Biesboer Caroline Herdeman Courtney Pokrzywa, MD Krissa Packard Juan Figueroa, MD Abdul Hafiz Al Tannir, MD

Date: 5/30/2023

 Re:
 Project Full Title: The Definition of a Full Time Employee amongst Trauma/ACS Surgeons within Trauma Centers

 PRO ID:
 PRO00036985

 Amendment
 Quantifying and assessing the impact of the shortage of trauma and acute care surgeons

 Amendment ID:
 AME00027311

Description of Amendment:

Adding new questions to survey to estimate the shortage of trauma and acute care surgeons Collecting the number of full-time employees at trauma centers Collecting hospital level outcomes (no patient level data). Outcomes include mortality and morbidity

The MCW Institutional Review Board #5 has reviewed the above-referenced amendment and determined that the project with these changes continues to satisfy the criteria for registration in accordance with the MCW IRB Policy: *Registration Projects: Human Subject Research Projects which Qualify for Flex Review*.

With this amendment, the project and the proposed activities meets the criteria for registration, under category 9.

All project activities must be conducted according to the protocol that was approved by the IRB.

Any and all proposed changes to this submission must be reviewed and approved by the IRB prior to implementation. When necessary to eliminate hazards to subjects, changes may be made first. This should be followed promptly by submission of a protocol deviation and amendment.

All Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) must be reported promptly to the MCW IRB according to IRB Standard Operating Procedures (SOPs).

If your project involves the use of any Froedtert Health resource such as, space, staff services, supplies/equipment or any ancillary services - lab, pharmacy, radiology, protected health/billing information or specimen requests, OCRICC approval is required before beginning any research activity at those sites.

With this Amendment, if your project involves the use of any Froedtert Health resource such as, space, staff services, supplies/equipment or any ancillary services - lab, pharmacy, radiology, protected health/billing information or specimen requests, OCRICC Review is necessary and their approval is now required before continuing the research at those sites.

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

Sincerely,

Nevin Uysal Biggs, MD IRB Chair MCW Institutional Review Board #5

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Multicenter Study:				
Enrolling Center: Enrolling Co-investigat Enrolling Co-investigat				
Hospital Variables:				
Hospital Name:				
City of Hospital:				
Level of Trauma Cente	r (circle one): I II			
Type of Verification (cir	rcle all that apply): A	merican College of Surg	jeon State	Non-Verified
ACS Emergency Gene	ral Surgery Verification:	Yes No		
Dedicated Division of T	rauma/Acute Care Surg	gery: Yes No		
Number of Hospital Be	ds:			
Number of Trauma Act	ivations in 2022 (Calenc	dar Year):		
Number of Trauma Adı	missions in 2022 (Calend	dar Year):		
Please mark with an 'X	" in the following table re	egarding your on-call co	verage (overnight and w	eekends).
Weeknight	In-House	In-House	At-Home	At-Home Back-Up
weekiigiit	1			

In the space below please describe how a 1.0 clinical full-time equivalent (FTE) is defined. This will be further explored in the qualitative interview.

Weekend

Surgeon Variables:

Surgeons outside the Division of Trauma/ACS contribute to clinical care of trauma/ACS/SICU: Yes No Example: Colorectal trained surgeon covers general surgery call on some Saturdays; Anesthesia covers the SICU occasionally then answer YES

Number of Physicians contributing any portion of FTE clinically to care of trauma/ACS/SICU: ______ Example: If you answered 'Yes' above include the non-Trauma/ACS surgeon in this number

Number of Surgeons **in the Division of Trauma/ACS** contributing any portion of FTE clinically to care of trauma/ACS/SICU: _____

In the calendar year our hospital hired additional surgeon(s) to cover Trauma/ACS/SICU: Yes No

If YES – Number hired and start date (MM/DD)

Hire #1 Last Name	FTE	Start Date (MM/DD)
Hire #2 Last Name	FTE	Start Date (MM/DD)
Hire #3 Last Name	FTE	Start Date (MM/DD)
Hire #4 Last Name	FTE	Start Date (MM/DD)
Hire #5 Last Name	FTE	Start Date (MM/DD)

In the calendar year our hospital lost surgeon(s) who cover Trauma/ACS/SICU: Yes No

If YES – Number lost and end date (MM/DD)

Loss #1 Last Name	FTE	End Date (MM/DD)
Loss #2 Last Name	FTE	End Date (MM/DD)
Loss #3 Last Name	FTE	End Date (MM/DD)
Loss #4 Last Name	FTE	End Date (MM/DD)
Loss #5 Last Name	FTE	End Date (MM/DD)

Please complete the following table for the **assigned CLINICAL FTE** for each physician for the calendar year 2022. For example, your Trauma Medical Directors is assigned 50% clinical and therefore in the Table below the assigned FTE would be 0.5. Some surgeons have protected administrative times (15%) and are therefore 0.85 clinical FTE.

Physician Last Name	Assigned Clinical FTE	Physician Last Name	Assigned Clinical FTE

Please share your 2022 Calendar Year clinical schedule, including all clinical coverage for your Division/Hospital with pmurphy@mcw.edu

Patient Outcomes:

Below, report your TQIP outcomes for Fall of 2022. This data is available from your TQIP reports.

FALL 2022								
Outcome	Observed (%)	Expected (%)	Odds Ratio	Lower	Upper	Decile		
MORTALITY								
All Patients								
Blunt Multisystem								
(MS)								
Penetrating								
Shock								
Severe TBI								
Elderly								
Elderly Blunt MS								
	MAJOR HOS	PITAL EVENTS (EXCLUDING DE	ATH)				
All Patients								
Blunt Multisystem								
(MS)								
Penetrating								
Shock								
Severe TBI								
Elderly								
Elderly Blunt MS								
	MOR	BIDITY (ALL PAT	IENTS ONLY)					
Acute Kidney Injury								
Ventilator Associated								
Pneumonia								
Pulmonary Embolism								
Surgical Site Infection								
Unplanned ICU Admit								
Unplanned OR								
CAUTI								

Below, report your TQIP outcomes for Spring of 2023.

SPRING 2023								
Outcome	Observed (%)	Expected (%)	Odds Ratio	Lower	Upper	Decile		
MORTÁLITY								
All Patients								
Blunt Multisystem (MS)								
Penetrating								
Shock								
Severe TBI								
Elderly								
Elderly Blunt MS								
	MAJOR HOS	PITAL EVENTS (EXCLUDING DE	ATH)				
All Patients								
Blunt Multisystem (MS)								
Penetrating								
Shock								
Severe TBI								

Elderly						
Elderly Blunt MS						
MORBIDITY (ALL PATIENTS ONLY)						
Acute Kidney Injury						
Ventilator Associated						
Pneumonia						
Pulmonary Embolism						
Surgical Site Infection						
Unplanned ICU Admit						
Unplanned OR						
CAUTI						