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**Study Title:** Interpersonal violence in the elderly

**NYULH Study Number:** s19-01097

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### **Statement of Compliance**

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

## **1 RESEARCH OBJECTIVES AND PURPOSE OF THE STUDY**

The purpose of this study is to determine the incidence of IPV in the elderly trauma patient. The secondary aim is to determine the predictive ability of EHR variables to identify IPV. Our overall goal is develop a tool to better predict high-risk IPV victims to tailor health care services and interventions.

## **2 BACKGROUND AND RATIONALE**

Intimate partner violence (IPV) is a serious and prevalent public health problem that often goes unrecognized in the clinical setting. Intimate partner violence in the abuse of elderly and vulnerable adults is common in the United States but often remains undetected. Nearly 31% of women and 26% of men report having some form of IPV in their lifetime with the elder population affected at a rate of 700,000 to 1.2 million. The last of the baby boomer population is expected to reach age retirement age by 2029 with this group currently accounting for 25% of the population.

Health care settings can serve as key points of entry into services for both victims and perpetrators and provide an important opportunity for intervention. However, barriers to screening, including lack of IPV awareness, lack of understanding from health care workers, and lack of resources to commit to universal screening result in underreporting of the true incidence of IPV in any population and in particular, the elderly.

Research has shown that elderly patients who are victims of abuse are 3.1 times more likely to die in 3 years as compared to like patients. The estimated prevalence of elder abuse ranges from two to 10% depending on the definitions and methods. While 1 in 10 elderly adults may experience abuse, only one in five will have the case reported.

Understanding the incidence and prevalence of IPV in the older population is tantamount to patient care.

### **3 STUDY DESIGN**

This is a multi-institutional, prospective, observational study. Collected data will include all variables defined and captured as outlined in TQUIP from the trauma registries: demographics (ethnicity, age, sex, race, income level, socioeconomic status, insurance status), comorbidities, medications, substance abuse, alcohol level at admission, residence at the time of injury, marital status, individuals living or caring for patient (skilled nurse, home health aide, spouse or partner, family member), mechanism of injury description, MiniCog assessment, Frailty score (using the Trauma Specific Frailty Index).

HIT: if patients are identified as being victims of IPV a positive screen; defined as a score of >1 an intervention plan will be as follows: Centers will be instructed to include in their IRB a plan to address a positive screen such as contacting the site PI, the attending covering the patient, or the treating team. Usual practice will be implemented.

### **4 SUBJECT SELECTION**

#### **4.1 Inclusion Criteria**

- Patients who are  $\geq 65$  years old and 89 years old who present after injury and are able to actively participate in completion of study surveys
- Able and willing to provide consent

#### **4.2 Exclusion Criteria:**

- Patients age  $\geq 65$  years of age who are unable to actively participate in completion of the survey tool.

#### **4.3 Vulnerable Subjects**

No vulnerable population will be included in this study.

## **5 DURATION OF STUDY PARTICIPATION**

The research study is expected to take approximately two years, but your participation may take a few hours of a single day at most. The total expected number of subjects recruited for the study will be 200 per site. This study currently will be conducted at several institutions through United States.

## **6 STRATEGIES FOR RECRUITMENT AND RETENTION**

Patients will be approached when they come through emergency room being evaluated and considered to participate in the study. They can be study team's patients or brand new ones. Each potential subject must provide written consent with full knowledge of the procedures involved. The informed consent, approved by the IRB and in accordance with regulatory guidelines, must be fully explained by the Investigator or member of the study staff including the study aims, methods, benefits and risks, and signed by the subject before enrollment into the study. Potential subjects will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment. The subjects will be informed that they will be authorizing access of investigational staff to confidential medical records. The subject will be given sufficient time to read the consent and ask any questions. Once the informed consent is signed, the subject will be given a copy of the document.

The total expected number of subjects recruited for the study will be 200 per site. This study currently will be conducted at several institutions through United States as part of a multi-institutional study sponsored by the American Association for the Surgery of Trauma (AAST).

Epic will be not used. The information needed will be taken from the Trauma Registry. Trauma registries is mandatory for each trauma center ACS level 1 verified in US. Only trauma centers has it, and every participating center will have access to their own.

