PennState

HRP-591 - Protocol for
Human Subject Research

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

Principal Investigator:
Name: Scarlett Miller
Department: Department of Surgery and the School of Engineering Design, Technology and Professional Programs
Telephone: 814-863-4143
E-mail Address: scarlettmiller33@gmail.com

Version Date:
11/25/2025

Clinicaltrials.gov Registration #:
NCT04541446

Important Instructions for Using This Protocol Template:
This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS:**
    - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
    - Do not change the protocol template version date located in the footer of this document.
    - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
    - **GRAY INSTRUCTIONAL BOXES:**
        - Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
        - **Penn State College of Medicine/Penn State Health researchers**: Delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (http://irb.psu.edu)**.**
        - **Penn State researchers at all other campuses**: Do NOT delete the instructional boxes from the final version of the protocol.
    - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.
2. **CATS IRB LIBRARY:**
    - Documents referenced in this protocol template (e.g. SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
    - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
    - Update the Version Date on page 1 each time revisions are made.

If you need help…	
University Park and other campuses: Office for Research Protections Human Research Protection Program The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: irb-orp@psu.edu	**College of Medicine and Penn State Health:** Human Subjects Protection Office 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Email: irb-hspo@psu.edu

Table of Contents

1.0 Objectives

2.0 Background

3.0 Inclusion and Exclusion Criteria

4.0 Recruitment Methods

5.0 Consent Process and Documentation

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

7.0 Study Design and Procedures

8.0 Subject Numbers and Statistical Plan

9.0 Data and Safety Monitoring Plan

10.0 Risks

11.0 Potential Benefits to Subjects and Others

12.0 Sharing Results with Subjects

13.0 Subject Payment and/or Travel Reimbursements

14.0 Economic Burden to Subjects

15.0 Resources Available

16.0 Other Approvals

17.0 Multi-Site Study

18.0 Adverse Event Reporting

19.0 Study Monitoring, Auditing and Inspecting

20.0 Future Undetermined Research: Data and Specimen Banking

21.0 References

22.0 Confidentiality, Privacy and Data Management

1.0 Objectives

1.1 Study Objectives

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 difference between these two systems is the DHRT focus primarily on the mechanical skills needed to complete the procedures while the DHRT+ system provides training on the entire procedure including items like aseptic techniques.

1.2 Primary Study Endpoints

1. Skill gains in needle insertion in central venous catheter placement during surgical residency skills training

2. Self-efficacy gains in CVC placement during surgical residency skills training

3. Performance on the first five attending supervised CVC insertions on patients.

1.3 Secondary Study Endpoints

1. Follow-up Self-efficacy survey sent approximately 4 months after completion of the training program

2.0 Background

2.1 Scientific Background and Gaps

The current state-of-the-art in CVC simulators includes a "realistic" Simulab CentralLineManV_R that features an arterial pulse (controlled through a hand-pump) and self-sealing veins. While these simulators have the capability to transform the medical curriculum to a "see one, *simulate many*, do one *competently*, and teach *everyone*" model (Vozenilek, Huff, Reznek, & Gordon, 2004), researchers have reported that current SBT methods only temporarily improve CVC *procedural skills* (Smith et al., 2010) and the benefits of this skill acquisition declines over time. In addition, SBT has been found to have only small to moderate patient benefits compared to no-intervention, and no statistical improvement over non-simulation instruction (Ma et al., 2011; Smith et al., 2010; Zendejas, Brydges, Wang, & Cook, 2013). This may be due, in part, to the fact that these simulators are static in nature and only represent a single anatomical patient configuration. In other words, residents can 'simulate many' of the *exact same* patient scenario. However, variations in patient anatomy make the placement of central lines significantly more difficult (Denys & Uretsky, 1991) and increase the risk of mechanical complications (Polderman & Girbes, 2002).

