Emulator Study Summary

1. **Abstract**
   a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

   Despite the existence of many technologically advanced devices to provide QCPR feedback, it has been repeatedly demonstrated that CPR quality during training and clinical practice does not meet AHA guidelines [1]. Guidelines for CPR include metrics that place importance on the quality of the resuscitative effort. Quality CPR (QCPR) metrics include chest compression depth, rate, and recoil, which can be measured in practice by QCPR-capable clinical monitors to provide real-time and post-event performance feedback. During simulation-based training, these metrics can be provided via simulators, clinical devices, and skill-reporting sensors. Use of an actual clinical device may be ideal in terms of realism, which has been shown to affect rate of skill decay and translation to practice [2], but can be prohibitive in terms of training device costs, learner to device ratio, and performance data collection for tracking, review, and research. This research aims to assess the overall and comparative training effectiveness of a device that emulates the ZOLL R Series Plus defibrillator to provide feedback in a realistic user interface.

   The study group participants will include medical staff and students who are participating in resuscitation training. Performance and outcome measurements will be obtained by collecting CPR quality performance data and through a post-training survey completed by each user. The survey specifically assesses the perceived benefits and realism of the emulator tool. We hypothesize that the use of the device will improve overall CPR quality and will result in equivalent outcomes to training with a Zoll R Series Plus defibrillator. By demonstrating the effectiveness of this device, we hope to provide an equivalent alternative to training with the clinical defibrillator used at the Johns Hopkins Hospital.

2. **Objectives** (include all primary and secondary objectives)

   CPR quality will be quantitatively assessed from data abstraction from the emulator tool and from the ZOLL R Series Plus defibrillator. Metrics include:
   i. Chest compression depth, rate, recoil
   ii. Time to start chest compressions
   iii. Chest compression fraction
   iv. Number of pauses in chest compressions
   v. Time to defibrillate simulator

   The proposed survey to supplement quantitative data collection is attached. Results of outcome measures will be used to further human factors research regarding user-device interaction, to improve the emulator tool, and to continue to improve the resuscitation performance of healthcare providers.
Appendix C: IRB Study Summaries

3. **Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The benefits of CPR training with real-time feedback are well documented [3, 1]. The emulator described above is a new tool developed in the Johns Hopkins Simulation Center. This system interfaces pre-existing CPR performance measurement devices with customizable performance assessment and visualization applications. The device’s hardware includes clinical defibrillator pads with integrated accelerometer (Zoll OneStep Complete Pads) and an analog-to-digital converter. Raw data are continuously sampled from the accelerometer output of the CPR quality sensor, minimally smoothed, and transmitted via serial communication to software components. Digital accelerometer data is filtered and is translated to position via linear estimation; compression depth, rate, and recoil are evaluated from calculated position data. Performance data is then presented to the trainee and/or trainer in real-time. The user interface emulates the Zoll R Series Plus defibrillator CPR Dashboard visual and audio cues, providing a low-cost, customizable model for realistic BLS training. An interactive CPR quality score sheet is displayed at the end of training with compression metrics graphed in relation to AHA guidelines. There is little documentation regarding the effects of providing feedback in a clinically realistic format; however, differences between training-specific device interfaces and those used clinically have been observed to cause trainee confusion and limit translation to practice.

4. **Study Procedures**

a. **Study design**, including the sequence and timing of study procedures

   Consent of participants will be obtained prior to participation in the study. The study will take place during existing BLS courses and clinician refresher trainings. Following a 2-minute set of chest compressions with QCPR feedback from the emulator or from the ZOLL R Series Plus, the individual will complete the attached survey and the CPR quality data that was collected by the feedback device during training will be saved.

b. **Study duration** and number of study visits required of research participants.

   The study will be a period of 1 year for us to obtain the information necessary from a variety of clinicians during different pre-existing training sessions. These will include, but are not limited to, the First Year Medical Student BLS training sessions that take place each fall, in-service training sessions for the Zoll R Series defibrillator, and clinician BLS certification and refresher trainings.

c. **Blinding**, including justification for blinding or not blinding the trial, if applicable. N/A

d. **Justification of why participants will not receive routine care or will have current therapy stopped.** N/A

e. **Justification for inclusion of a placebo or non-treatment group.**

   We chose to collect data from standard user training with the Zoll R Series defibrillator in order to collect preliminary qualitative and quantitative data regarding the training effectiveness of the Emulator with respect to the clinical
defibrillator. Because there is already overwhelming support in the literature for the use of real-time CPR quality feedback, we chose not to collect data from users who learn or train in CPR without feedback.

f. Definition of treatment failure or participant removal criteria. N/A

g. Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely. N/A

5. Inclusion/Exclusion Criteria
   a. Inclusion criteria: Students in chosen pre-existing BLS certification and refresher courses in the next 12 months.

