

RESEARCH INFORMATION SHEET and CONSENT FORM

TITLE: The Community of Trauma Care - Partnering with Patients and Caregivers to Improve Injury Outcomes (“I-REP”)

PROTOCOL NO.: CNTR-2021-01
WCG IRB Protocol #20215168

SPONSOR: Coalition for National Trauma Research

INVESTIGATOR(S): Name: Deborah Stein, MD, MPH
Address: University of Maryland Medical Center, 22 South Greene St.
City, State Zip: Baltimore, MD, 21201
Country: USA

Name: Anna Newcomb, PhD, MSW
Address: Inova Health System, 3300 Gallows Rd.
City, State Zip: Falls Church, VA 22031
Country: USA

**STUDY-RELATED
PHONE NUMBER(S):** 210-450-8038

This is a research study that involves an online survey. Your participation is completely voluntary. You may choose not to participate or continue in this study at any time. No matter what your decision is there will be no penalty or loss of benefits to which you are otherwise entitled.

PURPOSE OF STUDY

The purpose of this research study is to determine what matters most to patients when considering participation in research, the outcomes of research, and how researchers are most likely to attract, retain, or hinder participation in research studies. You are being asked to participate in this study because you have had a traumatic injury requiring treatment, or you have cared for a loved one during their recovery from a traumatic injury.

200 patients and caregivers will be enrolled in this study.

PROCEDURES

You will take the online survey on a laptop, smartphone or tablet at your convenience. The survey will take roughly 20 minutes to complete. You do not have to respond to any questions you are not comfortable answering. Your answers will be saved and analyzed later. After the completion of the survey, your participation in this portion of the study will be over. There may

be an opportunity to remain involved as an advisor on a council to assist researchers as they develop protocols in the future.

What will the survey ask me to talk about?

The survey will ask a series of questions to the group regarding your experiences, thoughts, and opinions regarding such things as:

- challenges related to consenting to research while in the hospital
- what is important for researchers to study with regard to trauma patients and their care
- how researchers might best maintain contact with patients after they are discharged, in order to collect follow-up data

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to complete the online survey.

POTENTIAL RISKS/DISCOMFORTS:

- Breach of confidentiality. This risk is unlikely and would be minimal due to the type of information we will be collecting. To minimize this risk:
 - The survey data will be scrubbed of names or identifying information of participants.
- Breach of privacy. Minimal.
- Psychological discomfort. You may feel uncomfortable with some of the topics or questions asked during the survey. To minimize this risk:
 - It is fine to not answer questions when you do not feel comfortable answering them
 - You can stop participating in the survey at any time
 - If questions are triggering, you may opt out and we can provide psychological support and safety as appropriate

POTENTIAL BENEFITS

You will not directly benefit from participating in this survey. However, you are contributing to research that could help research and patient-centered outcomes for trauma patients.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at your hospital will not be affected.

COSTS TO PARTICIPANTS

It will not cost you anything to take part in this study.

Will I be paid for taking part in this research?

No, you will not be paid for taking part in this research.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will not involve confidential information. The data from the study may be published. However, you will not be identified by name.

RIGHT TO WITHDRAW

You do not have to take part in this research. You are free to withdraw your consent at any time during the survey. If you decide to stop taking part, or if you have questions, concerns, or complaints about the research, please contact the Coalition for Trauma Research (Michelle Price) at 210-450-8038.

This research is being overseen by WCG Institutional Review Board (IRB). An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

There are no adverse consequences (physical, social, economic, legal, or psychological) if you decide not to participate in this survey or if you decide not to participate for the entire length of the survey.

Can I be removed from the research?

We do not anticipate removing a person from this study as their participation in this survey will only happen once.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. Visit <https://bit.ly/CNTR-IREP> to print a copy of this consent.

If you agree to participate in this study, please click on the “I consent” button below and hit submit.