



## **EAST MULTICENTER STUDY PROPOSAL**

*(Proposal forms must be completed in its entirety, incomplete forms will not be considered)*

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### **GENERAL INFORMATION**

**Study Title:**

**Screening All Trauma Patients for Inter-personal and Sexual Violence**

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**Primary investigator / Senior researcher:**

**Dr Tanya L. Zakrison**

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**Co-primary investigator:**

**Dr. Paula Ferrada, Dr. Rondi Gelbard**

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### **BACKGROUND AND SIGNIFICANCE**

Trauma patients may be at increased risk of intimate partner violence (IPV) or sexual violence (SV). Preliminary research at a busy, Level I Trauma Center has demonstrated that the rate of such violence to be as high as 12% when screening all patients who present, regardless of mechanism (1). Furthermore, we have found that both male and female trauma patients are equally at risk of both IPV and SV, with an equal prevalence of such violence (1). Screening tools exist that are validated in both men and women and in other languages (2,3). These rapid screening tools have been used in Emergency Departments across the country, and focus on women, but are not applied to the trauma setting (4). Currently, there are no national standards for screening **all** trauma patients on arrival to Level I trauma centers, despite such standards existing in emergency departments and other clinical settings (5). Patients there are screened in a non-standardized fashion, typically if there is pre-existing suspicion of intimate partner or sexual violence as the cause of the inciting trauma. Also trauma patients, at times, may only interact with health care professionals during these times of trauma due to barriers to care. We therefore propose to screen all eligible trauma patients – both men and women – for intimate partner and sexual violence upon arrival at Level I Trauma Centers. We hypothesize that all trauma patients may be at increased risk of both IPV and SV when compared to the general population. Trauma may therefore provide a unique opportunity for health care professionals to screen and intervene on such occult violence, preventing future injury and / or death by intimate partner homicide.

**The specific aims of this multicenter study are:**

Primary aim:

Our primary aim is to **determine the overall prevalence of IPV and SV** in all eligible trauma patients who present to Level I Trauma Centers.

Secondary aims:

Our secondary aims would be to:

- 1) **Determine the prevalence of IPV and SV** in trauma patients presenting with non-intentional, non-violent injuries (for example, motor vehicle collision) to assess if trauma patients, in general, are at higher risk of such violence, regardless of mechanism of injury.
- 2) **Determine the feasibility of screening** eligible adult male and female trauma patients for intimate partner and sexual violence
- 3) **Assess the barriers to screening**, if any exist.

## **EXPERIMENTAL DESIGN/METHODS**

### **Inclusion Criteria:**

Patients included in our study would be both adult male and female patients sustaining any traumatic injury, who consent to screening. These include pregnant women and prisoners as their rates of abuse are even higher than the average trauma cohort, representing a vulnerable population.

### **Exclusion Criteria:**

Our exclusion criteria would include any trauma patient who refuses screening, is a minor or is unable to participate in the study due to:

- 1) severity of injury with ongoing resuscitation
- 2) presence of traumatic brain injury
- 3) significant intoxication and inability to answer questions
- 4) intubation

### **Therapeutic Interventions:**

This would be a **prospective, observational study only**. Patients will be screened at all sites by clinical social workers using the validated HITS and SAVE screening tools. Patients who are identified as positive will be managed according to standard of care by local clinical social workers at each institution. Feasibility and barriers to screening will be explored using a mixed-methods approach by interviewing social workers quarterly. We will use previously designed (but non-validated) surveys exploring attitudes and barriers to screening for IPV and SV. Also we will conduct focus group interviews with clinical social workers to further explore these barriers using qualitative methodology and grounded theory analysis.

### **Outcomes Measures:**

#### Primary Outcome:

The primary outcome will be the **prevalence of intimate partner and sexual violence** in adult male and female trauma populations.

#### Secondary Outcomes:

Secondary outcomes will include:

- 1) The **prevalence of IPV and SV** in the subgroup of trauma patients presenting with **non-intentional, non-violent injuries**.
- 2) The **feasibility of screening this population** in the trauma bay after acute injury.

