Consent Document

Developing a deliberate practice intervention to recalibrate physician heuristics in trauma triage
NIA R21AG072072
Clinicaltrials.gov identifier #NCT05168579
Approved by University of Pittsburgh Office of Research Protections: January 6, 2021

FOR POTENTIAL PARTICIPANTS:

Thank you for your interest in this NIH-funded research study. My name is Deepika Mohan and I am a researcher at the University of Pittsburgh - School of Medicine. The purpose of this study is to test a deliberate practice intervention for changing physician decision making in trauma. Specifically, we are interested in whether coaching offered in conjunction with a video game would be more effective than a more conventional technique, like ATLS.

As part of this study, we will be randomizing 60 physicians to one of two arms: the intervention or nothing. Physicians in the intervention group will meet with a trauma surgeon virtually for 30 minutes a week, over three weeks, at which time they will play a video game on an iPad that we will provide you, and will receive coaching on key decision principles in trauma triage. They will be interviewed by study personnel after the coaching sessions to provide feedback on their experience, a process that will take about twenty minutes. In addition, physicians in both groups will also complete a virtual simulation online, and fill out two questionnaires. Completing study tasks should take about three hours (unless you are randomized to control arm – in which case you will only need to spend one hour), which you can do at your convenience. We will provide all trial participants with an honorarium of $100/hour spent on study tasks. As per IRS guidelines, all compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year form one organization, that organization is required by law to file a Form 1099-Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 28% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 72% of the expected payment.

There will be no direct benefit of participation to you. We will be analyzing the content of your responses to identify how you make decisions for patients in the Emergency Department, and the effect of the intervention on those decisions. The primary risk would be a breach of confidentiality, which might damage your reputation if your description of how you manage patients is judged in a negative fashion. To prevent this from happening, the identifiers will be stored separately, and your responses will be coded and stored on a secure server maintained by the Data Center in the Department of Critical Care Medicine.

The linkage file that ties your name to the identifier will be kept separately, on a secure server behind the University of Pittsburgh firewall. The research team and the University of Pittsburgh Office of Research Conduct and Compliance, will have access to the research records. Also, your research data may be shared with investigators conducting other research; however, this information will be shared in a de-identified manner (without identifiers).

Obviously, your participation in this study is completely voluntary (and much appreciated). You may withdraw at any time. Should you choose to withdraw, all date will continue to be used up to the point of withdrawal unless you request that we destroy it. There is no penalty for refusing to participate or withdrawing. A description of the clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most the website will include a summary of the results. You can search this website at any time. Any questions or

concerns should be directed to me as the principal investigator in this study: Deepika Mohan. My cell phone number where I can be reached is 404-375-9325. If you have any concerns about the study or your rights as a participant, you can contact the University of Pittsburgh human subject protection advocate phone line (1-866-212-2668).

If you are willing to participate, please fill out the following items below which will be used as an electronic signature:

1. Full name
2. Birthdate
3. Name of your high school
4. Are you willing to participate in this study (yes/no)
5. Do you provide your permission to be audio/video recorded for the purposes of this study (yes/no)