Title – Integrating Clinical Technology for Military Health: Automating Physiologic Controllers in an Animal ICU as a Platform to Achieve Autonomous Support during Evacuation

PI – Tracy Rausch
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EGS/EDMS #: JW160009
Contract: W81XWH–17–C–0013
Funding: $5.4M
Funding Source: JWF
COR: Tony Story
Contract Specialist: Matthew Teel
Period of Performance: 19 Jun 17 – 18 Jun 21
Current TRL: 5/6

Project Goals: To advance the development of an Integrated Clinical Environment (ICE) Platform, originally developed as a research effort in previously funded efforts (Phase I and Phase II). DocBox and the Institute of Surgical Research (ISR) chose the apps. We will work jointly to develop requirements and implement functionality for the remote supervision of warfighters during medical evacuation. DocBox will then test the apps to show that use of the DocBox ICE platform improves the safety and efficiency of medical evacuations. DocBox will use Massachusetts General Hospital's Medical Device Plug-and-Play (MDPnP) laboratory and ISR's facilities to demonstrate these benefits. The DocBox ICE platform is an open, distributed medical device platform, designed and implemented with a modularity that enables unique, efficient methods of validation and verification, and app development. Such design and methods also allow for a unique component based regulatory approval process. These features will enable faster, iterative deployments of clinical apps, and decrease the time required to develop clinical decision support apps and visualization apps.

Feedback from last IPR (Sep 2016): (Note these comments are relative to the project "Integrating Clinical Technology for Military Health" upon which this newly executed award was built). Dr. Salinas asked what, exactly, the platform is that DocBox is developing (e.g. library, widgets, applications, etc.). He said that he understood it to be a software layer between the medical devices and a management application that could synchronize time and use to pull in data from multiple devices and put it on a common display. He continued that it seemed the underlying architecture was based upon enrollment with ICE standards and they need a specific dongle on each device. He said that Dr. Goldman noted that the ICE standard should be mandated so that all devices incorporate it. Lt Col Holmes added that it is also a database effort. He was pleased to see they have received further outside funding with the Joint Warfighter but suggested the panel members request a briefing on progress even if the funding is not coming from JPC-1 for the sake of visibility of progress. He was concerned about the regulatory and legal standards surrounding such large amounts of personal physiological data.
Dr. Salinas was concerned about the integration of the ICE standards and resistance from medical device manufacturers who might not be willing to share their internal protocols, which would be necessary for this type of approach. Mr. Davis agreed and suggested that if this product is to be a viable approach, more information is needed to determine if the approach is correct. Dr. Salinas said if they would be willing, they could test it in the Brooke Army Medical

Center to see the exact type of data they could collect from it. Mr. Dahlheimer suggested that in future meetings the investigators should provide a demonstration of the developing product for better understanding of the goals and outcomes of each project.

Mr. Merino raised concerns over the legal implications of the product and the data being collected. Panel members suggested understanding the exact data collected by the product before involving the Office of General Counsel for legal advice.

Dr. Schlachta-Fairchild suggested Dr. Rausch be asked to come in for an update to the panel members in eight months assuming the Joint Warfighter project is awarded soon.

Current Status: Integrating Clinical Technology for Military Health Research effort is complete. The PI was fully funded by the JWF program. Monthly report for the period Dec 17 – Jan 18 received and reviewed.

Issues: None

Anticipated future actions: Current JWF research will continue in accordance with the SOW. Final report for the Integrating Clinical Technology for Military Health reviewed and found to be scientifically acceptable in accordance with the approved SOW**.**
