

**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 the research results. This waiver has 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**

**Global Blood Therapeutics**

This waiver allowed acceptance of a clinical trial award of \$124,533 with Global Blood Therapeutics for the project, "A Phase 3, Double-blind, Randomized, Placebo-controlled, Multicenter Study of GBT440 Administered Orally to Patients with Sickle Cell Disease." The study will include participants ages 12 to 65 years, and aims to determine the effect of the study drug, GBT440, compared to a placebo in increasing red blood cell counts and reducing the severity of symptoms of Sickle Cell Disease. The drug was designed to help the hemoglobin in red blood cells hold on to more oxygen as they travel through the body in an effort to keep cells in their normal shape versus sickle. GBT440 holds promise to improve symptoms in sickle cell disease and this study will assess its effect.

The project will be led by Michael Callaghan, MD, associate professor (clinical) in the Department of Pediatrics in the School of Medicine.

The project required a publication waiver to Board Statute 2.41.01.140 because the prime funding agency requires that all resulting publication submissions and presentations be delayed up to 135 days to allow for the sponsor to publish results from the trial.

**Michigan Nutrition Network**

An award of \$20,020 from the Michigan Nutrition Network was made to Wayne State for the project, "WSU Farmer's Market Pilot." This pilot project aimed to help determine how to best engage Detroit youth in city farmer's markets. Youth were to receive nutrition education and be connected to a farmer's market opportunities as an extension of their education.

The project was led by Nate McCaughtry, Ph.D., assistant dean, College of Education.

The project required a publication waiver to Board Statute 2.41.01.140 because the prime funding agency will not allow the publishing of data from the study due to the project not being able to proceed as planned. Michigan Nutrition Network plans to continue with Dr. McCaughtry to reestablish the study which later will have data that can be published.