In order to overcome the challenges associated with training resident surgeons on static manikins, the research team has developed a Dynamic Haptic Robotic Training (DHRT) simulator for CVC insertion. The DHRT consists of a 3D Systems Geomagic Touch (Rock Hill, SC), a virtual ultrasound system utilizing an Ascension 3D Guidance trakSTAR (Sheldburne, VT) electromagnetic position tracking system and a 3D printed ultrasound probe, and software visualizations and recordings developed in MatLab and Simulink.

The Geomagic provides positional data to the simulation, as well as haptic feedback to the user based on needle insertion characterizations (Gordon, Kim, Barnett, & Moore, 2015). The 3D printed probe uses the electromagnetic tracker in order to navigate a virtual ultrasound environment generated in MATLAB. The simulation has the capability to generate a variety of scenarios with different needle insertion forces, vessel locations, and vessel sizes. The haptic robot and virtual ultrasound work in tandem to provide a realistic CVC insertion environment.

To allow for complete CVC training a DHRT+ system is also being developed to guide training on all *four* steps of the CVC procedure. The current DHRT system only focuses on one of the four steps – the mechanical skills necessary to perform the procedure. Specifically, an Interactive Graphical User Interface (GUI) will guide users through patient profiles and visualizations will be provided to allow users to practice identifying which location is ideal for individual clinical scenarios (e.g. thrombosed initial choice of insertion site) as well as individual user preference (e.g. right vs. left hand dominant learner). It will also guide users through steps of CVC setup, sterilization, and applying anesthetic using a novel mixed reality smart tray. This system will also contain low cost non-contact radio-frequency identification (RFID) sensors to easily detect when a component is lifted out of the tray and put back into the tray. This detection will allow for effective assessment and feedback. The program's GUI and lighting will actively guide the user through procedural steps of CVC. This innovative concept allows for the user to have real interactions with the instruments, while still allowing for virtual guidance and active feedback to be provided. While innovative, it has not been tested yet for its ability to train residents on all aspects of CVC.

2.2 Previous Data

Two DHRT devices were implemented into the surgical residency program at HMC in order to compare it to the control group of the time-intensive manikin training that requires oral feedback (IRB 0004943). Differences in short-term skill performance gains and long-term skill transfer between these two systems have been disseminated (Chen et al., Accepted 2018. NIHMS ID: NIHMS 994094; Chen et al., 2019. NIHMS 991872; Mirkin et al., 2017; Pepley et al., 2017. PubMed PMID: 28645855; PubMed Central PMCID: PMC5732878; Sonntag, Chen, et al., 2018; Sonntag, Yovanoff, et al., 2018; M. Yovanoff et al., 2016. PubMed PMID: 29151778; PubMed Central PMCID: PMC5693425; M. A. Yovanoff et al., 2018. PubMed PMID: 29574019. NIHMS ID: NIHMS976064). Specifically, a 3-month study with 26 surgical residents showed significant improvements in CVC insertion on the DHRT system over the course of skills training; needle placement accuracy improved by 61%, needle insertion attempts declined by 36%, and time spent aspirating improved by 12% (Pepley et al., 2017. PubMed PMID: 28645855; PubMed Central PMCID: PMC5732878). In addition, a study comparing expert (attending) and novice (surgical resident) performance showed that the DHRT system could be used to distinguish CVC expertise and that novices approach expert performance through DHRT training (IRB 0007943). DHRT training was also found to offer significant benefits compared to manikin + oral feedback. Specifically, manikin trainees were found to be overconfident in their CVC insertion ratings as they provided higher self-evaluations of their performance compared to the DHRT group but only identified half of the insertion errors (M. Yovanoff et al., 2016. PubMed PMID: 29151778; PubMed Central PMCID: PMC5693425).

2.3 Study Rationale

While this prior work has shown that DHRT training is more efficient, offering automatic guided feedback as opposed to time intensive manikin training which required 1-hr of expert guidance, there has been limited investigations into the impact of CVC training on patient outcomes or a comparison to this approach to other more holistic systems like the DHRT+.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

All participants must be:

1. at least 18 years old and
2. be a first-year resident at Penn State Hershey Medical Center (HMC) or Cedar-Sinai Medical Center (CSMC).

