SUBMITTED BY: **STEPHEN M. LANIER, PH.D., VICE PRESIDENT FOR RESEARCH**

REPORT ON WAIVERS APPROVED TO BOARD STATUTE 2.41.01.140

BACKGROUND

Four research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing the research results. These waivers have been approved by the Vice President for Research to allow acceptance of the relevant grant or contract, acting in accordance with the University's research policy on restricted and proprietary research.

OVERVIEW

PERSYS MEDICAL

This waiver allowed acceptance of a clinical study agreement with PerSys Medical, "Depth of Soft Tissue Overlying Intraosseous Insertion Sites." The main purpose of this research study is to determine the appropriate depth of Intraosseous (IO) insertion for patients at the extremes of weight (<40 kg and > 100 kg). Proper IO catheter insertion is crucial to adequately administer life-saving therapies in an emergent situation when IV placement is delayed or not possible. Unfortunately, very little is known about the necessary depth of insertion for these catheters in patients who are morbidly obese or extremely low weight, such as neonates and premature infants. Additional data are needed to determine whether the patients require shorter or longer IO catheter insertion depths to achieve appropriate access to the intramedullary ("inside the bone") space of target bones. IO catheters inserted too deep may cause bone damage, and catheters that are not inserted deep enough may not function or may cause extravasation ("leakage of fluids and medicine") into the soft tissues, leading to tissue injury and other complications.

Data gathered from this study will aid clinicians in preventing inadequate or excessive IO insertion depths in these patient populations. In turn, this will prevent unnecessary failed or complicated IO insertion attempts in patients who require IO vascular access by being able to determine the correct needle length for proper IO catheter insertion depth. This information could potentially improve outcomes in emergent situations such as cardiac arrest.

This project required a waiver to Board Statute 2.41.01.140 because of the potential for publication related directly to certain subset of data to be delayed until January 1, 2020. The agreement language allows the PI to submit a manuscript prior to that date as long as any information that the sponsor flags as proprietary or confidential is removed from the final publication to preserve the sponsors interest in creating a new product using the results of this study. After January 1, 2020, the PI is able to submit publications on any and all data derived from the study. The publication review time for the sponsor has also been increased to 120 days.

The project is led by James Paxton, M.D., assistant professor – clinical, Department of Emergency Medicine, School of Medicine.