### **Variables:**

- 1) **Demographics:** age, gender, ISS, mechanism of injury
- 2) **Eligibility for screening:** compared to total trauma admissions
- 3) **Willingness to be screened:** yes or no; reason
- 4) **HITS results:** this generates a score out of 20 with the cutoff of 10 indicating positivity for IPV
- 5) **SAVE results:** any positive response indicated vulnerability and exposure to sexual violence

- 6) **Barriers and attitudes to screening:** survey and focus group (mixed-methods) results from clinical social workers

#### **Data Collection and Statistical Analysis:**

Standardized data will be included for each patient, starting with demographic data (see appendix A). Appendix B includes the screening tools for both intimate partner violence (HITS) and sexual violence (SAVE). Barriers to screening by clinical social workers will be explored using mixed methods by completing survey and qualitative, open-ended questions in Appendix C. Barriers will be explored with social workers every 3 months. Descriptive data will be collected and analyzed.

#### **Consent Procedures:**

Consent procedure will proceed in accordance with local standards of care by clinical social workers requesting information from patients. Consent will be verbal and flexible, obtained as per social worker standard of care. Formal consent for inclusion into a prospective, observational research study will be waived as this is no different from current standard of care for all clinical social workers already screening for intimate partner violence in trauma patients. The only difference is that they are screening all patients, not just those patients at high risk of intimate partner violence. Patient data will be recorded and protected by clinical social workers, again as per standard of care. Patient identifiers will not be provided to researchers. We will, however, request consent from clinical social workers participating in the screening to explore any perceived barriers to screening. Consent would be granted verbally with such wording:

“We are conducting a prospective, observational, cohort study designed to explore the prevalence of intimate partner and sexual violence in all trauma patients, and the feasibility for screening by clinical social workers. By completing the attached survey (Appendix C) you are consenting to participate in this study by sharing your beliefs on barriers to screening.”

#### **Risk / Benefit Analysis:**

The overall prevalence of intimate partner and sexual violence in trauma patients is unknown. Current national standards recommend routine screening for this in the emergency department and other areas but no such guidelines exist in trauma as it remains unclear how serious a problem this may be. A recent single-center study has demonstrated the prevalence for both intimate partner and sexual violence to be high, at 12% and 8%, respectively, with similar rates between men and women. This translates into one out of 8 or 12 patients being affected by some form of intimate partner violence, or both. It remains to be seen if this is representative of trauma patients across the country or is unique to one center. Nonetheless, if the prevalence is found to be not insignificant for trauma patients, routine screening of all patients, regardless of mechanism or gender, will lead to a higher rate of positive screens and intervention as per standard of care. This may have a significant beneficial outcome for trauma patients in the future that may remain at risk for intimate partner or sexual violence. Also, by identifying barriers to screening by clinical social workers, interventions to eliminate these in the future will lead to improved rates of screening and intervention.

#### **Instructions for submitting data collection tools:**

All data submissions should be entered through the EAST Multicenter Trial Taskforce website portal. Instructions can be found on the EAST website. The data collection sheet located under the Multicenter Trial Taskforce heading for this study can be utilized to record the data, and then the information transferred to the portal entry system. For any questions regarding this study, please contact the PI.

**References:**

1. Zakrison *et al.*, Unpublished data, EAST poster presentation 2015.
2. Sherin KM, Sinacore JM, Li XQ, et al. HITS: A Short Domestic Violence Screening Tool for Use in a Family Practice Setting. *Fam Med.* 1998;30(7):508-12.
3. Florida Council Against Sexual Violence. (2012). How to screen your patients for sexual assault: A guide for health care professionals. <http://www.fcasv.org/publications/save> (accessed Oct. 14th, 2014).
4. [http://aspe.hhs.gov/hsp/13/dv/pb\\_screeningdomestic.cfm](http://aspe.hhs.gov/hsp/13/dv/pb_screeningdomestic.cfm) (accessed Oct. 01, 2014).
5. <http://www.uspreventiveservicestaskforce.org/uspstf/uspsipv.htm> (accessed Oct. 25th, 2014).

## Appendix A:

### Patient Demographics:

Age (years)
Gender (M, F or other)
Race (White, non-hispanic, Hispanic, African-American, Asian, other)
Previous admission to a trauma center? Y or N
Mechanism of Injury:
Injury Severity Score:
Eligibility for screening: Y or N If N why not?