3.2 Exclusion Criteria

If they are not:

1. a first-year resident at HMC or CSMC or
2. Are not 18 years or older

they will not be eligible to participate in the study.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

If a resident leaves the residency program they would be removed from the study.

3.3.2 Follow-up for withdrawn subjects

The withdrawn subjects information that has been previously collected may be discarded and the participant will not be replaced.

4.0 Recruitment Methods

4.1 Identification of subjects

Prospective participants will be recruited from HMC's and CSMC's incoming first year residency program during the residency boot camps through a verbal script.

4.2 Recruitment process

4.2.1 How potential subjects will be recruited.

Prospective participants will be recruited through a verbal script.
The verbal script is included in the supplemental files.

4.2.2 Where potential subjects will be recruited.

Prospective participants will be recruited during HMC's and CSMC's first year residency program boot camps which occurs each summer.

4.2.3 When potential subjects will be recruited.

They will be recruited the first day of the boot camp program.

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their

eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

Not applicable.

5.0 Consent Process and Documentation

5.1 Consent Process:

Check all applicable boxes below:

☐ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☒ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ **<u>Exempt Research at all Locations Except Penn State Health and the College of Medicine</u>: If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination." Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in "HRP-590- Consent Guidance for Exempt Research"):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete): The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see "HRP-312- Worksheet- Exemption Determination") is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

At the start of the study, the Consent Guidance for Exempt Research document will be disseminated. Next, any questions will be answered. Completion of the questionnaire (self-efficacy) will imply voluntary consent. Once consent is attained, the participants will be assigned to one of two conditions: DHRT training or DHRT+ training. Participants will be given copy of the consent form for their records upon request.

In addition, the consent document will be placed at the beginning of the follow-up survey that will be sent out approximately 4 months after completion of the training program. The residents will once denote their voluntary consent to participate in the survey portion of the study by completing the survey.

5.2.2 Consent

Participants will be informed that their decision to participate or not participate in the study will not impact the outcome of their residency in any way. They will be informed that if they do not choose to participate they will still be required to participate in all aspects of the training as a requirement of their residency program; the only difference is that their performance will not be tracked.

5.3 Waiver of Written Documentation of Consent

5.3.1 Indicate which of the following conditions applies to this research:

☒ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

Participants will be provided with a Consent Guidance for Exempt Research form prior to the start of the study and prior to the follow-up survey.

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

5.4.1 Indicate the elements of informed consent to be omitted or altered

Not applicable.

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

Not applicable.

5.4.3 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.4.6 Debriefing

Not applicable.

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

Not applicable.

5.5.2 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.5.5 Additional pertinent information after participation

Not applicable.

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Not applicable.

5.6.2 Cognitively Impaired Adults

5.6.2.1 Capability of Providing Consent

Not applicable.

5.6.2.2 Adults Unable to Consent

Not applicable.

5.6.2.3 Assent of Adults Unable to Consent

Not applicable.

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Not applicable.

5.6.3.2 Assent of subjects who are not yet adults

Not applicable.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Not applicable.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Not applicable.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Not applicable.

6.3 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

This study was designed to capture both qualitative and quantitative information about the effectiveness of the Dynamic Haptic Robotic Trainer (DHRT) compared to DHRT+ condition. Qualitative results are captured through open-ended survey questions and quantitative results are captured through, surveys, skill performance, error rates, motion tracking, eye tracking and performance data captured through the training device's software. A 6-digit participant code will be generated by the participant that is the last 2 letters of their mother's first name, the last 2 letters of birth city, and the last two letters of the birth month.

7.2 Study Procedures

At the start of the study, the Consent Guidance for Exempt Research form will be disseminated. Next, any questions will be answered. Next, all residents, regardless of participation in the study, will be assigned to one of the two conditions: DHRT or DHRT+ training.
Participants codes will be put into excel and assigned a random number. The first half will be assigned to DHRT training, the second half will be assigned to DHRT+.
Remaining residents who choose not to participate will be evenly split between training conditions. Participants in the study will be given a CVC self-efficacy and Prior Experience survey, which will include information about previous experience and knowledge that directly or indirectly relates to Internal Jugular Central Venous Catheter Placement. A secured box with a slit in the top will be available for participants to submit their self-efficacy surveys and consent forms. Videos will be anonymized through blurring of facial features or other identifying features.

