

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

**REPORT ON WAIVERS APPROVED
TO BOARD STATUTE 2.41.01.140**

BACKGROUND

Two research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing results. This waiver has been approved by the Vice President for Research to allow acceptance of the relevant grants or contracts, acting in accordance with the University's research policy on restricted and proprietary research.

OVERVIEW

LE BONHEUR CHILDREN'S HOSPITAL FOUNDATION

This waiver allowed acceptance of a research services agreement with Le Bonheur Children's Hospital Foundation to create a registry database that will be used in a multi-site study titled, "Transcatheter PDA Closure Using the ADO II AS Device in Premature Infants Less than Two Kilograms: Real World Registry Study." Dr. Forbes and his team will be responsible for creating a study specific database and housing and maintaining the data from multiple sites.

This project required a waiver to Board Statute 2.41.01.140 because the funding agency will not allow any publications relating to the creation of this database or any data from the other sites using this database. Dr. Forbes will also be involved in the clinical study for which this database is being created and will be allowed to publish his own results from the study. This study will be a separate agreement with Le Bonheur Children's Hospital Foundation.

The project is led by Thomas Forbes, M.D., clinical professor of pediatrics in the School of Medicine and director of the Cardiac Catheterization Laboratory at Children's Hospital of Michigan.

COMMUNITY FOUNDATION FOR SOUTHEAST MICHIGAN

This waiver allowed acceptance of a research study agreement with the Community Foundation for Southeast Michigan to facilitate an understanding of how COVID-19 impacted jail facilities in a research study titled, "Study of COVID-19 in Michigan Department of Correction Facilities." Dr. Phillip Levy and Dr. James Blessman will be leading the study.

This project required a waiver to Board Statute 2.41.01.140 because the Michigan Department of Corrections requires review and approval of any publications and communications resulting from the study. This project will assist with determining next steps to help prevention of COVID-19 in the Wayne County jail facilities and beyond.

Dr. Phillip Levy, assistant vice president of Translational Science and Clinical Research Innovation in the Office of the Vice President for Research, the Edward S. Thomas Endowed Professor and associate chair for Research in Emergency Medicine, and chief innovation officer of the Wayne State University Physician Group, and Dr. James Blessman, assistant professor of Family Medicine and Public Health Sciences, will lead this project.