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SUMMARY EXPLANATION OF RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: Dynamic Haptic Robotic Trainer (DHRT) and DHRT+ for CVC insertion training for Surgical Residents

Principal Investigator: Scarlett Miller

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You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains key information about this research. You are urged to ask questions about anything that is unclear to you.

- The purpose of this study is to compare the learning gains on Central Venous Catherization (CVC) insertion procedures of first year residents between the Dynamic Haptic Robotic Training (DHRT) system and the Dynamic Haptic Robotic Training Plus Cognitive Learning (DHRT+) system.
- The study includes several aspects. First, you will be randomly assigned to one of two conditions: DHRT or DHRT+ training. Next, you will complete a short self-efficacy and prior experience survey and will complete a pre-test on central venous catheterization. Training will then commence on your training condition assigned (DHRT or DHRT+). Once the training is complete, you will complete a post-test and a self-efficacy and prior-experience survey. You will then be asked to have 5 supervising physicians complete the survey after you place a central-lines under their supervision for your first five attempts through an online system. Finally, approximately four-months after training you will be asked to complete a final online CVC self-efficacy survey.
- The study will continue for the first year of residency (June – May).
- There are minimum risks associated with completing the study. However, given that the average time of completing a CVC needle insertion attempt is less than two minutes for a single trial, subjects may incur boredom by repetition. In addition, a failure to remove personal identifier may violate their privacy. Loss of confidentiality is a risk. Participants will be informed that their participation in the study will not affect their academic standing in the residency program, however there is a possibility of psychological risks if they are concerned about their standing.
- You will not benefit from taking part in this research study. However, the results of this research may guide the development of better training systems for central venous catherization.
- No confidential records identifying you as a subject will be collected or maintained as part of this study.
- Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.
- There is no cost to participating in the study.

- This study is funded by an R01 grant from the National Institute of Health (NIH)
- Drs. Miller and Moore own equity in Medulate, which has an interest in this project. Dr. Miller's ownership in this company has been reviewed by the University's Individual Conflict of Interest Committee and is currently being managed by the University.
- Drs. Han, Miller and Moore have applied for a patent on the new device being studied. Research studies like the one you are thinking about joining are done to determine whether the new device is safe and effective. If research shows the new device is safe and effective, David Han would receive a part of the profits from any sales of this device. This financial interest has been reviewed by the Penn State Institutional Review Board and Conflict of Interest Review Committee. If you would like more information, please contact the Conflict of Interest Program at 717-531-0003, ext. 283526.

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Scarlett Miller at (814) 863-4143. If you have questions regarding your rights as a research subject or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

You do not have to participate in this research. Taking part in the research study is voluntary. Your decision to participate or to decline the research will not result in any penalty or loss of benefits to which you are entitled.

Tell the researcher your decision regarding whether or not to participate in the research.