7.2.1 Demonstration

Next, the residents will receive instruction on how to perform an Internal Jugular Central Venous Cather placement per standard medical residency training at HMC and CSMC. This is done through a video as well as a visual demonstration which is standard practice. This instruction will be provided to all residents whether or not they participate in the study.

7.2.2 CVC Insertion Pre-Test

All residents will participate in the CVC insertion Pre-test, but data will be gathered only for the residents participating in the study.

1. Once the instruction has been given, residents will individually perform a pre-test needle insertion on a manikin. For study participants, the needle pathway will be tracked using a magnetic motion tracker and the insertion will be videotaped. Participants' gaze patterns

will be recorded using Tobii eye tracking software. Participants will be asked to use a think aloud procedure to identify the rationale behind what they are doing. Residents will be evaluated using a CVC skills checklist, as is standard procedure, by a study team member (the bootcamp trainer). Non-participants will still perform the pre-test and be evaluated using the CVC skills checklist but we will not retain a record of this checklist and they will not participate in motion tracking, eye tracking or any other data collection.

2. The resident will receive verbal feedback on their performance regardless of study participation. This feedback will be recorded, via videotape, only for participants in the study.

7.2.3 DHRT Condition

All residents assigned to the DHRT training condition will participate in the following, but the data will only be collected for residents participating in the study.

1. Residents in the DHRT condition will be required to complete a total of 16 CVC needle insertion attempts into the DHRT system over the three-month surgical residency training period.
2. Each needle insertion practice will be guided by one of 16 clinical patient cases, which is provided in the supplemental materials.
3. After each practice attempt, the resident will be required to complete a Case Survey which will ask about their experience and the relationship between the clinical case and their experience during the insertion procedure.
4. Each resident in this condition will also be required to practice the entire CVC insertion procedure (which extends beyond the scope of this study but includes the needle insertion procedure that we are studying) on the Manikin a minimum of three times and log their performance using the CVC skills checklist.

7.2.4 DHRT+ Condition

All residents assigned to the DHRT+ training condition will participate in the following, but the data will only be collected for residents participating in the study.

5. Residents in the DHRT+ condition will be required to complete a total of 16 CVC needle insertion attempts into the DHRT+ system over the three-month surgical residency training period.
6. Each needle insertion practice will be guided by one of 16 clinical patient cases, which is provided in the supplemental materials.
7. After each practice attempt, the resident will be required to complete a Case Survey which will ask about their experience and the relationship between the clinical case and their experience during the insertion procedure.
8. Each resident in this condition will also be required to practice the entire CVC insertion procedure on the DHRT+ program a minimum of three times. Their performance will be automatically captured in the system.

7.2.5 CVC Insertion Post-Test

All residents will participate in the CVC insertion Post-test, but data will be gathered only for the residents participating in the study. This test is standard procedure to verify competency on the CVC insertion procedure and allow residents to move forward to performing this procedure in a clinical setting.

1. Once training has been completed, residents will individually perform a post-test needle insertion on a significantly modified manikin. The post-test manikin will have modified anatomy to represent a new patient scenario. During the post-test the needle pathway will be tracked using a magnetic motion tracker and the insertion will be videotaped. Participants' gaze patterns will be recorded using Tobii eye tracking software. Participants will be asked to use a think aloud procedure to identify the rationale behind what they are doing. Participants will be evaluated using the CVC skills checklist, as is standard procedure, by a study team member (the bootcamp trainer). Non-participants will still perform the post-test but they will not participate in motion tracking or any other data collection.
2. The resident will receive verbal feedback on their performance regardless of study participation. This feedback will be recorded, via videotape, only for residents participating in the study.

7.2.6 Post-Training Survey

1. Immediately following the post-test, the participants will be asked to complete the same CVC self-efficacy and Prior Experience survey that was completed at the start of the study.