## **8 STUDY PROCEDURES / EVALUATIONS**

A data collection form will be completed, and a series of forms will be filled out in order to collect as much information as possible, including Functional Independence Measure (FIM), Hurt, Insulted, Threatened with harm and Screamed (HITS) Domestic Violence Screening Tool, Trauma Specific Frailty Index, and the administration of the Universal Mini-Cog form.

## **9 RISKS AND BENEFITS**

It will be no direct benefits to the subjects of this study. The only risk is the loss of confidentiality to study subjects.

## **10 STATISTICAL ANALYSIS**

Descriptive statistics will be conducted with SPSS statistical software. Multiple logistic regression analyses will be conducted to identify predictors of current IPV and to determine the best predictive models of any psychological and physical IPV. Odds ratios from the final models will be calculated and used to develop the cumulative risk model.

Variables significant ( $p < 0.05$ ) in the bivariate analysis will be selected for the multiple logistic regression models. The total number of predictors in the models will be minimized.

## **11 DATA SAFETY MONITORING**

PI will have periodic meetings with the research team to ensure the appropriate steps are taken in order to obtain the maximum information, ensuring the data obtained is accurate, and to minimize any risk in term of confidentiality. The study team does not anticipate subjects experiencing any adverse events solely due to being in the study. Therefore, a formal Data Safety Monitoring Board will not be needed for this study.

## **13 ETHICS / PROTOCOL OF HUMAN SUBJECTS**

### **13.1 Ethical Standard**

The investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

### **13.2 Institutional Review Board**

The protocol, key information form, informed consent form, recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any

amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

### **13.3 Consent Procedures and Documentation**

Potential subjects will be approached when they come through emergency room being evaluated and considered to participate in the study. Each potential subject must provide written consent with full knowledge of the procedures involved. The informed consent, approved by the IRB and in accordance with regulatory guidelines, must be fully explained by the Investigator or member of the study team including the study aims, methods, benefits and risks, and signed by the subject before enrollment into the study. The consent process will take place in the Emergency Department, in a private room to protect the subject's privacy. Potential subjects will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment. The subjects will be informed that they will be authorizing access of investigational staff to confidential medical records. The subject will be given sufficient time to read the consent and ask any questions. Once the informed consent is signed, the subject will be given a copy of the document.

### **13.4 Participant and Data Confidentiality**

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (i.e. that the subject is alive) at the end of their scheduled study period.

### **13.4.1 Research Use of Stored Human Samples, Specimens, or Data**

Data collected for this study will be analyzed and stored at the PI's secure and locked office. Electronic data will be stored in MCIT-managed network drive. After the study is completed, the de-identified, and archived under the direct supervision of Dr. Joseph and Dr. Petrone.

## **14 DATA HANDLING AND RECORD KEEPING**

### **14.1 Data Collection and Management Responsibilities**

Data collection is the responsibility of the study staff at the site under the supervision of the site PI. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Black ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. **DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.**

Copies of the electronic CRF (eCRF) will be provided for use as source documents and maintained for recording data for each participant enrolled in the study. Data reported in the eCRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official electronic study record.

Clinical data and clinical laboratory data will be entered into an excel file where it will be collected for future statistical analysis. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

### **14.2 Study Records Retention**

Study documents will be retained for the longer of 3 years after close out or 5 years after final reporting/publication. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

### **14.3 Publication and Data Sharing Policy**

This study will comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. NYU PHI will not be shared outside of NYU.

## **15 STUDY FINANCES**

### **15.1 Funding Source**

N/A

### **15.2 Costs to the Subjects**

None

### **15.3 Subject Reimbursements or Payments**

None

## **16 ANTICIPATED RESULTS**

This project has the potential to increase awareness of IPV in a rapidly expanding population with the potential reduction of the risk of death in that group. The development of a predictor for IPV in the elder population will provide an important model for the ACS surgeon in the management of the injured elder patient. This pilot study will provide data for initial testing and construction of a probabilistic algorithm. We anticipate using initial data to provide justification for a more research, which could provide power for testing of additional risk factors/predictors pulled from patient charts.



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