**Appendix B: Standardized Data Collection Sheet – HITS & SAVE**

**A) HITS SCREENING TOOL (INTIMATE PARTNER VIOLENCE):**

**HITS Tool for Intimate Partner Violence Screening:** Please read each of the following activities and fill in circle that best indicates the frequency with which you partner acts in the way depicted.

How often does your partner?	Never	Rarely	Sometimes	Fairly often	Frequently
1. Physically hurt you	<input type="radio"/>				
2. Insult or talk down to you	<input type="radio"/>				
3. Threaten you with harm	<input type="radio"/>				
4. Scream or curse at you	<input type="radio"/>				
	1	2	3	4	5

Each item is scored from 1-5. Thus, scores for this inventory range from 4-20. A score of greater than 10 is considered positive.

*Clinical Research and Methods*  
(Fam Med 1998;30(7):508-12.)

<b>Score:</b>	<b>      / 20</b>
<b>&gt; 10:</b>	<b>YES            NO</b>

**B) SAVE SCREENING TOOL (SEXUAL VIOLENCE):**

Screening Questions: This project promotes the SAVE screening method, developed by the Florida Council Against Sexual Violence (Florida Council Against Sexual Violence, 2002). Adapted with permission from the Florida Council Against Sexual Violence

**S**

Screen all of your patients for sexual violence. Anyone could be a victim of sexual violence.

Ask the patient when no one else is in the examining room.  
Make direct eye contact and actively listen to the response.

**A**

Ask direct questions in a non-judgmental way. Avoid technical or medical language. Begin by first normalizing the topic. For example:

- “I need to ask you some personal questions. Let me explain why. Asking these questions can help me care for you better.”

- “Since I am your social worker, we need to have a good partnership. I can better understand your health if you would answer some questions about your sexual history.”
- “I ask all of my patients these questions because it is important for me to know what has gone on in their lives.”

Next ask the patient directly:

1. **“Have you ever been touched sexually against your will or without your consent?”**
2. **“Have you ever been forced or pressured to have sex?”**
3. **“Do you feel that you have control over your sexual relationships and will be listened to if you say “no” to having sex?”**

<b>Score:</b>	<b>/ 3</b>
<b>&gt; 0:</b>	<b>YES      NO</b>

**V**

Validate your patient’s response:

- “Thank you for telling me about such a difficult experience.”
- “I’m sure that was hard for you to tell me. It is good that you told me.”
- “Rape is devastating in many ways. Let’s talk about some of the ways you need support.”
- Be sure to document the response in your chart using the patient’s own words.

**E**

Evaluate, Educate and make Referrals.

If your patient says “yes,”

- Immediately evaluate present-day level of danger, other violence, drug and alcohol use and health habits.
- Mention the disclosure again during another visit and ask about the patient’s needs.
- Request a one to two-week follow-up appointment if necessary.

If your patient says “no,”

- offer education and prevention information and provide follow-up at next visit.
- If your patient is “not sure,” evaluate the experience(s) with the patient and provide education about violence and consent.

**Offer all patients the local rape crisis center information.**



EAST MULTICENTER STUDY  
DATA COLLECTION TOOL #1

**Multicenter Study: Intimate Partner and Sexual Violence**

Enrolling Center: \_\_\_\_\_

Enrolling Co-investigator: \_\_\_\_\_

**1) Demographics / Injury Variables:**

Age: \_\_\_\_\_ Gender: \_\_\_\_\_

**2) Mechanism of initial injury:**

Blunt: YES / NO

Penetrating: YES / NO

ISS: \_\_\_\_\_ AIS Head: \_\_\_\_\_ AIS Chest: \_\_\_\_\_ AIS Abdomen: \_\_\_\_\_

**3) Patient Eligible for Screening?**

- > 17 years old? Y N
- patient consented? Y N
- Patient not consentable due to:
  - Severity of injury
  - Presence of traumatic brain injury
  - Apparent intoxication
  - Patient is intubated
  - Other: \_\_\_\_\_

**4) Is the patient willing to be screened?**

Y N  
If NO, why not? \_\_\_\_\_

If YES, please read this Screening Prompt:

Ask the patient when no one else is in the examining room.  
Make direct eye contact and actively listen to the response.