7.2.7 Operating Suite Performance

All residents, regardless of participation in the study, need to perform five supervised CVC insertions on patients and document them in order to be 'approved' to perform CVC on patients without supervision.

1. Participants will be asked to collect five short surveys on CVC performance to be completed by the supervising physicians when placing a central-lines under supervision for their first five attempts through an online system in order to monitor complications that occur during the placement of the line. Non-participants will still be asked to collect this data but their data will not be analyzed as part of the current study. The survey will include the patient medical record number. Importantly any identifiable health information will only be transferred into HMC and not out of HMC.

7.2.8 Retrospective Chart Review

The research team will complete a retrospective chart review to identify any complications resulting from central line placement. Patients who received central lines will be identified by utilizing the electronic medical record (EMR) database to identify cases of central venous catheterization using relevant Current Procedural Terminology (CPT) codes. CPT is the standardized coding system maintained by the American Medical Association (AMA) used to describe medical, surgical, and diagnostic services. Each CPT code corresponds to a specific procedure or service performed by healthcare providers. For the purposes of this study, the following codes will be queried: 36555, Insertion of a non-tunneled, centrally inserted central venous catheter in a patient younger than 5 years of age; 36556, Insertion of a non-tunneled, centrally inserted central venous catheter in a patient 5 years of age or older; 36557, Insertion of a tunneled, centrally inserted central venous catheter without a subcutaneous port or pump in a patient younger than 5 years of age; and 36558, Insertion of a tunneled, centrally inserted central venous catheter without a subcutaneous port or pump in a patient 5 years of age or older. Specifically, these codes will be queried to generate a list of patient medical record numbers (MRNs) associated with the procedures of interest. Once identified, the research team will conduct a retrospective review of these charts to extract data on error characteristics, including the type of error (arterial puncture, catheter misplacement, hematoma, hemothorax, pneumothorax, stenosis, infection, thrombosis), as well as central line information (location: Internal Jugular, Subclavian, femoral; location: left/right; and Ultrasound guidance: yes/no). Patient demographics (age, gender, comorbidities) as well as the level of the physician performing the procedure (attending, fellow, resident and PGY level), as well as if the line was placed under supervision will also be collected. Patient identifiers and physician information will

will not be documented during the chart review to ensure confidentiality. As such, all data will be anonymized during the chart review process.

7.2.9 Follow-Up Survey

2. Participants will be contacted via email through the residency list-serv 4 months after completing their training and asked to complete an online version of the same CVC self-efficacy and Prior Experience survey completed in 7.2.7.

7.3 Duration of Participation

The participant will continue to participate in the study for one full year (June – May).

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

We anticipate an enrollment of at least 625 (200 DHRT+ and 425 DHRT) first year residents over the course of the study. There are approximately 1000 first year residents who start at HMC and CSMC each summer who will be offered the opportunity to participate in the study.

8.2 Sample size determination

The sample size was determined by power analysis based on preliminary results and a power of 0.8. Based on this data, we need a minimum of 200 residents would need to be monitored from each group (DHRT and DHRT+) in future studies to examine these effects, as discussed in Aim 2 preliminary data and sample size determination.

8.3 Statistical methods

The interviews and think aloud procedures will be transcribed and analyzed using inductive content analysis. Survey results, motion tracking, and data capture will be statistically analyzed using a paired sample t-test in SPSS. Eye tracking results will be analyzed using the Tobii Eye Tracking software to identify differences in gaze patterns.

9.0 Data and Safety Monitoring Plan

9.1 Periodic evaluation of data

Not applicable.

9.2 Data that are reviewed

Not applicable.

9.3 Method of collection of safety information

Not applicable.

9.4 Frequency of data collection

Not applicable.

9.5 Individuals reviewing the data

Not applicable.

9.6 Frequency of review of cumulative data

Not applicable.

9.7 Statistical tests

Not applicable.

9.8 Suspension of research

Not applicable.

10.0 Risks

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.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Participants can better understand their performance in CVC insertion procedures through learning feedback.