6. Drugs/ Substances/ Devices
   a. The rationale for choosing the drug and dose or for choosing the device to be used. N/A
   b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. N/A
   c. Justification and safety information if non-FDA approved drugs without an IND will be administered. N/A
7. **Study Statistics**
   a. Primary outcome variable.
      CPR quality as compared to AHA standards
   b. Secondary outcome variables.
      See attached survey
   c. Statistical plan including sample size justification and interim data analysis.
      Means and standard errors will be calculated for continuous variables and compared by use of t-test, proportion variables will be compared by using chi-squared analysis. If distributions of values are non-gaussian, non-parametric methods will be employed.
   d. Early stopping rules.
      Participants may choose to leave survey questions unanswered or to decline permission for us to collect their CPR quality data for use in this study. Participation in this study will not affect a clinician’s likelihood of certification/recertification in the pre-existing training session.

8. **Risks**
   a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
      Performance of CPR requires substantial physical exertion for a short period of time (~2 minutes); however, this physical activity is taking place during training regardless of participation in this study.
   b. Steps taken to minimize the risks. N/A
   c. Plan for reporting unanticipated problems or study deviations. N/A
   d. Legal risks such as the risks that would be associated with breach of confidentiality.
      No personal identifiers will be collected. Each participant is asked to document their position and department on the survey; however, data will only be reviewed by study team members as designated on this IRB proposal.
   e. Financial risks to the participants. N/A

9. **Benefits**
   a. Description of the probable benefits for the participant and for society.
      - Participant: Participants may retain learned information regarding goals for CPR metrics because they are asked to recall this information after training. If participants would have otherwise trained without feedback, the feedback provided by either the Emulator or the Zoll R Series defibrillator will likely improve CPR quality and psychomotor retention of CPR skills.
      - Society: Research has demonstrated that real-time CPR quality feedback not only improves a provider’s current CPR performance but may also increase the retention of psychomotor skills associated with effective chest compressions. Unfortunately, there is little research regarding the presentation of this feedback and whether clinically-relevant presentation of data impacts the translation of psychomotor skills attained during training to clinical practice. This study will provide preliminary data for
Appendix C: IRB Study Summaries

the effectiveness of using the Emulator device as a substitute to the Zoll R Series defibrillator for chest compression quality training and in-service training.

10. Payment and Remuneration
   a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol. N/A

11. Costs
   a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

All study materials will be provided free of charge by the Johns Hopkins Simulation Center.


Appendix C: IRB Study Summaries

AP Belt Study Summary

1. **Abstract**
   a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

   Evidence increasingly suggests that training using high-technology simulators (HTS) results in significant performance advantages for learners in comparison with low-technology simulators (LTS) [1, 2, 3]. HTS currently used to teach basic and advanced life support (BLS, ALS) only allow for defibrillation with pads or paddles in the anterior-lateral (AL) position; the majority of simulators used for BLS training offer no defibrillation capability. Providers caring for pediatric patients frequently place pads in the anterior-posterior (AP) position. This reflects defibrillator manufacturer recommendation, which often influences hospital protocol. There are currently a limited number of HTS that allow for realistic training of AP defibrillation. Additionally, training programs in lower resourced areas often do not have access to HTS. This research aims to assess the training impact and the accessibility of a novel device that provides AP defibrillation functionalities to HTS, LTS, and simulator substitutes.

   The study group participants will include nurse educators, AHA-certified educators, and simulation center educators who facilitate resuscitation training with a device-adapted simulator. Outcome measures will be obtained by surveying participants after they voluntarily use the device in resuscitation training. The survey collects data regarding use of the device, objectives attained through device incorporation, and training session size/purpose. We hypothesize that users will be capable of setting up the device for use and that the device will provide a platform for more realistic defibrillation training and that the user interaction with the defibrillation contacts on the belt will be similar to defibrillation contacts on HTS.

2. **Objectives** (include all primary and secondary objectives)
   The primary objectives of the attached survey are to:
   - Collect data regarding the ease of use and durability of the device when used in different scenarios and by different educators
   - Identify training objectives that are made possible by the inclusion of this device in training
   - Collect quantitative data regarding defibrillation of the device

3. **Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

   A number of work-around solutions have been developed to increase interoperability between simulators and clinical defibrillators [4, 5, 6]; however, the majority of these solutions are temporary and require an operator to change simulator connectivity with a clinical device during simulation training, research,
or testing. For example, resuscitation training studies at this institution required the trainer to attach a rhythm generator to the defibrillator at the same time trainees position pads on a LTS in order to allow for trainees to have a realistic interaction with the defibrillator. The device used in this study, the AP Belt, fulfills the unmet needs of providing AL and AP defibrillation capabilities to low-technology simulators and of providing AP defibrillation capabilities to high-technology simulators. It is a non-conductive 2” x 36” x 0.125” belt, made of silicon rubber or polyvinyl chloride plastic. The belt encircles the chest, and stainless steel disks act as conductive contacts. Contacts are secured to the belt with stainless steel hardware. Test lead wire with silicone insulation is fastened to the conductive contact and embedded within the belt. Analog signal flow of the simulated heart rhythm is redirected from the point of generation to conductive contacts in the AP or AL position. Defibrillator electrode pads can be placed over these contacts to continue signal flow into the defibrillator, allowing for providers to defibrillate the simulator and for display of the rhythm on the defibrillator. This device is designed to safely conduct an average defibrillation voltage (10 kV) and current (25 A).