Ask direct questions in a non-judgmental way. Avoid technical or medical language. Begin by first normalizing the topic. For example:

- "I need to ask you some personal questions. Let me explain why. Asking these questions can help me care for you better."
- "Since I am your social worker, we need to have a good partnership. I can better understand your health if you would answer some questions about your sexual history."
- "I ask all of my patients these questions because it is important for me to know what has gone on in their lives."

**5) Now please ask the HITS Screening Tool Questions:**

**HITS SCREENING TOOL (INTIMATE PARTNER VIOLENCE):**

**HITS Tool for Intimate Partner Violence Screening:** Please read each of the following activities and fill in circle that best indicates the frequency with which you partner acts in the way depicted.

How often does your partner?	Never	Rarely	Sometimes	Fairly often	Frequently
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*Clinical Research and Methods*  
(Fam Med 1998;30(7):508-12.)

**Score:            / 20**  
**> 10:            YES            NO**

**6) Next please ask the SAVE Screening Tool Questions:**

1. "Have you ever been touched sexually against your will or without your consent?"
2. "Have you ever been forced or pressured to have sex?"
3. "Do you feel that you have control over your sexual relationships and will be listened to if you say "no" to having sex?"

**Score:            / 3**  
**> 0:            YES            NO**

**V**

Validate your patient's response:

- "Thank you for telling me about such a difficult experience."
- "I'm sure that was hard for you to tell me. It is good that you told me."
- "Rape is devastating in many ways. Let's talk about some of the ways you need support."
- Be sure to document the response in your chart using the patient's own words.

**E**

Evaluate, Educate and make Referrals.

If your patient says "yes,"

- Immediately evaluate present-day level of danger, other violence, drug and alcohol use and health habits.
- Mention the disclosure again during another visit and ask about the patient's needs.

- Request a one to two-week follow-up appointment if necessary.

If your patient says “no,”

- Offer education and prevention information and provide follow-up at next visit.
- If your patient is “not sure,” evaluate the experience(s) with the patient and provide education about violence and consent.

**Offer all patients the local rape crisis center information.**

Thank you for your participation!



EAST MULTICENTER STUDY  
DATA COLLECTION TOOL - #2

**Multicenter Study: Intimate Partner and Sexual Violence**

Enrolling Center: \_\_\_\_\_  
Enrolling Co-investigator: \_\_\_\_\_

Thank you for your participation!

**8) Each 3 months please ask your social workers conducting the interviews the following questions:**

*Quantitative Questions:*

On a scale of 1 to 10 (10 being the most important) how would you rate these factors as influencing your ability to screen patients?