11.2 Potential Benefits to Others

The research results will contribute to innovative resident training methods and potentially improve patient safety.

12.0 Sharing Results with Subjects

Study results will not be shared directly with the participants, but indirectly with other research groups, especially experts in medical education. Published results will be available on the britelab website.

13.0 Subject Payment and/or Travel Reimbursements

Not applicable.

14.0 Economic Burden to Subjects

14.1 Costs

Not applicable.

14.2 Compensation for research-related injury

Not applicable.

15.0 Resources Available

15.1 Facilities and locations

The study will be conducted at Penn State Hershey Medical Center and Cedar-Sinai Simulation Centers. The rooms are approximately 140 sq-ft. The facilities are a table, a DHRT or DHRT+ simulator, a manikin and an ultrasound imaging device. The specific room number may vary based on availability.

15.2 Feasibility of recruiting the required number of subjects

The study team has access to approximately 200 participants per year. This is feasible given the incoming residency group size.

15.3 PI Time devoted to conducting the research

The PI will assume responsibility of research planning, recruitment, logistics, analysis and publication. Based on the research outcome, the PI will plan subsequent research direction for developing and commercializing the training methodology.

15.4 Availability of medical or psychological resources

This study is not expected to inflict over normal psychological risk. We will make contact information for PSU or CSMC medical and psychological resources available for participants.

15.5 Process for informing Study Team

All members of the study team have completed IRB training for human subjects in social science research. Members will remain in contact through email at least once a week leading up to the start of the study, and more frequently as needed.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Not applicable.

16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of "HRP-901 - Human Body Fluids for Research Form" in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

☒ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study

involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

17.0 Multi-Site Study

17.1 Other sites

Cedar Sinai Medical Center
8700 Beverly Boulevard
Los Angeles, CA 90048-1804

Philip K. Ng, MD, Principal-Investigator, CSMC Medical Director, Procedure Center and VAS
Phone: 310-423-6326
E-Mail: Philip.Ng@cshs.org

Margaret Kelley, MS, Project Manager,
Email: Margaret.kelly@cshs.org

17.2 Communication Plans

The study directors will be Drs. Miller and Moore. The team will have a web conference at least once a week leading up to the start of the study, and more frequently as needed. As the study progresses, the study team will remain in contact for bi-weekly meetings. If there are any modifications to the protocol or study documents, an email will immediately be sent with the updated document and a follow-up teleconference will be scheduled.

Problems with the study will be communicated through the weekly meetings as well as interim results. Drs. Miller and Moore will signify with the study has closed.

17.3 Data Submission and Security Plan

One of the study team members will be physically present for the bootcamp programs at HMC and CSMC and thus will directly gather data at that time. Other hard copies will be transcribed by the research teams at their respective units at the end of each procedural step identified in section 7 through RedCap.

17.4 Subject Enrollment

Drs. Miller and Moore will provide the logistics for both the randomization and the enrollment 1 month prior to the start of the residency bootcamps.

17.5 Reporting of Adverse Events and New Information

Adverse effects will immediately be reported by phone to Drs. Miller and Moore. A follow-up email will be sent to maintain a record of the incident and the event will be reported to the IRB within 24 hours of the report.

17.6 Audit and Monitoring Plans

Drs. Miller and Moore will make 1-2 trips to LA each year to monitor progress of the study. Teleconferences will also be schedule with the CSMC teams to ensure data tracking is on target.

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

20.1 Data and/or specimens being stored

Not applicable

20.2 Location of storage

Not applicable

20.3 Duration of storage

Not applicable

20.4 Access to data and/or specimens

Not applicable

20.5 Procedures to release data or specimens

Not applicable

20.6 Process for returning results

Not applicable

21.0 References

Chen, H.-E., Yovanoff, M., Pepley, D., Sonntag, C. C., Mirkin, K., Han, D., . . . Miller, S. (Accepted 2018. NIHMS ID: NIHMS 994094). Can Haptic Simulators Distinguish Expert Performance? A Case Study in Central Venous Catheterization in Medical Education. *Journal of the Society for Simulation in Healthcare*.