Figure 1. Diagram of device used with HTS (left) and LTS (right). Dotted lines show wiring/studs on a lower plane.

When used with high-technology simulators, which have AL defibrillation functionality, the device redirects simulated cardiac rhythm signals and defibrillator electricity from the simulator’s internal heart rhythm generator to the defibrillation electrode pads via conductive contacts in the AP position, allowing for defibrillation in the AP position (Fig. 1, left). This device can also be used with low-technology simulators or simulator substitutes, such as a pillow, both of which do not have the functionality to be defibrillated in any position. When used with these non-defibrillatable simulators, the device directs the signal flow between an external rhythm simulator and the defibrillator (Fig. 1, right). Analogue signal flow travels through the conductive studs in the AP or AL position via attachment of the electrode pads to the contacts and attachment of the device to the rhythm simulator, allowing for interchangeable AP and AL
defibrillation functionality. Analog signal connectivity from point of generation to defibrillator is diagrammed with arrows. The LTS-specific device (right) is diagrammed to allow for AP defibrillation functionality, but this same concept can be used to provide AL defibrillation functionality through changing the position of the conductive contacts to the anterior and lateral positions. This study will assist us in recognizing any unidentified usability issues with the device.

4. **Study Procedures**
a. Study design, including the sequence and timing of study procedures
   This study will be an ongoing means of collecting user data each time the AP Belt is employed in pre-existing training sessions. AP Belts will be kept in the Simulation Center, and BLS trainers, nurse educators, resuscitation research coordinators, etc. will be offered the attached survey to document data related to the AP Belt when they pick up the device for use. The survey will be filled out by the trainer for each session in which the AP Belt is included.

b. Study duration and number of study visits required of research participants. This study will be a period of 12 months. The number of surveys collected and instances of AP Belt use is dependent on the frequency of requests for the AP Belt by educators and trainers.

c. Blinding, including justification for blinding or not blinding the trial, if applicable. N/A

d. Justification of why participants will not receive routine care or will have current therapy stopped. N/A

e. Justification for inclusion of a placebo or non-treatment group. N/A

f. Definition of treatment failure or participant removal criteria. N/A

g. Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely. N/A

5. **Inclusion/Exclusion Criteria**
a. Inclusion criteria: Medical educator who requests to use the AP Belt.

6. **Drugs/Substances/Devices**
a. The rationale for choosing the drug and dose or for choosing the device to be used. N/A

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. N/A

c. Justification and safety information if non-FDA approved drugs without an IND will be administered. N/A
7. **Study Statistics**
   
ed. Primary outcome variable.
   
See attached survey
   
f. Secondary outcome variables. N/A
   
g. Statistical plan including sample size justification and interim data analysis.
   
Means and standard errors will be calculated for continuous variables and compared by use of t-test, proportion variables will be compared by using chi-squared analysis. If distributions of values are non-gaussian, non-parametric methods will be employed.
   
h. Early stopping rules. N/A

8. **Risks**
   
f. Medical risks, listing all procedures, their major and minor risks and expected frequency. N/A
   
g. Steps taken to minimize the risks.
   
The AP Belt device has been approved by Johns Hopkins Hospital Clinical Engineering for use in training.
   
h. Plan for reporting unanticipated problems or study deviations. N/A
   
i. Legal risks such as the risks that would be associated with breach of confidentiality.
   
No personal identifiers will be collected on the survey. The Simulation Center records contact information of educators who borrow equipment; however, this data will only be reviewed by study team members designated on this IRB proposal in the context of this study if an AP Belt is reported damaged.
   
j. Financial risks to the participants. N/A

9. **Benefits**
   
b. Description of the probable benefits for the participant and for society.
   
   - **Participant:** Participants will have access to the AP Belt as a tool for resuscitation training, which will provide a more realistic model for clinician interaction with the defibrillator. Because the Johns Hopkins Hospital uses defibrillator pads that are designed to be placed in the AP position, the incorporation of this device will likely limit confusion regarding defibrillator pad placement and reduce time to defibrillation.
   
   - **Society:** This device extends defibrillation capabilities of high-technology simulators, low-technology simulators, and simulator substitutes. It has been observed that increased realism in simulation-based training improves the effectiveness of training. Before disseminating this device to the external parties interested in incorporating it in their own training, we need to collect this initial usability data to ensure device robustness. Once these steps have been taken, we can disseminate the device to those outside of our current training network.
10. **Payment and Remuneration**
   b. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol. N/A

11. **Costs**
   b. Detail costs of study procedure(s) or drug(s) or substance(s) to participants and identify who will pay for them.
   All study materials are provided free of charge by the Johns Hopkins Simulation Center.