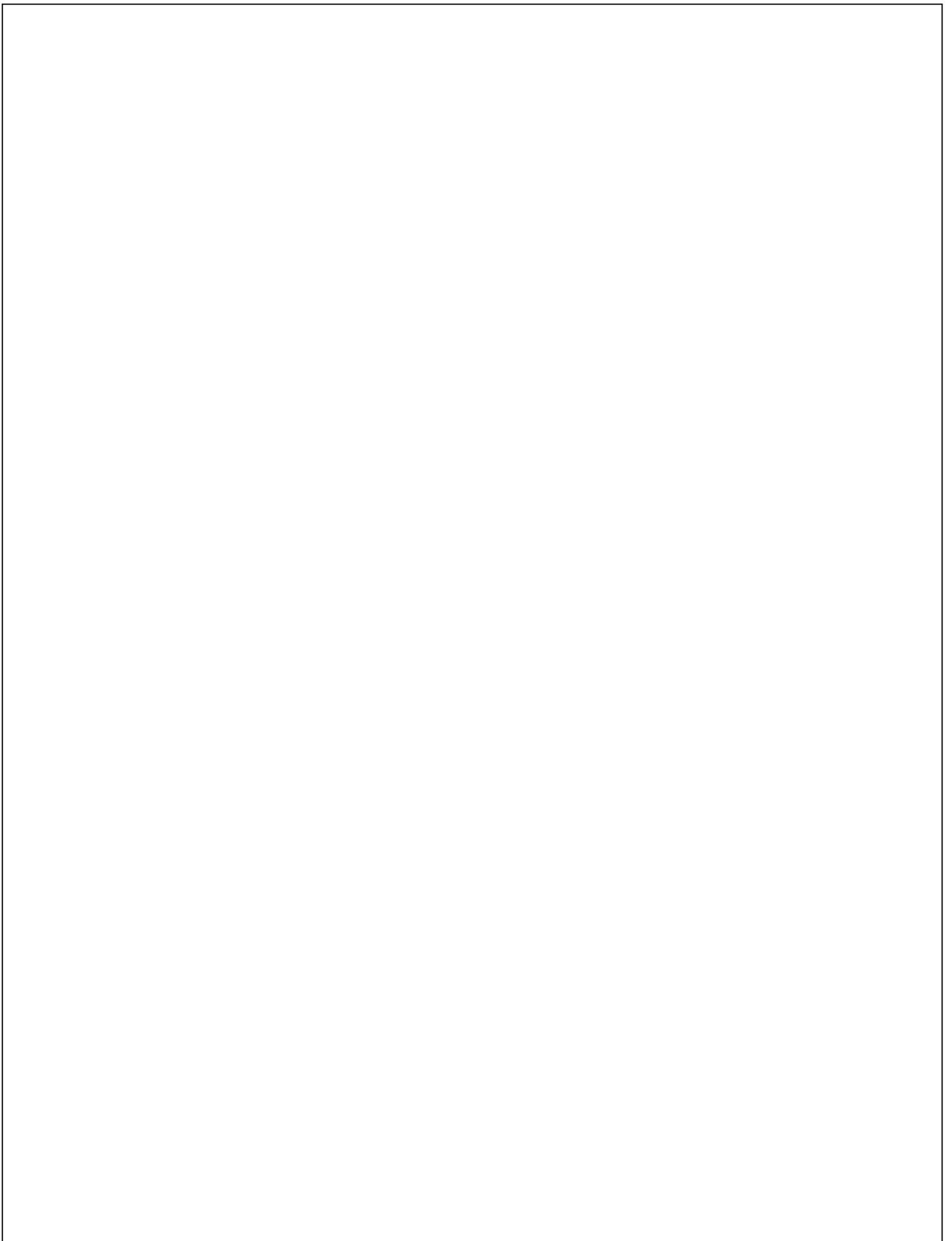
1. Lack of time
2. Lack of training
3. Patient refusal
4. Language/cultural practices
5. Partner presence
6. Lack of resources
7. Lack of space/privacy
8. Discomfort with topic
9. Lack of practitioner knowledge of resources
10. Other (please specify):

*Qualitative Questions:*

What do you experience as barriers to screening for abuse?

What has helped or would help make screening for abuse easier for you?

Thank you for your participation!





## **EAST MULTICENTER STUDY DATA DICTIONARY**

### Intimate Partner and Sexual Violence – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

<u>Entry space</u>	<u>Definition / Instructions</u>
<b><u>Standard Study Questions</u></b>	
Admit Date	Admission date of the patient enrolled
Admit Time	Admission time of the patient enrolled
Age	Age of patient enrolled
<b><u>Case Information</u></b>	
Gender	Gender of Patient enrolled
<b><u>Mechanism of initial Injury</u></b>	
Blunt	Single choice for best description of blunt Mechanism (if penetrating mechanism proceed to next data point) Options include: MVC, Auto vs. Peds (Pedestrian), Fall, Assault, MCC (Motorcycle Collision / Crash) Machinery Other
Penetrating	Single choice for best description of penetrating mechanism. Options include: GSW (Gunshot wound) Shotgun (Shotgun wound) Stab (Stab Wound) Other
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head	Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)



4. Language/cultural practices
5. Partner presence
6. Lack of resources
7. Lack of space/privacy
8. Discomfort with topic
9. Lack of practitioner knowledge of resources
10. Other (please specify):

*Qualitative Questions:*

What do you experience as barriers to screening for abuse?

What has helped or would help make screening for abuse easier for you?