Chen, H.-E., Yovanoff, M. A., Pepley, D. F., Prabhu, R. S., Sonntag, C. C., Han, D. C., . . . Miller, S. R. (2019. NIHMS 991872). Evaluating surgical resident needle insertion skill gains in central venous catheterization training. *Journal of Surgical Research, 233*, 351-359. doi:10.1016/j.jss.2018.07.040

Denys, B. G., & Uretsky, B. F. (1991). Anatomical variations of internal jugular vein location: impact on central venous access. *Critical care medicine, 19*(12), 1516-1519.

Ma, I. W., Brindle, M. E., Ronksley, P. E., Lorenzetti, D. L., Sauve, R. S., & Ghali, W. A. (2011). Use of simulation-based education to improve outcomes of central venous catheterization: a systematic review and meta-analysis. *Academic Medicine, 86*(9), 1137-1147.

Mirkin, K., Pepley, D., Yovanoff, M., Miller, S., Moore, J. Z., & Han, D. (2017, February 7-9). *Surgeons, engineers, & haptics: Designing a better robot training model for central line insertion.* Paper presented at the 12th Annual Academic Surgical Congress, Las Vegas, NV.

Pepley, D. F., Gordon, A. B., Yovanoff, M. A., Mirkin, K. A., Miller, S. R., Han, D. C., & Moore, J. Z. (2017. PubMed PMID: 28645855; PubMed Central PMCID: PMC5732878). Training Surgical Residents With a Haptic Robotic Central Venous Catheterization Simulator. *Journal of Surgical Education, 74*(6), 1066-1073.

Polderman, K. H., & Girbes, A. R. (2002). Central venous catheter use. *Intensive care medicine, 28*(1), 1-17.

Smith, C. C., Huang, G. C., Newman, L. R., Clardy, P. F., Feller-Kopman, D., Cho, M., . . . Schwartzstein, R. M. (2010). Simulation training and its effect on long-term resident performance in central venous catheterization. *Simulation in Healthcare, 5*(3), 146-151.

Sonntag, C. C., Chen, H.-E., Pepley, D. F., Han, D. C., Moore, J., & Miller, S. (2018, May 1-3). *Procedural confidence is improved when using a dynamic haptic robot compared to a standard manikin trainer.* Paper presented at the Association for Surgical Education Annual Meeting, Austin, TX.

Sonntag, C. C., Yovanoff, M., Pepley, D., Prabhu, R. S., Miller, S., Moore, J. Z., & Han, D. (2018). *Can a Haptic Robotic Train New Interns to Place Central Venous Lines?* Paper presented at the 13th Annual Academic Surgical Congress, Jacksonville, Florida.

Vozenilek, J., Huff, J. S., Reznek, M., & Gordon, J. A. (2004). See one, do one, teach one: advanced technology in medical education. *Academic Emergency Medicine, 11*(11), 1149-1154.

Yovanoff, M., Pepley, D., Mirkin, K., Moore, J., Han, D., & Miller, S. (2016. PubMed PMID: 29151778; PubMed Central PMCID: PMC5693425). Improving Medical Education: Simulating Changes in Patient Anatomy Using Dynamic Haptic Feedback. *Proc Hum Factors Ergon Soc Annu Meet, 60*(1), 603-607. doi:10.1177/1541931213601138

Yovanoff, M. A., Chen, H. E., Pepley, D. F., Mirkin, K. A., Han, D. C., Moore, J. Z., & Miller, S. R. (2018. PubMed PMID: 29574019. NIHMS ID: NIHMS976064). Investigating the Effect of Simulator Functional Fidelity and Personalized Feedback on Central Venous Catheterization Training. *J Surg Educ*. doi:10.1016/j.jsurg.2018.02.018

Zendejas, B., Brydges, R., Wang, A. T., & Cook, D. A. (2013). Patient outcomes in simulation-based medical education: a systematic review. *Journal of general internal medicine, 28*(8), 1078-1089.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598

Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.